

GALILEO

Intelligent Ventilation

Operator's manual

610862/05

Software version 3.44d

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MEDICAL**

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HAMILTON MEDICAL will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions, or other information that will assist the user's appropriately trained personnel to repair those parts of the equipment designated by HAMILTON MEDICAL to be repairable.

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GALILEO model and software information

Two models comprise the GALILEO ventilator family: the premium GALILEO Gold and the classic GALILEO. This manual describes both models with software version 3. In the manual, the generic “GALILEO” refers to either device. The words “ONLY IN Gold” in the margin denote features specific to the GALILEO Gold.

CAUTION

Classic GALILEO ventilator is not available in the USA.

Functionally, the GALILEO Gold is a superset of the classic GALILEO. In addition to the functions of the classic GALILEO, the GALILEO Gold also features tube resistance compensation (TRC) and the P/V Tool maneuvers.

To determine whether the ventilator is a classic GALILEO or a GALILEO Gold, look at the label in the upper right-hand corner of the front panel. The GALILEO Gold has a three-dimensional label with a gold background, while the classic GALILEO has a three-dimensional label with a dark blue background. If the GALILEO has neither type of label described, it is an earlier version, and this manual is not applicable. **GALILEO Gold** is also visible during power-up in the setup screen.

The software version for the GALILEO is visible during power-up in the setup screen. The software version on the screen (that is, the digit to the left of the decimal point) should match the version on the title page of this manual. See Section 2.12 for details.

About this manual

- The displays shown in this manual may not exactly match what you see on your own ventilator.
- Familiarize yourself with this operator’s manual before using the ventilator on a patient.

Definitions of warning, caution and notes

WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTE:

Emphasizes information of particular importance.



This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.

ONLY IN
Gold

Applies only to the GALILEO Gold

Intended use

GALILEO Gold ventilator

- The GALILEO ventilator is intended to provide positive pressure ventilatory support to adult, pediatric, infant, and neonatal patients.
- The GALILEO ventilator is intended for use in the hospital and institutional environment where healthcare professionals provide patient care, including use at the patient bedside and for intra-facility transport, provided compressed gas is supplied. The GALILEO ventilator is not intended for transportation outside the hospital or for use in the home environment.
- The GALILEO ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.

CAUTION

**Federal (USA) law restricts this device to sale by or on the order of a physician.
Classic GALILEO ventilator is not available in the USA.**

General operation notes

- Familiarize yourself with this operator's manual before using the ventilator on a patient.
- The displays shown in this manual may not exactly match what you see on your own ventilator. Your ventilator may not include all the modes and features described in this manual.
- The “infant” application of GALILEO ventilator covers both infant and neonatal populations. “Neonatal” in this manual refers to patients less than 1 month old, while “infant” refers to patients from 1 month to 2 years old.

Monitoring and alarms

- The GALILEO is not intended to be a comprehensive vital sign monitor for patients on life-support equipment. Patients on life-support equipment should be appropriately monitored by qualified medical personnel and suitable monitoring devices. The use of an alarm monitoring system does not give absolute assurance of warning for every form of malfunction that may occur with the ventilator. Alarm messages may not exactly pinpoint a problem; the exercise of clinical judgment is necessary.
- An alternative means of ventilation shall be available whenever the ventilator is in use. If a fault is detected in the ventilator or its life-support functions are in doubt, disconnect the GALILEO from the patient and immediately start ventilation with such a device (for example, a resuscitation bag), using PEEP and/or increased oxygen concentration when appropriate. The ventilator must be removed from clinical use and serviced by HAMILTON MEDICAL authorized service personnel.
- It is recommended that additional independent monitoring devices be used during mechanical ventilation. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.
- Do not silence the audible alarm when leaving the patient unattended.
- Do not use the exhaust port of the expiratory valve for spirometry. Due to the GALILEO's base flow, the exhaust gas output is larger than the patient's actual exhaled volume.
- Do not put a vessel filled with a liquid on the ventilator. If a liquid enters the product, a fire and/or electrical shock may occur.

Fire and other hazards

- To reduce the risk of fire or explosion, do not place the GALILEO in a combustible or explosive environment (for example, around flammable anesthetics or other ignition sources). Do not use it with any equipment contaminated with oil or grease.
- To reduce the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.
- To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.
- In case of fire, immediately secure the patient's ventilatory needs, switch off the GALILEO, and disconnect it from its gas and electrical sources.

Service and testing

- To ensure proper servicing and to prevent possible physical injury, only HAMILTON MEDICAL authorized service personnel should attempt to service the ventilator.
- To reduce the risk of electrical shock, do not open the ventilator housing. Refer the ventilator for servicing by qualified personnel.
- To reduce the risk of electrical shock, disconnect electrical power from the ventilator before servicing. Be aware that battery power remains even after the mains is disconnected. Be aware that if the power switch is off, some parts still carry high voltage.
- Do not attempt service procedures other than those specified in the service manual.
- Use replacement parts supplied by HAMILTON MEDICAL only.
- Any attempt to modify the ventilator hardware or software without the express written approval of HAMILTON MEDICAL automatically voids all warranties and liabilities.

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- The preventive maintenance program requires a general service every 5000 hours or yearly, whichever comes first.
 - To ensure the ventilator's safe operation, always run the tests and calibrations prescribed in Section 3 before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.

Electromagnetic susceptibility

The GALILEO complies with the IEC 60601-1-2 EMC (Electro Magnetic Compatibility) Collateral Standard. Certain transmitting devices (for example, cellular phones, walkietalkies, cordless phones, paging transmitters), however, emit radio frequencies that could interrupt the GALILEO operation.

Do not operate these transmitting devices within the vicinity of the GALILEO. Do not use the GALILEO in an environment with magnetic resonance imaging (MRI) equipment.

Section 8 lists the alarms that can possibly occur due to such disruption, along with the corresponding corrective actions.

Consult your service representative in case of interrupted ventilator operation.

Electromagnetic emissions

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to both Part 15 of the FCC Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

Units of measure

Pressures are indicated on the GALILEO in cmH₂O or mbar. Hectopascals (hPa) are used by some institutions instead. Since 1 mbar equals 1 hPa, which equals 1.016 cmH₂O, the units may be used interchangeably.

Disposal

Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).

Year of manufacture

The year of manufacture can be determined from the serial number label, which is on the GALILEO back panel. The first two digits of the part number are the last two digits of the year of manufacture.

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1.1 Introduction

The GALILEO is designed for intensive care ventilation of adult, pediatric, and infant patients up to 200 kg.

Ventilation modes. This full-functioned intensive care ventilator offers conventional volume- and pressure-controlled and spontaneous modes, as well as advanced modes. The conventional modes include the volume-controlled modes (S)CMV (also called A/C) and SIMV; the pressure-controlled modes P-CMV (also called P-A/C) and P-SIMV; and the pressure support mode (SPONT). The APV[®] (adaptive pressure ventilation) modes, APVcmv and APVsimv, are dual-control modes that combine the attributes of pressure- and volume-controlled ventilation.

The advanced modes include ASV[®] (adaptive support ventilation), DuoPAP[®], APRV, and NIV (noninvasive ventilation). ASV calculates an optimal breath pattern, based on minimal operator inputs. It guarantees that the patient receives selected minute ventilation, at the lowest possible pressures. DuoPAP and APRV are two related pressure-controlled modes in which the operator sets two pressure levels and the patient can breathe spontaneously at either level (similar to having an upper and lower level of CPAP. Both modes provide a combination of control and spontaneous breaths at either level, and let the patient breathe freely throughout the entire breath cycle. NIV provides pressure support ventilation through a mask or other noninvasive interface.

Patient-triggered breaths may be flow- or pressure-triggered.

ONLY IN Gold To reduce the patient's work of breathing while on the GALILEO, the ventilator's tube resistance compensation (TRC) feature offsets the resistance imposed by the endotracheal (ET) or tracheostomy tube.

Monitoring. The GALILEO offers a variety of monitoring capabilities. It displays 26 monitored parameters as numbers. You can also see this data graphically, as up to three waveforms (curves) or a loop. You can freeze the waveforms, and use the cursor measurement function to determine a value at a selected point on the waveform. The GALILEO's trending

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Gold

function lets you view up to 24 hours of data. Additionally, in the GALILEO Gold the P/V Tool® maneuvers are automated maneuvers that let you measure and display the pressure-volume curve of the lungs for determination of the lower and upper inflection points. The P/V Tool displays the inflation limb data only, while the P/V Tool 2 is an advanced version, offering both inflation and deflation limb data.

The GALILEO's monitored data is based on pressure and flow measurements collected by the HAMILTON MEDICAL proximal Flow Sensor, between the Y-piece and the patient; as well as by the integral oxygen monitor. Optionally the pressure measurements can come from an auxiliary pressure sensing site (Paux).

Alarms. The GALILEO offers ten operator-adjustable alarms, which can be set individually or automatically, through the Auto alarm button. You can switch off all but the most important alarms in the configuration mode. Other nonadjustable alarms help ensure your patient's safety.

User interface. The ventilator's ergonomic design, including a color display screen, two press-and-turn knobs, and keys, let you easily access the ventilator settings and monitored parameters.

Configuration. The language, ventilation philosophy, alarms, and options can be preselected in the configuration mode.

Power. The GALILEO is normally powered from ac mains, covering a voltage range of 100 to 240 V ac, 50/60 Hz. In the event of an ac mains power failure, the internal backup batteries automatically switch on to provide power typically for one hour when batteries are fully charged.

Mounting options for the GALILEO include standard and short trolleys, which have space for a VENTILAIR^{II} compressor, and a shelf-mount version.

Options. Built-in options available with your GALILEO include nebulization and a communications interface. The nebulization function lets your GALILEO power a nebulizer connected to the nebulizer outlet. The communications interface lets you monitor the patient from a remote workstation, transmits alarms through a nurse call relay system, and transmits I:E timing signals.

1.2 Functional description

The following paragraphs describe the operation of the GALILEO Ventilator from a hardware perspective.

1.2.1 System overview

The GALILEO is an electronically controlled pneumatic ventilation system. It is powered by ac with internal battery backup to protect against power failure or unstable power and to facilitate intrahospital transport. The GALILEO's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.

The user provides inputs to the GALILEO microprocessor system through the keys and the two press-and-turn knobs. These inputs become instructions for the GALILEO's pneumatics to deliver a precisely controlled gas mixture to the patient. The GALILEO receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Based on this monitored data, the GALILEO adjusts gas delivery to the patient. Monitored data is also displayed by the graphic user interface.

The GALILEO's microprocessor system controls gas delivery and monitors the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.

A comprehensive system of visual and audible alarms helps ensure the patient's safety. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's ongoing background checks, can indicate a hardware or software failure. When a condition is critical enough to possibly compromise safe ventilation, the GALILEO is placed into the ambient state. The ambient and exhalation valves are opened, letting the patient inhale room air through the ambient valve and exhale through the exhalation valve.

The GALILEO has several means to ensure that safe patient pressures are maintained. The minimum and maximum working pressures are ensured by the low and high pressure alarm limits. If the set high pressure limit is reached, the expiratory valve opens. If the ventilator pressure exceeds 120 cmH₂O, the overpressure valve mechanically releases pressure.

1.2.2 Gas supply and delivery

The GALILEO uses high-pressure oxygen and air from wall supplies, cylinders, or the VENTILAIR^{II} compressor (Figure 1-1). These gases enter through water traps with integrated high-efficiency particle filters at the gas inlets.

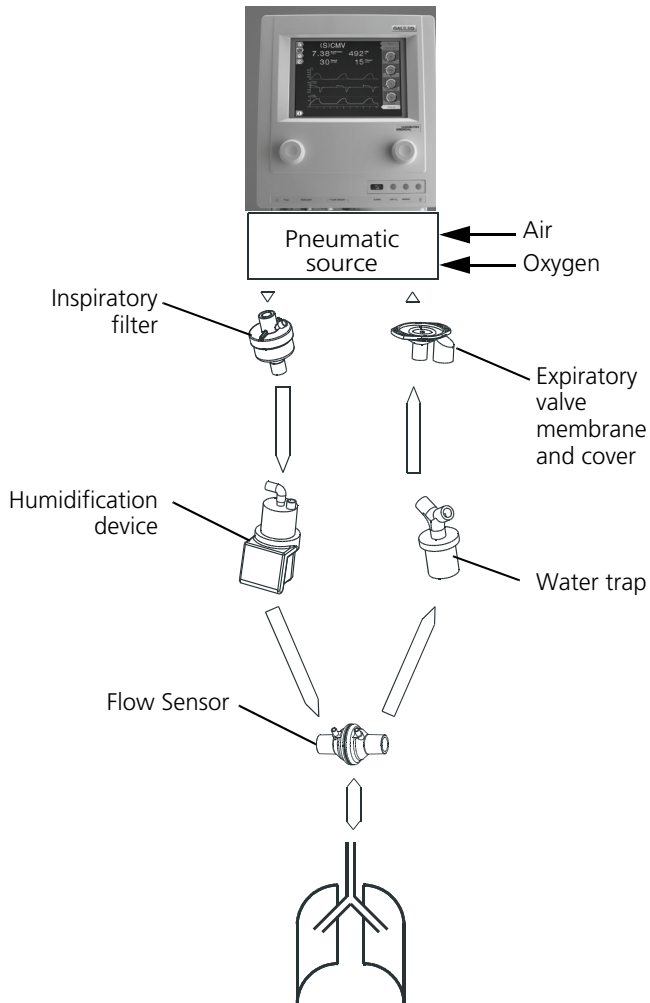


Figure 1-1. GALILEO functional diagram

Within the ventilator, the gas enters the GALILEO's pneumatic system. An electronic mixer combines oxygen and air according to the user-set concentration. This mixture fills a reservoir, which is maintained within a prescribed pressure range. As the gas mixture is delivered to the patient, the pressure drops, and the reservoir is refilled.

Gas in the reservoir supplies the inspiratory valve. The microprocessor controls the size of the inspiratory valve opening and the length of time it is open to meet the user settings. The opening of the valve is then adjusted based on feedback in the form of monitored data.

The GALILEO delivers gas to the patient through the inspiratory limb breathing circuit parts, including possibly the inspiratory filter, flex tubes, the humidification system, a water trap, the Y-piece, and the Flow Sensor. If the nebulizer option is installed, an internal nebulizer compressor supplies the nebulizer flow.

Gas exhaled by the patient passes through the expiratory limb breathing circuit parts, including flex tubes, the Flow Sensor, the Y-piece, a water trap, and an expiratory valve cover and membrane. Gas is vented through the expiratory valve cover such that no exhaled gas comes into contact with any internal components of the GALILEO. Measurements taken at the Flow Sensor are used in the pressure, flow, and volume measurements.

An oxygen cell (sensor) monitors the oxygen concentration of the gas to be delivered to the patient, which is the same as the reservoir concentration. This galvanic cell generates a voltage proportional to the partial pressure of oxygen in the delivered gas. Neither the pressure nor the humidity of the inspired gas affects the oxygen measurement. The ventilator alarms if the monitored oxygen concentration is more than 5% above or below the oxygen setting, less than 18%, or more than 105%.

The operations of the inspiratory and expiratory valves are coordinated to maintain system pressure levels.

1.2.3 Gas monitoring with the Flow Sensor

The GALILEO accurately measures flow, volume, and pressure in the patient's airway with the HAMILTON MEDICAL Flow Sensor. There is an infant version of the Flow Sensor and a pediatric/adult version. This proximal Flow Sensor lets the GALILEO sense even weak patient breathing efforts. Between its highly sensitive flow trigger and fast response time, the GALILEO helps minimize the patient's work of breathing.

The Flow Sensor contains a thin, diamond-shaped membrane within the outer housing and has a pressure port on either side. The membrane allows bidirectional flow through its variable orifice (Figure 1-2).

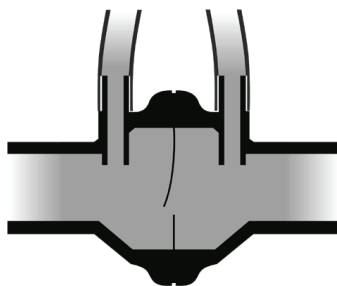


Figure 1-2. Flow Sensor variable orifice

The area of the orifice changes depending on the flow rate. It opens progressively as the flow increases, creating a pressure drop across the orifice. The pressure difference is measured by a high-precision differential pressure sensor inside the ventilator. The pressure difference varies with flow (relationship determined during Flow Sensor calibration), so the patient's flow is determined from the pressure drop. The GALILEO calculates volume from the flow measurements.

The Flow Sensor is highly accurate even in the presence of secretions, moisture, and nebulized medications. The GALILEO continuously flushes the sensing tubes with mixed gases (rinse flow) to prevent blockage.

1.3 Physical description

1.3.1 Breathing circuits and accessories

Figure 1-3 shows the GALILEO with its breathing circuit and accessories. See Appendix F for details on breathing circuits and accessories supplied by HAMILTON MEDICAL. See Table 1-1 for information on other compatible breathing circuits and accessories.

NOTE:

To ensure proper ventilation operation, use only parts and accessories specified in Table 1-1.

Table 1-1. Compatible parts and accessories

Part	Use...
Patient tubing circuit	• HAMILTON MEDICAL reusable patient tubing circuits • Other circuits that meet the ventilator breathing system specifications in Appendix A
Mask	• HAMILTON MEDICAL reusable face masks (see <i>Product Catalog</i>) • Other face or nasal masks
Inspiratory filter	• HAMILTON MEDICAL reusable inspiratory bacteria filter • Other filters that have a 22 mm female conical inlet connector, a 22 mm male conical outlet connector, and that meet the ventilator breathing system specifications in Appendix A
Humidification device	• Any Fisher & Paykel humidifier. HAMILTON MEDICAL supplies the Fisher & Paykel MR850, MR730, and MR410 humidifiers • Any active humidifier with a flow capability of up to 120 l/min • Heat and moisture exchanger
Flow Sensor	HAMILTON MEDICAL parts only (marked with the HAMILTON "H")

Table 1-1. Compatible parts and accessories (continued)

Part	Use...
Expiratory valve membrane and housing	HAMILTON MEDICAL parts only
Compressor	HAMILTON MEDICAL VENTILAIR ^{II} compressor
Nebulizer	Pneumatic nebulizer specified for approximately 6 to 7 l/min

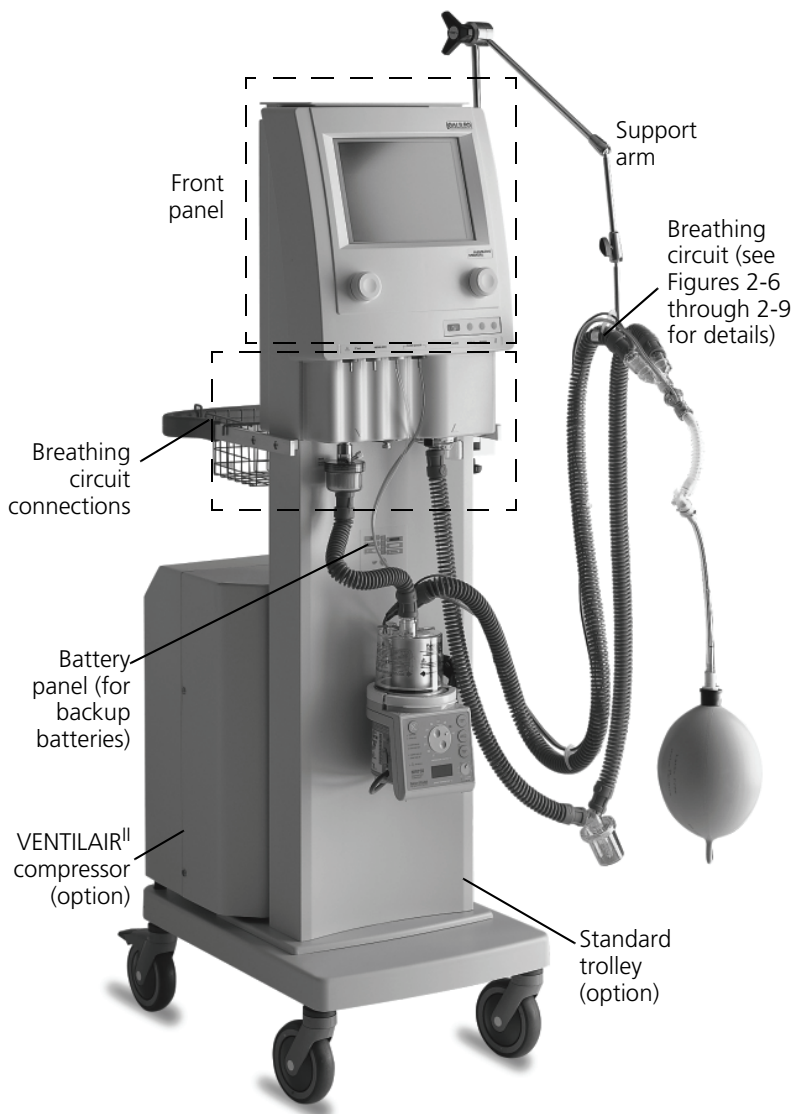


Figure 1-3. GALILEO with accessories

1.3.2 Ventilator unit

Figure 1-4 through Figure 1-7 show the controls, indicators, and other important parts of the ventilator unit.

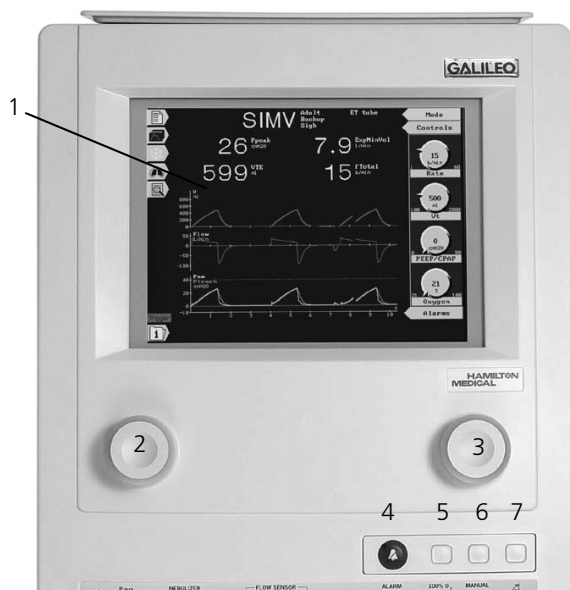


Figure 1-4. Front panel

Item	Description
1	Screen
2	Monitoring (M-) knob. Also called the left-hand knob, a press-and-turn knob for selecting monitored data.
3	Control (C-) knob. Also called the right-hand knob, a press-and-turn knob for selecting and adjusting ventilator settings.
4 	Alarm silence key. Silences the main ventilator audible alarm for 2 min. Pushing a second time cancels the alarm silence. The indicator blinks when an alarm is active, and it stays lit during alarm silence with no active alarms.

Item	Description
5	100% O₂ key. Delivers 100% oxygen for 2 min. Pushing a second time ends the 100% oxygen enrichment period.
6	MANUAL key. Triggers a mandatory breath when pressed and released during exhalation. The mandatory breath is delivered using the current active settings.
7 	Nebulizer key. Activates nebulization during the breath phases and for the duration selected during configuration. You can switch nebulization off earlier by pressing the key again.



Figure 1-5. Patient breathing circuit connections

Item	Description
1	Paux connector. Connects to an auxiliary pressure sensing site, for use as the pressure input in addition to the proximal Flow Sensor measurement.
2	NEBULIZER connector
3	FLOW SENSOR connection. Always attach the blue tube to the blue connector and the clear tube to the silver connector. The blue tube should always be toward the patient.
4 	To patient port (inspiratory outlet). The inspiratory filter and the inspiratory limb of the patient breathing circuit are connected here.
5	Inspiratory filter
6	Oxygen cell carrier
7	Exhaust port. Expiratory valve cover opening to ambient air.

Item	Description
8	Expiratory valve cover and membrane
9 	From patient port. The expiratory limb of the patient breathing circuit and the expiratory valve are connected here.

1.3.3 Battery panel

A panel on the front of GALILEO's column displays information about the batteries. It also lets you test the batteries and silence battery-related alarms. Figure 1-6 shows the battery panel indicators and keys and describes their functions.

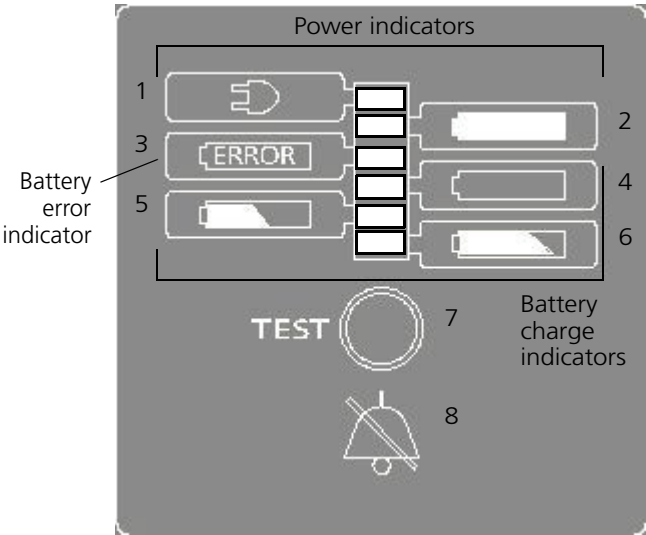


Figure 1-6. Battery panel

Item		Description
Power indicators: One of these indicators is always lit.		
1	ac power indicator (green)	ac power is in use.
2	Battery power indicator (yellow)	
3	Battery error indicator (red)	Battery malfunction.

Item	Description
Battery charge indicators: Whenever the GALILEO is running on battery, or when the TEST key is pressed while the GALILEO is running on ac power, one of these indicators is lit. 4  Battery full indicator (green) 5  Battery partly charged indicator (yellow) 6  Battery low indicator (red)	Batteries fully charged. Batteries partly charged. Battery charge low.
7 TEST key	Tests battery charge while ventilator is running on ac power.
8  Alarm silence key for battery alarm system	Indefinitely silences battery system audible alarm following switchover to batteries. The battery low alarm cannot be silenced.

1.3.4 Rear view

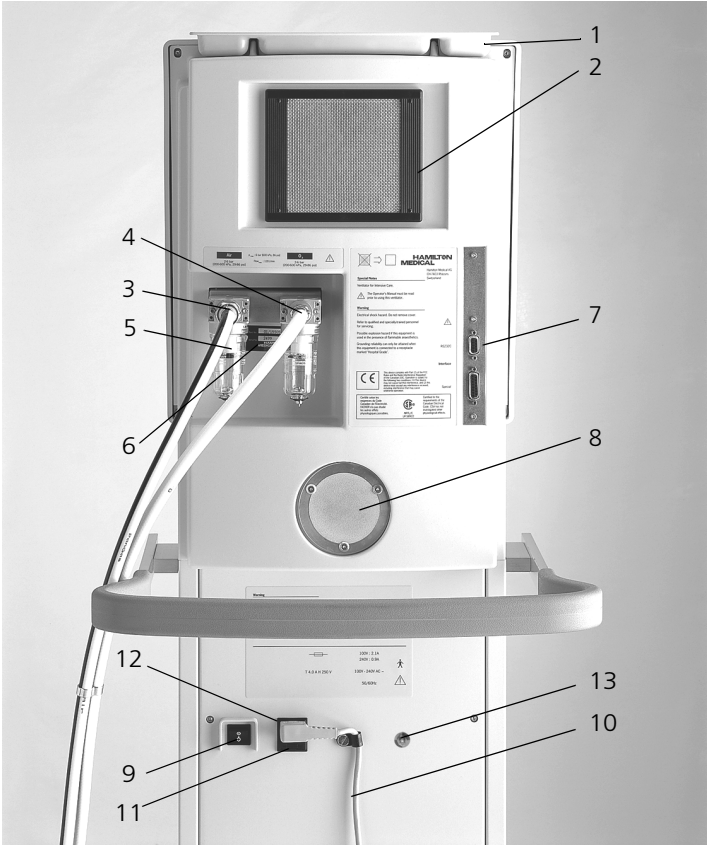


Figure 1-7. Rear view (standard trolley shown)

Item	Description
1	Top tray for medication
2	Fan filter
3	High-pressure air DISS or NIST fitting
4	High-pressure oxygen DISS or NIST fitting
5	High-pressure gas water trap with filter

Item	Description
6	Serial number label. The first two digits of the Part No. on this label are the ventilator's year of manufacture.
7	Communications interface connectors
8	Reservoir pressure relief valve exhaust
9	Power switch  represents the on position.  represents the off position for only a part of the equipment. In this position, power to the ventilator is turned off, but the batteries are charged if ac power is present.
10	Power cord with retaining clip
11	Fuse drawer. Holds two mains fuses.
12	Power receptacle. Make sure the power cord is secured with the retaining clip.
13	Potential equalization (ground) point conductor terminal

1.3.5 Screen

The screen provides information about the status of the patient and ventilator. The basic screen (Figure 1-8) is the default screen. You can directly access all the windows for mode, controls, alarms, and monitoring from the basic screen, even during normal ventilation. Icons with a point lead to additional setting and monitoring windows, while boxed icons and windows do not.

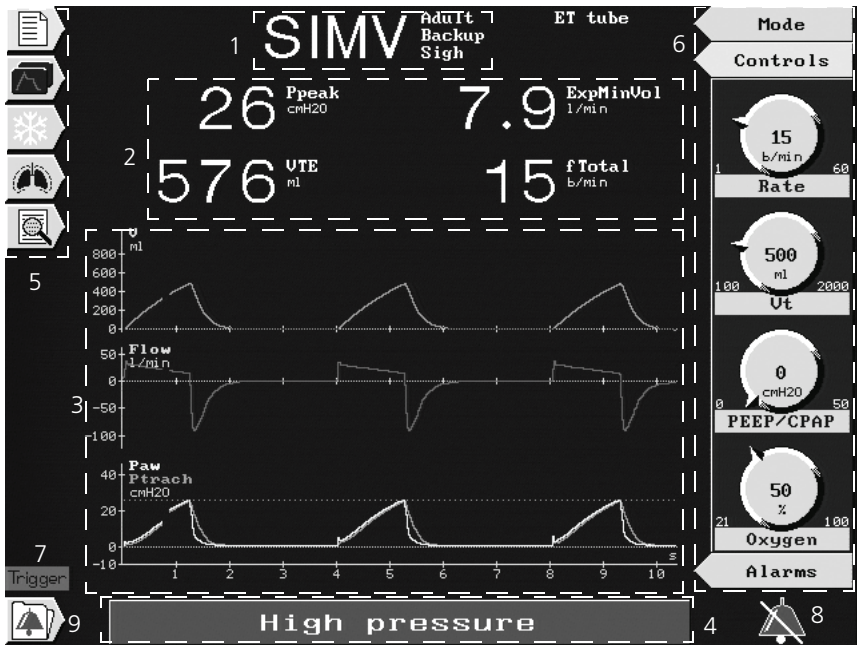


Figure 1-8. Basic screen

Item	Description
1	Active mode, mode additions, and others , including patient age group, sigh, backup, 100% O ₂ , nebulizer, and, in the GALILEO Gold, tube resistance compensation (TRC).
2	Main monitoring parameters (MMP) . Four numeric parameters set during configuration.

Item	Description
3	Graphic display. Real-time waveforms (curves), loop, trends, or other graphic, depending on user selection.
4	Message bar. Displays alarm and other messages for user guidance and status report. See Section 8 for further information.
5	Monitoring menu. Use the M-knob to select the icon for the monitoring window you want to open.
6	Mode, Controls, and Alarms menu. Use the C-knob to select the icon for the control window you want to open.
7	Trigger symbol. Indicates the patient is triggering a breath. Orange represents a pressure trigger, and pink represents a flow trigger.
8	Alarm silence symbol. Indicates the main ventilator audible alarm is silenced.
9	Alarm buffer symbol. Either the alarm information buffer symbol or the active alarm buffer symbol may be shown, indicating the presence of reset or active alarms.

1.4 Icons and symbols

Table 1-2 describes the icons used on the GALILEO screen. Table 1-3 describes the symbols used on the rear panel, including its labels.

Table 1-2. Onscreen symbols

Symbol	Definition
	Alarm silence. Indicates that the main ventilator audible alarm has been silenced. If the alarm condition is not resolved, the audible alarm resumes after 2 min.
	Alarm information buffer. Indicates that alarms have occurred and been reset. The symbol guides you to view the alarm information buffer, which contains up to six most recent reset alarms. View the buffer contents by selecting the symbol with the M-knob, then pressing the knob.
	Active alarm buffer. Indicates that multiple alarms are active. The symbol guides you to view the active alarm buffer, which contains up to six current active alarms. View the buffer contents by selecting the symbol with the M-knob, then pressing the knob. When multiple alarms are active, the alarm messages also alternate in the message bar.
	Numeric patient data. Opens the menu for selection of 26 monitored parameters, ASV parameters, or numeric data pressure source.
	26-parameter monitoring window. Opens the larger window to show 26 monitored parameters.
	ASV. Lets you display ASV numeric parameters (through the numeric patient data symbol) or the ASV target graphics screen (through the graphic selection symbol). This symbol is displayed only when the ASV ventilation mode is active.
	Airway pressure/auxiliary pressure. Selects the patient airway pressure (Paw) or a user-selected auxiliary pressure tap (Paux) as the pressure input for monitoring purposes, for numeric monitored data only. When the Paux pressure input is active, the color of the pressure-based parameters changes to orange.
	Graphic selection. Opens the menu for selection of graphic display.

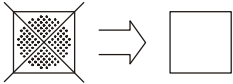
Table 1-2. Onscreen symbols (continued)

Symbol	Definition
	Curves. Lets you select up to three running waveforms for display.
	Loops. Lets you select and configure a loop for display.
	Trends. Lets you select up to three monitored data trends for display.

Table 1-2. Onscreen symbols (continued)

Symbol	Definition
	Freeze and cursor measurement. Freezes running waveforms or trends and activates cursor measurement.
	Respiratory mechanics. Opens the window for maneuver selection.
	Hold maneuver. Lets you access the inspiratory and expiratory hold functions.
	ONLY IN <i>Gold</i> P/V Tool. Performs a pressure/volume (P/V) curve maneuver that displays an inflation limb only.
	ONLY IN <i>Gold</i> P/V Tool 2. Performs a pressure/volume (P/V) curve maneuver that displays deflation and inflation limbs.
	Event log. Indicates there are events in the Event log (alarms, setting changes).
	Back. Returns to previous menu.

Table 1-3. Back panel symbols

Symbol	Definition
	Replace or clean fan filter when dirty (see Section 10).
	Fuse
	Classification of Medical Electrical Equipment, type B, as specified by IEC 60601-1.
	Refer to the operator's manual for complete information.
	CE Marking of Conformity.
	Canadian Standards Association and National Recognized Test Laboratory approval

2 Preparing for ventilation

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WARNING

- To prevent possible patient injury, do not block the holes located to the left of the GALILEO's oxygen cell. These holes are vents for the overpressure and ambient valves.
 - To prevent back pressure and possible patient injury, do not attach a spirometer, tube, or other device to the exhaust port of the exhalation valve housing.
 - To prevent interrupted operation of the GALILEO or any accessories, use only accessories or cables that are expressly stated in this manual or that comply with IEC 60601-1-2.
 - To prevent interrupted operation of the GALILEO due to electromagnetic interference, avoid using it adjacent to or stacking other devices on it. If adjacent or stacked use is necessary, verify the GALILEO's normal operation in the configuration in which it will be used.
 - To prevent possible personal injury and equipment damage, make sure the GALILEO is secured to the trolley or shelf with the attaching screws.
-

CAUTION

- To prevent ventilator components from overheating, do not obstruct the cooling fan vents.
 - To prevent possible equipment damage, avoid overloading the GALILEO's basket and tray or placing objects on the GALILEO that might compromise its stability.
 - To prevent possible equipment damage, lock the trolley's wheels when parking the ventilator.
-

NOTE:

Before using the ventilator for the first time, HAMILTON MEDICAL recommends that you clean its exterior and sterilize its components as described in Section 9.

2.1 Connecting to ac power

WARNING

To minimize the risk of electrical shock, plug the ventilator power cord into a grounded ac power receptacle. To ensure grounding reliability, use a special hospital-grade receptacle. It is the hospital's responsibility to ensure that the receptacle is properly grounded.

NOTE:

To prevent unintentional disconnection of the power cord, make sure it is well seated into the ventilator's socket and secured with the power cord retaining clip (Figure 2-1).



Connect the GALILEO to a grounded outlet that supplies ac power of 100 to 240 V, 50/60 Hz. Always check the reliability of the ac outlet. The ac power indicator on the battery panel will light to show that the GALILEO is running on ac rather than batteries.

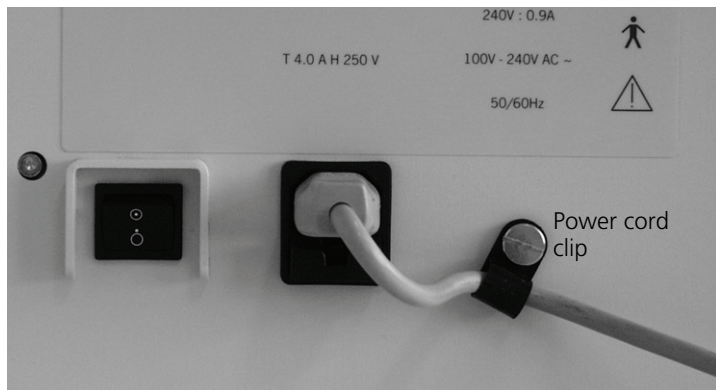


Figure 2-1. Power cord retaining clip (standard trolley shown)

2.2 Connecting the gas supplies

WARNING

- **Always check the status of the gas cylinders before using the GALILEO during transport.**
 - **Make sure gas cylinders are equipped with pressure-reducing valves.**
 - **To reduce the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.**
-

CAUTION

To prevent damage to the ventilator, connect only clean, dry medical-grade gases. Check for water and particle build-up in the gas supply water traps before each use and periodically during operation; empty by pressing on drain valve.



The GALILEO uses compressed air and oxygen with pressures between 200 to 600 kPa / 2 to 6 bar / 29 to 86 psi. It has DISS male or NIST gas fittings.

The supplied gases should be dry, clean and qualified for medical use.

If an oxygen concentrator is used to supply hospital oxygen pipeline system, make sure the oxygen concentration is 95% or higher. Otherwise, the "High Oxygen" alarm may be activated. Contact the oxygen concentrator manufacturer if unsure.

The compressed gases can come from central gas supplies, from gas cylinders, or from the VENTILAIR^{II} compressor. The GALILEO's trolley provides space for the compressor or two cylinders (if you have the optional cylinder holder). If you are using gases from cylinders, secure the cylinders to the trolley with the accompanying straps.

Connect the air and oxygen hoses to the GALILEO's inlet fittings, shown in Figure 2-2.

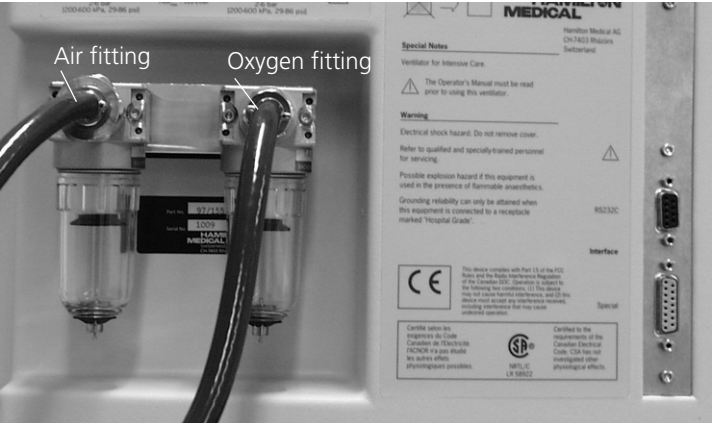


Figure 2-2. Connecting the air and oxygen supplies

2.3 Installing the humidifier

WARNING

To prevent possible patient injury and possible water damage to the GALILEO, make sure the humidifier is set to appropriate temperature and humidification settings.

Install a humidifier to the GALILEO using the slide bracket on the trolley column (Figure 2-3). Prepare the humidifier as described in the manufacturer's operation manual.



Figure 2-3. Installing the humidifier

2.4 Installing the patient tubing support arm

Install the patient tubing support arm on either side of the GALILEO (Figure 2-4). Assure the arm is fixed firmly.

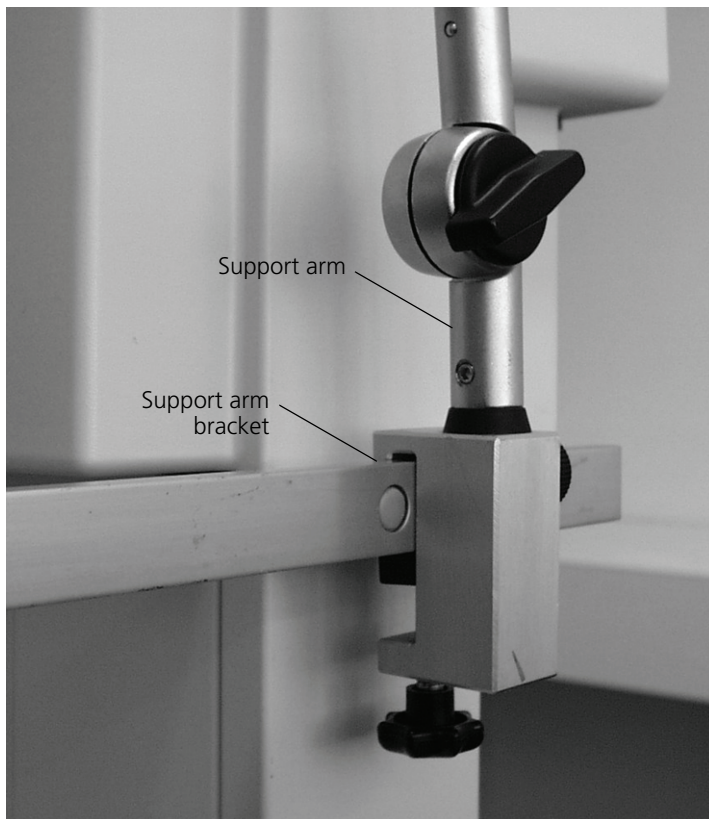


Figure 2-4. Installing the patient tubing support arm

2.5 Installing the patient breathing circuit

WARNING

- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
 - **To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the inspiratory limb of the patient breathing circuit.**
 - **To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.**
-

NOTE:

- For optimal ventilator operation, use HAMILTON MEDICAL breathing circuits or other circuits that meet the specifications given in Appendix A. When altering the HAMILTON MEDICAL breathing circuit configurations (for example, when adding accessories or components), make sure not to exceed these inspiratory and expiratory resistance values of the ventilator breathing system, as required by EN 794-1: adult, 6 cmH₂O at 60 l/min; pediatric, 6 cmH₂O at 30 l/min; and infant, 6 cmH₂O at 5 l/min).
 - Any bacteria filter, HME, or additional accessories in the expiratory limb may substantially increase flow resistance and impair ventilation.
 - HAMILTON MEDICAL recommends that breathing circuit parts that are in contact with the patient (for example, tubes, HMEs) be biocompatible, as described in ISO 10993.
-

NOTE:

- To ensure that all breathing circuit connections are leak-tight, perform the tightness test every time you install a circuit or change a circuit part.
 - Regularly check water traps, breathing circuit hoses, and Flow Sensor tubes for water accumulation. Empty as required.
-

Install the breathing circuit as follows:

1. Determine the patient age group (infant, pediatric, or adult) from Table 2-1. Select the correct breathing circuit parts for your patient.

NOTE:

For patients with bodyweights at the high end of the infant setting range (> 7 kg), you may want to select the pediatric patient type. This prevents you from having to change circuits and calibrate the flow sensor should you later decide that your patient requires more support.

Table 2-1. Patient age groups and breathing circuit parts

Actual body weight	Patient population	Recommended tube inner diameter of breathing circuit	Flow Sensor
≤ 10 kg	Neonates & infants	10 mm	Infant flow sensor
7 to 42 kg	Pediatric	15 mm	Pediatric/adult flow sensor
> 30 kg	Adults	22 mm	Pediatric/adult flow sensor

2. Assemble the patient breathing circuit. Figure 2-5 through Figure 2-8 show four typical circuit configurations; for ordering information, see Appendix F or the HAMILTON MEDICAL *Product Catalog*. Follow the specific guidelines for the different parts.
3. Properly position the breathing circuit after assembly. Make sure the hoses will not be pushed, pulled, or kinked during patient's movement, nebulization, or other procedures.

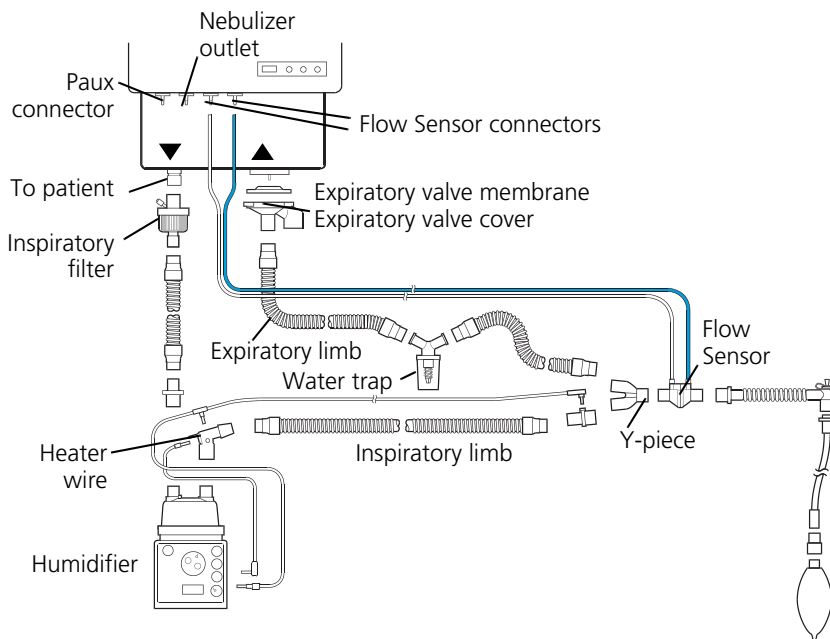


Figure 2-5. Patient breathing circuit for use with inspiratory heater wire (pediatric/adult)

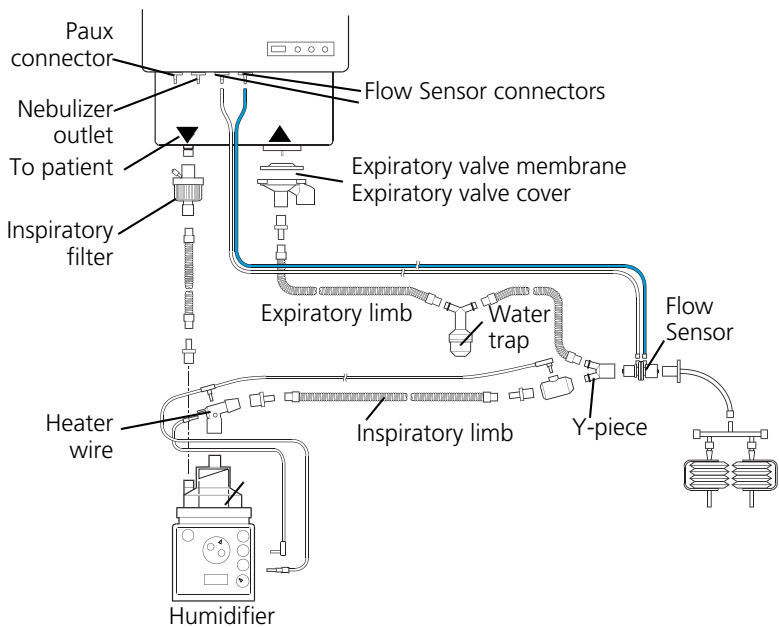


Figure 2-6. Patient breathing circuit for use with inspiratory heater wire (infant)

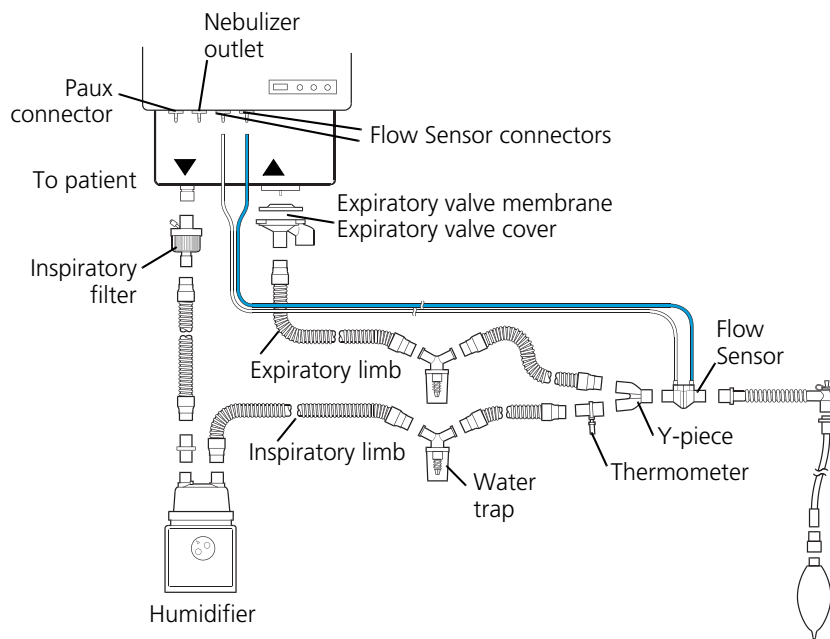


Figure 2-7. Patient breathing circuit for use without heater wires (pediatric/adult)

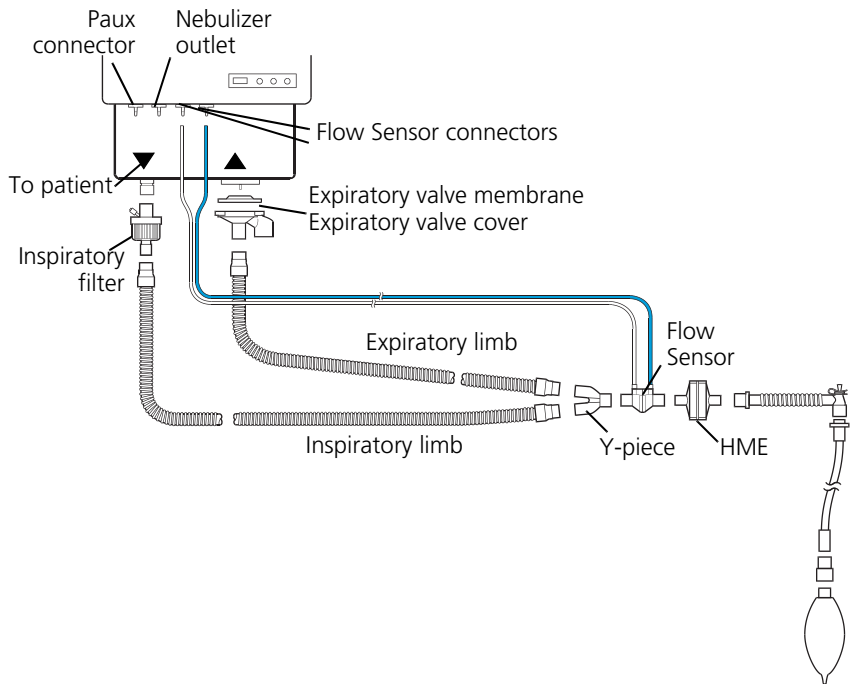


Figure 2-8. Patient breathing circuit for use with HME

Expiratory valve membrane: Place the silicone membrane into the valve cover with the metal plate upwards (Figure 2-9). The side that is marked DOWN must be placed downwards.



Figure 2-9. Installing the expiratory valve membrane

Position the cover and twist clockwise into place (Figure 2-10).

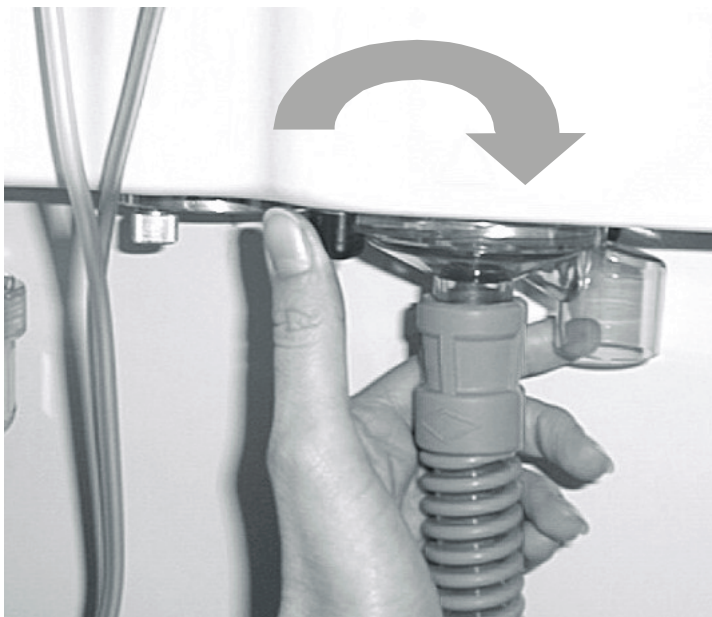


Figure 2-10. Installing the expiratory valve cover

Flow Sensor: Insert a Flow Sensor for the proper patient age group between the Y-piece of the breathing circuit and the patient connection (Figure 2-11). The blue tube is closest to the patient. Connect the blue and colorless tubes to the Flow Sensor connectors in the front panel. The blue tube goes to the blue connector. The colorless tube goes to the silver connector. Position the Flow Sensor upright to prevent kinking and moisture buildup.

WARNING

To prevent inaccurate Flow Sensor readings, make sure the Flow Sensor is correctly installed:

- **The blue Flow Sensor tube must be toward the patient.**
 - **The Flow Sensor tubings must be upright.**
 - **The Flow Sensor tubings must not be kinked.**
 - **The Flow Sensor tubings must be secured with clamp (included with Flow Sensor).**
-

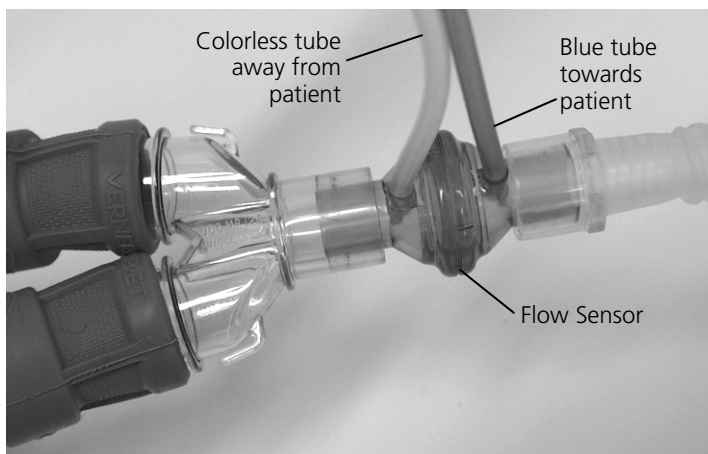


Figure 2-11. Installing the Flow Sensor

2.6 Using the auxiliary pressure (Paux) measurement



WARNING

The GALILEO generates a weak rinse flow of approximately 9 ml/min in the patient's direction. When the carina pressure is used as the Paux pressure input, this rinse flow helps keep the lumen of the carina clear of mucus.

To use an esophageal balloon as the Paux pressure, the internal rinse flow must be disabled by an authorized HAMILTON MEDICAL service engineer. Failure to disable the Paux rinse flow will cause the esophageal balloon to overinflate, resulting in possible patient injury.

The GALILEO uses the airway pressure (Paw) as its standard pressure input. You can reassign the GALILEO's pressure input, so that monitored numeric parameters are based on a pressure from a different site, such as the carina. This auxiliary pressure input can be particularly useful when conducting scientific and clinical studies.

To use the auxiliary pressure input, you must connect the site to the ventilator through the Paux connector. Use at least 1 m of 3 mm ID tubing (Flow Sensor tubing works) for the connection.

You must also set up the GALILEO's monitoring functions to recognize the Paux input; otherwise, the ventilator will continue to use the standard Paw input. Section 6.2.1.3, Section 6.2.2.1, and Section 6.2.2.2 tell you how to assign the Paux input for use in displayed numeric data, curves, and loops.

2.7 Checking for the oxygen cell

The GALILEO uses an integrated oxygen cell to monitor the delivered oxygen concentration. A high-priority alarm sounds if the measured concentration is 5 percentage points above or below the set oxygen concentration.

Before operating the ventilator, make sure the cell is present, as follows, referring to Figure 2-12:

1. Loosen the thumbscrew that retains the oxygen cell carrier.
2. Pull out the oxygen cell carrier gently. Verify that a cell is present and connected. If a cell is not present, install a cell (Section 10.3.3).

NOTE:

Observe the orientation of the connector when installing the oxygen cell.

3. Replace the carrier and thumbscrew.

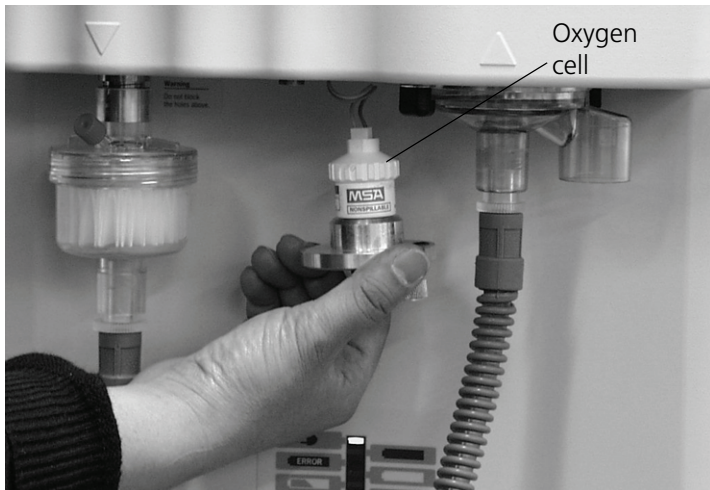


Figure 2-12. Checking for the oxygen cell

2.8 Installing a nebulizer

NOTE:

To determine whether your ventilator has the nebulization option, look at the setup screen (Figure 2-15). In the configuration mode you can view the nebulizer settings.

If your GALILEO has the nebulization option, it provides a stable driving pressure to power a pneumatic nebulizer connected to the nebulizer outlet, optimally specified for a flow of 6 to 7 l/min flow. Nebulization does not affect delivered oxygen concentration.

Connect the nebulizer and accessories as shown in Figure 2-13. Table 1-1 has information about compatible nebulizers.

WARNING

- **Do not use an expiratory filter or HME in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.**
 - **Connect the nebulizer in the inspiratory limb per your institution's policy and procedure. Connecting the nebulizer between the Flow Sensor and the endotracheal tube increases dead space ventilation.**
-

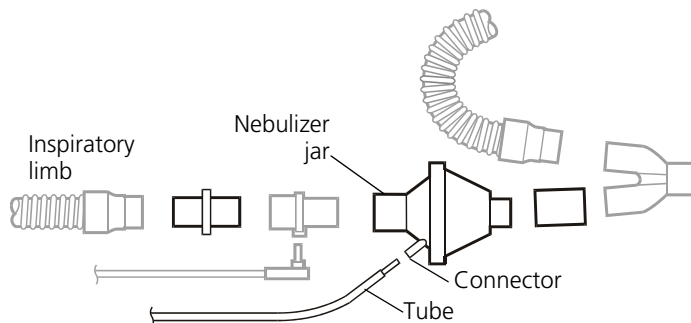


Figure 2-13. Connecting a nebulizer

2.9 Using an expiratory filter

WARNING

The use of an expiratory filter may lead to a significant increase in expiratory circuit resistance. Excessive expiratory circuit resistance may compromise ventilation and increased patient work of breathing and/or AutoPEEP.

An expiratory filter is not required on the GALILEO, but you may use one according to your institution's protocol. An expiratory filter is not required, because the expiratory valve design prevents internal ventilator components from contact with the patient's exhaled gas.

If you do use an expiratory filter, place it on the patient side of the expiratory valve cover. Remove any expiratory filter or HME during nebulization. Monitor closely for increased expiratory circuit resistance. An **Exhalation obstruction** alarm may also indicate excessive expiratory circuit resistance. If the **Exhalation obstruction** alarm occurs repeatedly, remove the expiratory filter immediately. If you otherwise suspect increased expiratory circuit resistance, remove the expiratory filter or install a new filter to eliminate it as a potential cause.

NOTE:

Monitored parameters for increased expiratory resistance are not specific to the breathing circuit and may indicate increased patient airway resistance and/or increased resistance of the artificial airway (if used). Always check the patient and confirm adequate ventilation.

2.10 Connecting to an external patient monitor or other device

NOTE:

All devices connected to the GALILEO must be for medical use and meet the requirements of standard IEC 601-1.

If your GALILEO has the communications interface option, you can connect your GALILEO to a patient monitor, computer, or a nurse's call device. See Appendix G for details on the communications interface.

Before connecting the device, make sure the GALILEO is properly configured (see Appendix H).

2.11 About the backup batteries

NOTE:

- The backup batteries are intended for short-term use only. They are not intended to be a primary power source.
 - HAMILTON MEDICAL recommends that the ventilator's batteries be fully charged before you ventilate a patient. If the batteries are not fully charged and ac power fails, always pay close attention to the level of battery charge.
-

The backup batteries protect the GALILEO from low or failure of ac power. When ac mains fail to provide power during ventilation, the batteries automatically switch on with no interruption in ventilation. An alarm sounds to signal the switchover. You must silence the alarm to confirm notification of the power system change. The batteries power the ventilator until ac power is restored.

The ventilator recharges the batteries whenever the ventilator is connected to ac mains power, with or without the ventilator power switch on.

Check the battery charge level before putting the ventilator on a patient and before unplugging the ventilator for transport or other purposes. (You can see the level of battery charge by observing the battery indicators on the battery panel.) If the batteries are not fully charged, recharge them by plugging in the ventilator for a minimum of 8 hours. If the batteries are not fully charged at this time, have the ventilator serviced.

2.12 Starting up the ventilator

NOTE:

After you switch on power to the ventilator, a self-test is performed prior to startup (approximately 35 s).

1. Switch on the ventilator power switch (Figure 2-14). You will hear the emergency buzzer.

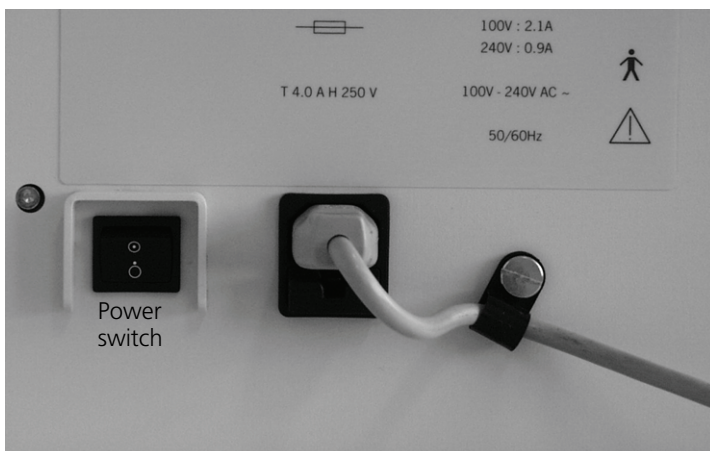


Figure 2-14. Power switch

- After some seconds, you will see the setup screen (Figure 2-15). The screen shows the **Self-test** bar, the installed software versions, the ventilator's total operating hours, and the active options. You will hear the speaker and buzzer tones during the self-test. The software version noted in the figure (that is, the digit to the left of the decimal point) should match the version on the title page of this manual.

WARNING

If you do not hear the audible alarm during startup, it may be malfunctioning. Remove the ventilator from use and contact service.

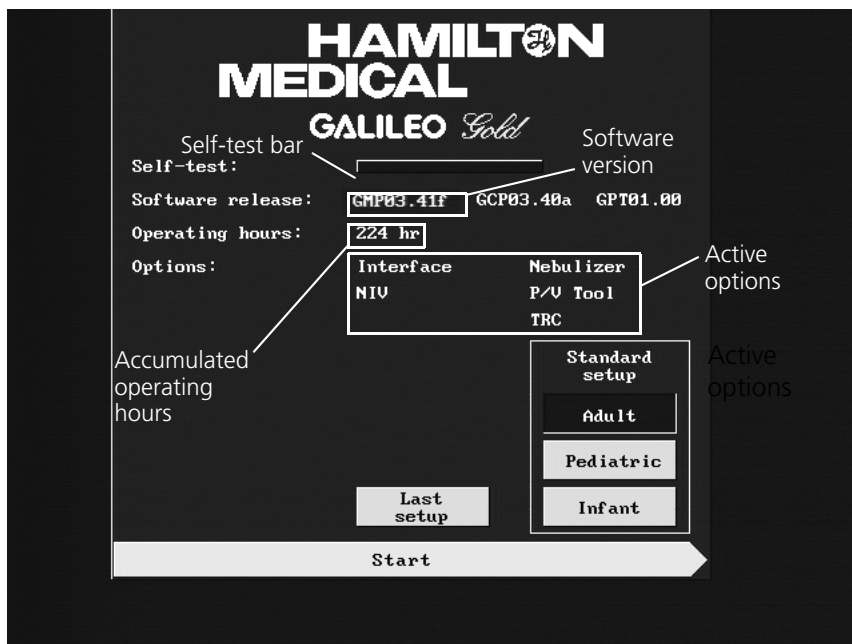


Figure 2-15. Setup screen

-
3. A patient age group under **Standard setup** will be highlighted. If you select this, the GALILEO starts up with the default factory settings (refer to Table A-6). If desired, turn the C-knob (right-hand knob) to select a different patient age group under **Standard setup**, or select **Last setup**. If you select the **Last setup**, the GALILEO starts up with the last active ventilator parameters in use before it was switched off.

NOTE:

The GALILEO's default trigger setting is flow triggering. When you start up the ventilator, you may see the message **Flow Sensor cal.needed**. If you do not perform a Flow Sensor calibration now, pressure triggering will be active instead.

4. Turn the knob to highlight **Start**, then press the C-knob to start ventilation.

2.13 Running tests and calibrations

WARNING

To ensure the ventilator's safe operation, always run the prescribed tests and calibrations before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.

Run the required tests and calibrations, listed in Table 3-1. Access the tests and calibrations as follows:

1. Open the **Ventilation mode** window.
2. Open the **Calibration** menu.

Follow the instructions in Section 3 to run the tests and calibrations.

NOTE:

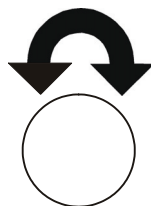
If the GALILEO is new, be sure it has been properly configured for default language, ventilation philosophy, alarms, and others (see Appendix H).

2.14 Guidelines for using the press-and-turn knobs

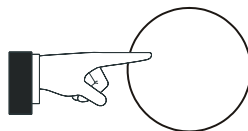
The press-and-turn knobs provide access to the GALILEO's windows for the ventilation parameters and the patient monitoring display. The left-hand (monitoring or M-) knob lets you access monitored data. The right-hand (control or C-) knob lets you access ventilator settings. The C-knob always takes priority over the M-knob.

Follow these simple guidelines:

Turn the knob to select a menu, parameter, or other item. Your selection becomes orange.



Press the knob to open the window or activate your selection.



If you are adjusting a setting, the control becomes red. *Turn* the knob as required. Then *press* the knob to activate the adjustment.

Continue the process by *turning* and *pressing*.

If required, *turn* the knob to select **Close**. Confirm the **Close** by pressing the knob.

3 Tests and calibrations

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3.2	Calibration menu	3-3
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	3.2.2 Flow Sensor calibration	3-5
	3.2.3 Tightness test	3-7
3.3	Battery test	3-8
3.4	Preoperational check	3-9

3.1 Introduction

WARNING

To ensure the ventilator's safe operation, always run the prescribed tests and calibrations before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.

The tests and calibrations described in this section help verify the safety and reliability of the GALILEO. Perform the GALILEO's tests and calibrations as described in Table 3-1. If a test fails, troubleshoot the ventilator as indicated or have the ventilator serviced. Make sure the tests pass before you return the ventilator to clinical use.

Table 3-1. When to perform tests and calibrations

Perform in any of these cases	Test or calibration
 Before placing a new patient on the ventilator	Preoperational check
After changing patient age group	Flow Sensor calibration
After installing a new or decontaminated breathing circuit, before performing a P/V Tool or P/V Tool 2 maneuver	Tightness test, Flow Sensor calibration
After installing a new or decontaminated Flow Sensor	Flow Sensor calibration
After installing a new oxygen cell	Oxygen cell calibration
Before transporting a patient within the hospital	Battery test, check of gas cylinder contents

3.2 Calibration menu

To access the GALILEO's automatic tests and calibrations, open the **Ventilation mode** window, then the **Calibration** menu.

NOTE:

The audible alarm is silenced during the calibration functions and for 30 s thereafter.

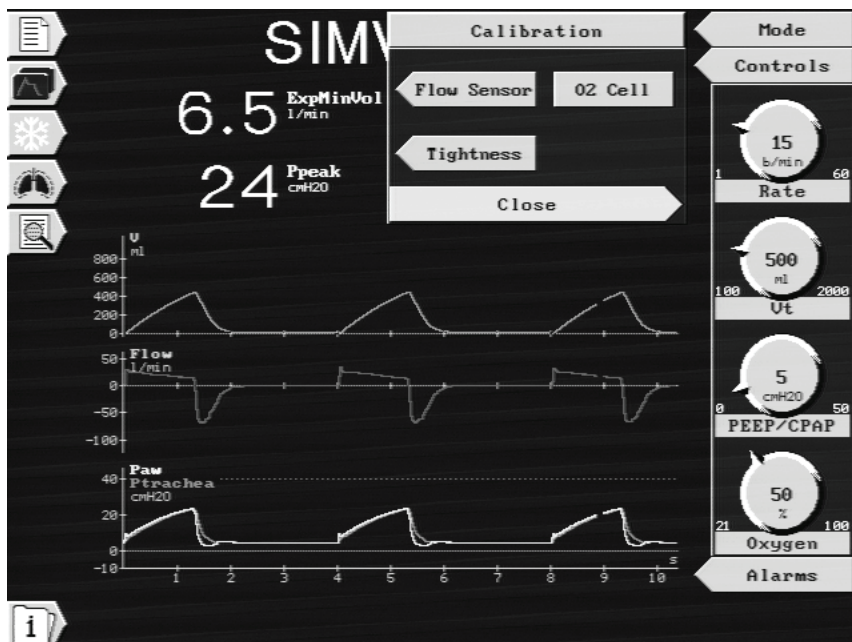


Figure 3-1. Calibration menu

3.2.1 Oxygen cell calibration

NOTE:

- There is no need to disconnect the patient from the ventilator when performing the oxygen cell calibration.
 - The oxygen cell calibration requires that an oxygen cell be installed, that the GALILEO's **O2 measurement** be enabled, and that oxygen be available. To check for an oxygen cell, see Section 2.7. To determine whether oxygen monitoring is disabled, check for the message **O2 alarm off** in the **Alarms** window.
-

When to perform: After installing a new oxygen cell or whenever the message **O2 cell cal. needed** is displayed.

Description: During this 2-min calibration of the oxygen cell, the GALILEO delivers the operator-set oxygen percentage to the patient. It tests the cell and resets the calibration points specific to the cell in use.

Procedure:

1. Make sure that gas supplies are connected to the GALILEO.
2. From the **Calibration** menu, select and activate **O2 cell**.
3. **VERIFY** that, after 2 min, **O2 cell calibrated OK** is displayed. **Close** the **Calibration** menu.

Corrective action: If **O2 cell cal. needed** is displayed, the cell could not be calibrated. Verify that the oxygen cell and cover are correctly installed and that oxygen is available. Repeat the calibration. If the calibration fails again, install a new oxygen cell.

If **O2 cell defective** is displayed, install a new cell.

3.2.2 Flow Sensor calibration

NOTE:

Make sure another source of ventilatory support is available during this calibration. The patient must be disconnected from the ventilator during it.

When to perform: Before placing a new patient on the ventilator, after installing a new Flow Sensor or breathing circuit, after changing the patient age group, before performing a P/V Tool or P/V Tool 2 maneuver, whenever the message **Flow Sensor cal. needed** is displayed, or whenever the displayed waveforms (especially volume) are questionable.

Description: This calibration checks and resets the calibration points specific to the Flow Sensor in use.

Procedure for pediatric/adult Flow Sensor:

1. Set the ventilator up as for normal ventilation, complete with breathing circuit, Flow Sensor, and expiratory membrane and cover. Make sure that the appropriate patient age group is selected and that the appropriate Flow Sensor type (pediatric/adult) is installed.
2. From the **Calibration** menu, select and activate **Flow Sensor**.
3. The message bar now displays **Disconnect patient**. Disconnect the breathing circuit at the patient side of the Flow Sensor. Do not block the open end of the Flow Sensor.
4. When the message bar displays **Turn the Flow Sensor**, reverse the ends of the Flow Sensor so that the blue tube is closest to the Y-piece.
5. When the message bar again displays **Turn the Flow Sensor**, reverse the ends of the Flow Sensor so that the blue tube is in its normal position, away from the Y-piece.
6. VERIFY that the message bar displays **Flow Sensor calibrated OK**.

7. Reconnect the patient, and **Close** the **Calibration** menu.

Corrective action: If the message bar displays **Flow Sensor cal. needed**, repeat the calibration. If the calibration still fails, install a new Flow Sensor.

NOTE:

If you close the **Calibration** menu when the calibration has failed, the GALILEO starts ventilating but continues to display **Flow Sensor cal. needed**. This may result in inaccurate monitoring.

Procedure for infant Flow Sensor:

1. Set the ventilator up as for normal ventilation, complete with breathing circuit, Flow Sensor, and expiratory membrane and cover. Make sure that the infant patient age group is selected and that the infant Flow Sensor type is installed.
2. From the **Calibration** menu, select and activate **Flow Sensor**.
3. The message bar now displays **Disconnect patient**. Disconnect the breathing circuit at the patient side of the Flow Sensor. Do not block the open end of the Flow Sensor.

NOTE:

Do *not* turn the infant Flow Sensor during calibration.

4. VERIFY that the message bar displays **Flow Sensor calibrated OK**.
5. Reconnect the patient, and **Close** the **Calibration** menu.

Corrective action: If the message bar displays **Flow Sensor cal. needed**, run the calibration again. If the calibration still fails, install a new Flow Sensor.

NOTE:

- If you close the **Calibration** menu when the calibration has failed, the GALILEO starts ventilating but continues to display **Flow Sensor cal. needed**. This may result in inaccurate monitoring.
 - During Flow Sensor calibration, the GALILEO can recognize a mismatch between the set patient age group and the Flow Sensor type in use. In response it annunciates a **Wrong Flow Sensor type** alarm.
-

3.2.3 Tightness test

NOTE:

Make sure another source of ventilatory support is available during this test. The patient must be disconnected from the ventilator during it.

When to perform: After installing a new patient breathing circuit or adding new components to the breathing circuit, before performing a P/V Tool or P/V Tool 2 maneuver, or when leaks are detected or suspected.

Description: This test checks for leakage in the patient breathing circuit and determines the circuit's compliance compensation factor. The GALILEO uses this factor to compensate the volume lost due to circuit compliance. The ventilator is pressurized to 50 cmH₂O. The circuit is considered tight if this pressure can be maintained. If there is a leak, the pressure falls in proportion to the size of leak.

Procedure:

1. Set the ventilator up as for normal ventilation, complete with breathing circuit.
2. From the **Calibration** menu, select and activate **Tightness**.

3. If you have not already disconnected the patient, the message bar displays **Disconnect patient**. Disconnect the breathing circuit at the patient side of the Flow Sensor.
4. The message bar displays **Tighten patient system**. Block the opening (a finger covered with an alcohol pad may be used).
5. Wait for a few seconds, and VERIFY that the message bar displays **Patient system tight**.
6. Reconnect the patient, and **Close** the **Calibration** menu.

Corrective action: If the test does not proceed or if the message bar displays **Check patient system**, check the circuit connections. Replace leaking parts and repeat the tightness test.

3.3 Battery test

When to perform: Perform this test before placing the ventilator on a patient.

Description: This test displays the level of battery charge while the ventilator runs on ac power. It also tests the battery system audible alarm. When the ventilator is running on battery, the battery panel indicators show the level of battery charge.

Procedure:

1. Press the TEST button on the battery panel while the ventilator is running on ac power. VERIFY that the battery full indicator lights.

If the yellow or red battery charge indicator lights instead, charge the batteries by leaving the GALILEO plugged into ac power for a minimum of 8 hours or until the green indicator lights during the battery test.
2. Unplug the power cord. VERIFY that the continuous battery system buzzer sounds. Reconnect the power cord. The buzzer should stop.

Corrective action: If the buzzer does not sound, have the ventilator serviced.

NOTE:

Be aware that if the ac power fails during the battery test, the alarm will not sound to alert you. The appropriate battery panel indicators will light, however.

3.4 Preoperational check

WARNING

To prevent possible patient injury, disconnect the patient from the ventilator before running this test. Make sure another source of ventilatory support is available.

NOTE:

- Before running this check, make sure that O₂ measurement is configured on.
 - The preoperational check card attached to the ventilator provides an abbreviated version of this check.
-

When to perform: Before placing the ventilator on a patient.

Required materials: Use the setup below appropriate to your patient age group. To ensure that the ventilator also functions according to specifications on your patient, we recommend that your test circuit be equivalent to the circuit used for ventilation.

- | | |
|--------------------|---|
| Adult patients | <ul style="list-style-type: none">• Breathing circuit, 22 mm ID• Flow Sensor, pediatric/adult• Demonstration lung, 2 l, with adult ET tube between Flow Sensor and lung (PN 151815 or equivalent) |
| Pediatric patients | <ul style="list-style-type: none">• Breathing circuit, 15 mm ID• Flow Sensor, pediatric/adult• Demonstration lung, 0.5 l, with pediatric ET tube between Flow Sensor and lung (PN 151816 or equivalent) |
| Infant patients | <ul style="list-style-type: none">• Breathing circuit, 10 mm ID• Flow Sensor, infant• Lung model, neonatal, with infant ET tube between Flow Sensor and lung model (An IngMar neonatal lung model, HAMILTON MEDICAL PN 53353, is recommended) |

Description: This test checks the GALILEO's main functions, including the control, monitoring, and trigger sensitivity.

Preparation: Connect the ventilator to ac power and to a compressed air supply only (not to the oxygen supply). Set the ventilator up as for normal ventilation, complete with appropriate breathing circuit, appropriate Flow Sensor, appropriate demonstration lung or lung model, and expiratory membrane and cover:

Procedure:

Do or observe...	Verify...	Notes
1. Switch on power.	Emergency buzzer sounds briefly.	
2. After some seconds, you will see setup screen with its Self-test bar.	Speaker sounds while setup screen is visible.	
3. Select Standard setup , then a patient type (Adult/Pediatric/Infant). Close Controls window without changing any settings, so that ventilator starts with standard settings listed in Table 3-2 through Table 3-4.	After a few seconds: Oxygen supply failed in message bar. Alarm silence key blinks.	Use only standard ventilator settings when running the preoperational check. Do not make any changes in any windows except those described. For further details on standard settings, see Table A-6.
4. Ventilation continues with air.	After a few minutes: Low oxygen in message bar.	Alternatively, you may continue the preoperational check while waiting for the Low oxygen alarm. Do not forget to verify this important alarm, however.
5. Connect oxygen supply hose.	Alarms reset.	
6. Perform Flow Sensor calibration (Section 3.2.2), tightness test (Section 3.2.3), and battery test (Section 3.3), which includes a mains power fail check.	These tests pass.	
7. Open numeric patient data window.	Monitored data is within ranges listed in Table 3-2 through Table 3-4. Date and time shown at top of window are current.	Make sure monitoring parameters are stable first.
8. Squeeze demonstration lung several times.	Trigger indicator displayed each time.	
9. Disconnect demonstration lung.	Disconnection pat. side and Low minute volume alternate in message bar.	

Do or observe...	Verify...	Notes
10.Reconnect demonstration lung. Disconnect expiratory limb from expiratory valve and occlude limb at circuit side. Reconnect the limb.	Exhalation obstructed in message bar.	Alternatively, you can verify the Exhalation obstructed alarm by occluding the expiratory valve exhaust port.
11.Induce a high Pressure alarm by lowering alarm limit setting.	High pressure in message bar.	
12.Change ventilation mode to SPONT. Wait for 20 s (adult/pediatric patients) or 15 s (infant patients).	• Apnea or Apnea ventilation in message bar. • Remote monitor or alarm device also annunciates alarm, if applicable.	

Table 3-2. Preoperational check expected values for adult patients

Control	Default setting	Monitored parameter	Expected range
Mode	(S)CMV (A/C)	--	--
--	--	ExpMinVol	6.3 to 8.8 l/min
Rate	15 b/min	fTotal	14 to 16 b/min
Vt	500 ml	VTE	450 to 550 ml
PEEP/CPAP	5 cmH ₂ O	PEEP/CPAP	4 to 6 cmH ₂ O
Oxygen	50%	Oxygen	47 to 53% (if oxygen monitoring enabled)

Table 3-3. Preoperational check expected values for pediatric patients

Control	Default setting	Monitored parameter	Expected range
Mode	(S)CMV (A/C)	--	--
--	--	ExpMinVol	1.9 to 3.1 l/min
Rate	25 b/min	fTotal	24 to 26 b/min
Vt	100 ml	VTE	80 to 110 ml
PEEP/CPAP	5 cmH ₂ O	PEEP/CPAP	4 to 6 cmH ₂ O
Oxygen	50%	Oxygen	47 to 53% (if oxygen monitoring enabled)

Table 3-4. Preoperational check expected values for infant patients

Control	Default setting	Monitored parameter	Expected range
Mode	P-CMV (P-A/C)	--	--
Rate	30 b/min	fTotal	29 to 31 b/min
Pcontrol	15 cmH ₂ O	Ppeak (Pcontrol + PEEP/CPAP)	18 to 23 cmH ₂ O
PEEP/CPAP	5 cmH ₂ O	PEEP/CPAP	4 to 6 cmH ₂ O
Oxygen	50%	Oxygen	47 to 53% (if oxygen monitoring enabled)

Corrective action: If the GALILEO's audio alarm is not loud enough, adjust the loudness (Section 4.9). If the date and time are not current, adjust them (see Section H.7). If the GALILEO otherwise does not pass the preoperational check, have it serviced. If the remote monitor or alarm device does not annunciate an alarm, check the device or have it serviced.

4 Ventilator settings

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4.1 Introduction

WARNING

- To prevent possible patient injury, make sure the ventilator is set up for the appropriate patient age group with the appropriate breathing circuit parts, including the appropriate Flow Sensor, as described in Section 2. *Make sure the Flow Sensor calibration is performed before you use the ventilator.*
 - To ensure the ventilator's safe operation, always run the prescribed tests and calibrations (see Table 3-1) before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.
 - It is the clinician's responsibility to ensure that all ventilator settings are appropriate, even when "automatic" features such as automatic alarm setting, ASV, or standard settings are used.
-

NOTE:

- If you selected **Standard setup**, the basic screen will open with the default factory settings for mode, control, and alarm parameters. If you selected **Last setup**, the settings you see are the last active ventilator parameters in use before the ventilator was switched off.
 - If you inadvertently make a false setting but haven't yet confirmed it, you can wait 30 s for the knob time-out, which cancels the setting. Alternatively, the setting windows close after 60 s, canceling your settings.
-

This section tells you how to set up the GALILEO for ventilation. Prepare the ventilator as instructed in Section 2.

You must be familiar with selecting, activating, and confirming parameters. For details, see Section 2.14.

4.2 Changing the ventilation mode

NOTE:

If you intend to use the adaptive support ventilation mode ASV, we recommend that you consult Appendix D for more details.

The active ventilation mode is displayed at the top center of the screen. To change the mode, do the following:

1. Open the **Ventilation mode** window (Figure 4-1).
2. Select a mode. (Table 4-1 tells you which modes apply to which patient age groups. Appendix B has details on all modes.) Activate the selection.

NOTE:

If a mode is shown outlined in white, it is the corresponding backup mode for apnea backup ventilation.

3. **Close** the **Ventilation mode** window to confirm the selection. If you changed the mode, the **Controls** window opens automatically so you can review and confirm the control settings (see Section 4.7.1). If the control settings are not confirmed after 60 s, the window automatically closes. The new mode selection will not be valid, and the previous settings remain in effect.

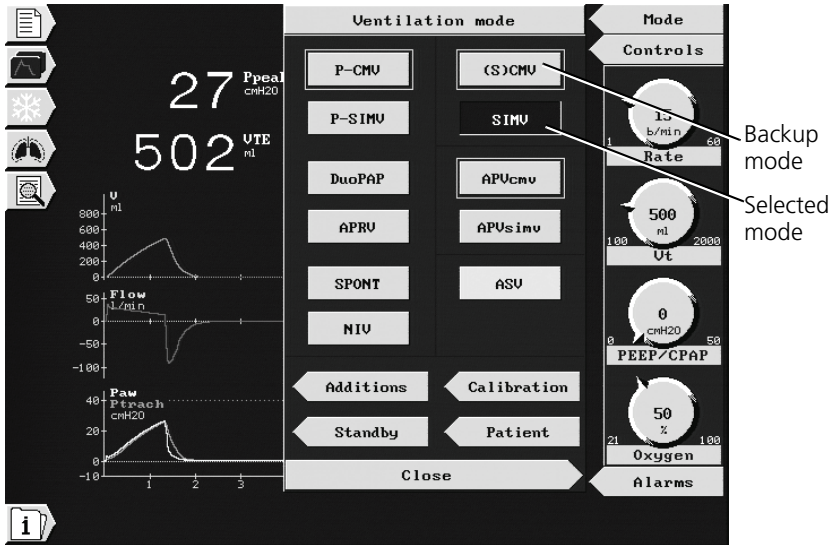


Figure 4-1. Ventilation mode window

Table 4-1. Ventilation modes and patient age groups

Mode	Adult (> 30 kg)	Pediatric (7 to 42 kg)	Infant (< 10 kg)
(S)CMV (A/C) - Assist/ control/ synchronized controlled mandatory ventilation	✓	✓	
SIMV - Synchronized intermittent mandatory ventilation	✓	✓	
SPONT - Pressure support mode	✓	✓	✓
P-A/C / P-CMV - Pressure- controlled assist/control / pressure-controlled mandatory ventilation	✓	✓	✓

Table 4-1. Ventilation modes and patient age groups (continued)

Mode	Adult (> 30 kg)	Pediatric (7 to 42 kg)	Infant (< 10 kg)
APVcmv - Pressure-controlled mandatory ventilation with adaptive pressure ventilation	✓	✓	✓
P-SIMV - Pressure-controlled synchronized intermittent mandatory ventilation	✓	✓	✓
APVsimv - Pressure-controlled synchronized intermittent mandatory ventilation with adaptive pressure ventilation	✓	✓	✓
ASV - Adaptive support ventilation	✓	✓	
DuoPAP - dual positive airway pressure mode	✓	✓	✓
APRV - airway pressure release ventilation	✓	✓	✓
NIV - noninvasive ventilation	✓	✓	

NOTE:

Tidal volume delivered in pressure-based modes depends on a) applied inspiratory pressure, b) lung mechanics and c) inspiratory time. In GALILEO infant application, this volume may be as low as 2 ml. This is different from GALILEO APV modes, where the smallest tidal volume setting is 10 ml.

4.3 Changing the patient age group

WARNING

To prevent possible hyper- or hypoinflation, make sure the patient age group setting matches the actual patient status.

The GALILEO sets defaults and makes assumptions based on the patient age group (infant, pediatric, or adult). To input the patient age group, do the following:

1. Determine the patient age group from Table 2-1. Make sure the ventilator is configured with the appropriate breathing circuit parts, as described in Section 2.5. Section 5 includes additional information you might find valuable when ventilating an infant patient.
2. Open the **Ventilation mode** window (Figure 4-1).
3. Open the **Patient** window (Figure 4-2).
4. Select and activate the patient age group (**Infant**, **Paediatric**, or **Adult**).
5. **Close** the **Patient** and **Ventilation mode** windows to confirm the selection. The **Controls** window opens automatically. Confirm the settings.

The patient age group is displayed beside the current mode on the basic screen.

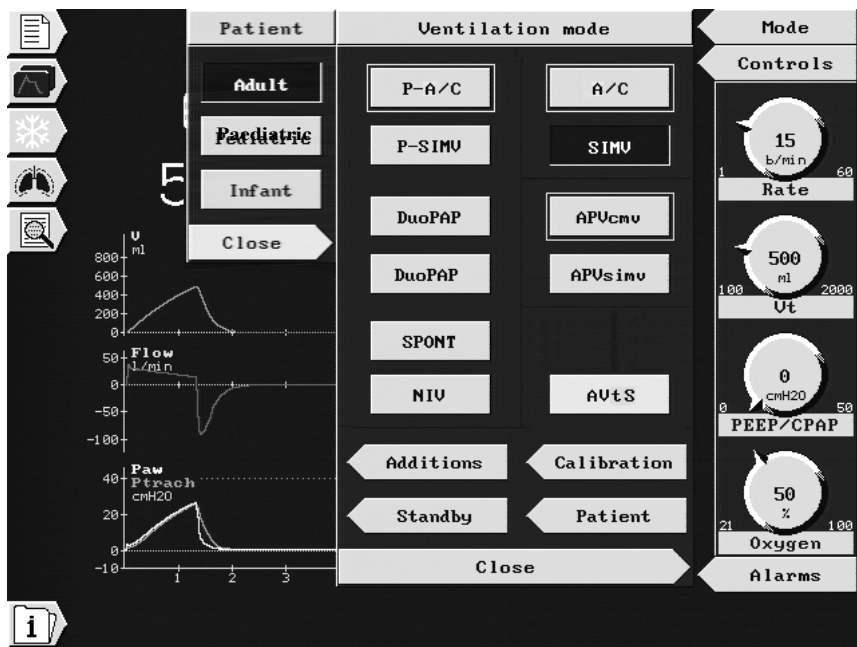


Figure 4-2. Patient window

4.4 Setting mode additions

You can enable or disable sigh and apnea backup ventilation and set tube resistance compensation (TRC) from the **Additions** window. To access the **Additions** window, first open the **Ventilation mode** window (Figure 4-3).

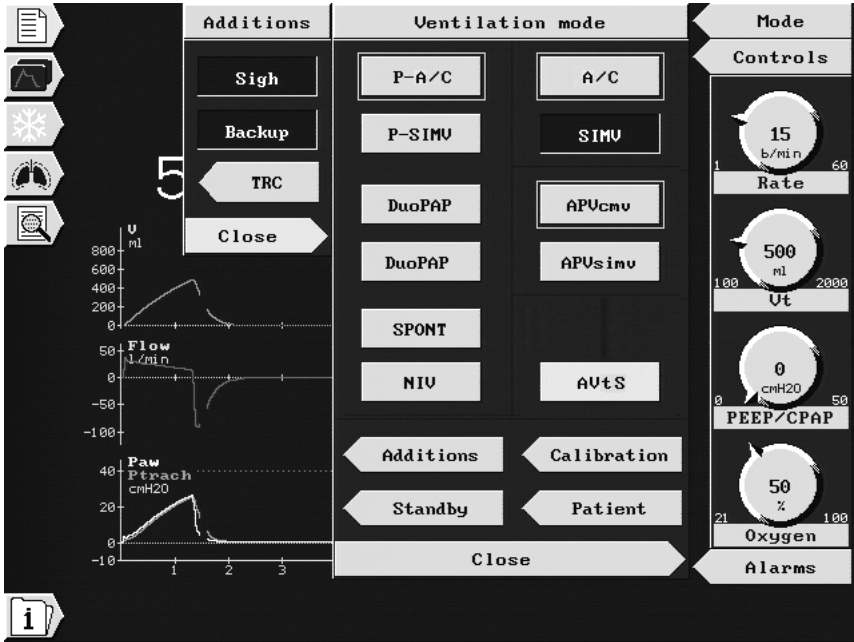


Figure 4-3. Additions window

4.4.1 Enabling/disabling the sigh function

The sigh function delivers a sigh breath at a regular interval, with a higher-than-normal pressure or volume.

In all modes except ASV, the sigh is delivered every 100 breaths. In volume-controlled modes, sigh breaths have a tidal volume 50% higher than nonsigh breaths, up to a maximum of 2000 ml. In pressure-controlled modes, sigh breaths are delivered at a pressure up to 10 cmH₂O higher than nonsigh breaths, as allowed by the high Pressure alarm limit.

In ASV mode, the sigh is delivered every 50 breaths, at a pressure 10 cmH₂O higher than nonsigh breaths.

During sigh breaths, the high Pressure limit remains in effect to help protect the patient from excessive pressures.

Enable or disable the sigh function as follows:

1. From the **Additions** window, select and activate or deactivate **Sigh**.
2. **Close** the **Additions** and the **Ventilation mode** windows to confirm the selection.

Once the sigh function is enabled, **Sigh** is displayed beside the current mode.

4.4.2 Enabling/disabling apnea backup ventilation

WARNING

HAMILTON MEDICAL recommends that apnea backup ventilation be enabled whenever a mode that allows spontaneous breathing is selected.

NOTE:

When enabling apnea backup ventilation, verify appropriate apnea backup control settings in the **Controls** window (Figure 4-5).

4.4.2.1 About apnea backup ventilation

Apnea backup ventilation is active wherever applicable as factory default.

The GALILEO provides apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea can occur in modes that allow spontaneous breathing (that is, all modes except (S)CMV (A/C), P-CMV (P-A/C), and APVcmv). When the GALILEO is in such a mode and no inspiratory efforts are detected or control breaths are delivered during an operator-set interval, it declares apnea. If apnea backup ventilation is enabled, ventilation continues.

When apnea backup ventilation is enabled, it provides ventilation after the Apnea time passes with no breath attempts detected. (You set the Apnea time in the **Alarms** window.) When this occurs, the GALILEO automatically and immediately switches into apnea backup ventilation. It annunciates a medium-priority alarm, displays **Apnea**

ventilation, and provides ventilation at the following settings:

If the original support mode is...	the GALILEO enters this backup mode...	and ventilates using these settings
SIMV	(S)CMV (A/C)	Control settings shown in the Controls window. (Settings shown are from original mode where possible, or they are standard settings.)
SPONT, P-SIMV, DuoPAP, APRV, NIV	P-CMV (P-A/C)	
APVsimv	APVcmv	

If the patient triggers two consecutive breaths, the GALILEO reverts to ventilation at the original support mode and settings, and it displays **Apnea ventilation ended**.

Once apnea backup ventilation is enabled, it stays active in all applicable modes. Apnea backup ventilation requires no clinician intervention, although you can freely change the mode during apnea backup ventilation, either switching to a new mode or accepting the backup mode as the new mode.

When apnea backup ventilation is disabled, the high-priority alarm message **Apnea** is displayed when apnea occurs. **Backup disabled** is displayed in the yellow column on the left-hand side of the **Controls** window.

4.4.2.2 Procedure

Enable or disable apnea backup ventilation as follows:

1. From the **Additions** window, select and activate or deactivate **Backup**.
2. **Close** the **Additions** and the **Ventilation mode** windows to confirm the selection.

If the backup function is enabled, **Backup** is displayed beside the current mode.

To check or change backup control settings, refer to Section 4.7.

4.4.3 Setting tube resistance compensation (TRC)

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WARNING

- **Using the incorrect tube type or size setting can be dangerous. To prevent possible patient injury due to inappropriate compensation, make sure to set these appropriately.**
- **TRC may induce autotriggering. If autotriggering occurs, lower or disable the TRC setting.**

NOTE:

- TRC is intended for use with spontaneously breathing patients. It is not recommended for use with passive patients.
- When TRC is enabled, the displayed Ppeak may be higher than expected (that is, the sum of the set PEEP/CPAP plus Pcontrol/Psupport). This is especially likely in passive patients with low airway resistance. Look closely at the calculated tracheal pressure, which is simultaneously displayed as an orange curve.
- The tracheal pressure curve displayed is *calculated* from the proximal flow and pressure signals rather than *measured*.

To reduce the patient's work of breathing while on the GALILEO, the ventilator's tube resistance compensation (TRC) feature offsets the flow resistance imposed by the endotracheal (ET) or tracheostomy tube. TRC is active during exhalation in volume modes, and in both inspiration and exhalation in the other modes.

Enable or disable TRC and adjust the settings as follows:

1. From the **Additions** window, open the **TRC** window (Figure 4-4).

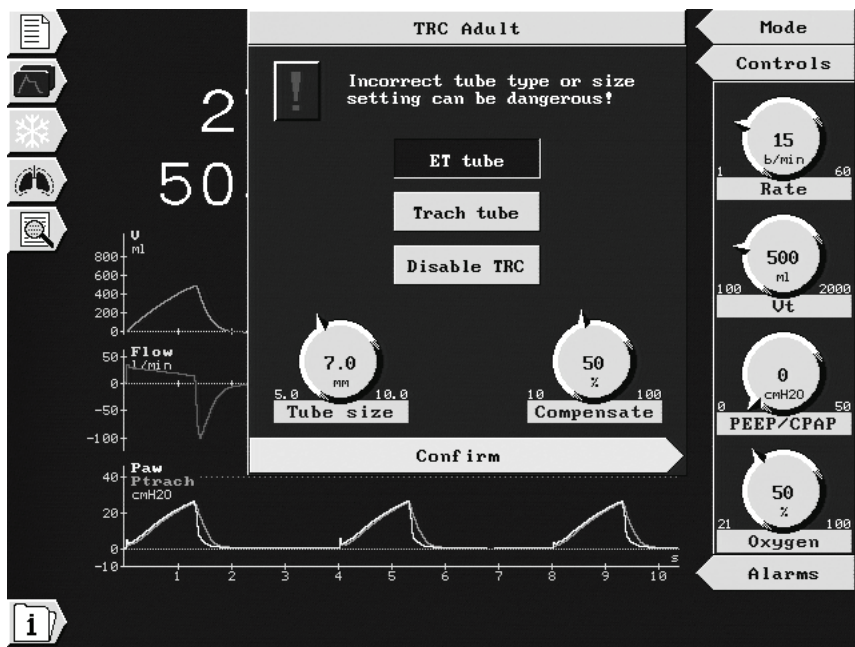


Figure 4-4. TRC window

2. Select and activate **ET tube** (endotracheal tube), **Trach tube** (tracheostomy tube), or **Disable TRC**.
3. If you selected **ET tube** or **Trach tube**, select and activate the **Tube size** (tube ID) and **Compensate** settings. If the ET tube is shortened, lower the **Compensate** setting. Adjust as required, then activate.

NOTE:

100% compensation means the maximum practicable compensation under the given conditions. It is not necessarily the theoretical full compensation of the tube resistance.

4. **Confirm** the entire selection.

If TRC is enabled, **TRC** is displayed beside the current mode.

4.5 Activating standby mode

See Section 9.2 for a description of standby mode.

4.6 Calibrations

See Section 3 for a description of calibrations.

4.7 Adjusting and confirming control settings

NOTE:

- If you intend to use the adaptive support ventilation mode ASV, we recommend that you consult Appendix D for more details.
 - When adjusting control settings, also verify appropriate apnea backup ventilation control settings if applicable.
-

Table 4-2 is an alphabetical list of the control settings. For control setting ranges and standard settings, see Table A-6. For control settings applicable to the different ventilation modes, see Table A-7.

4.7.1 Adjusting and confirming control settings after mode change

After you select a different mode, the **Controls** window automatically opens (Figure 4-5). It displays the following:

- Control settings for normal ventilation
- Control settings for apnea backup ventilation (if SPONT, SIMV, P-SIMV, APVsimv, DuoPAP, APRV, or NIV is active and apnea backup ventilation is enabled)
- Timing parameters, determined from the timing settings (if control breaths are permitted in the selected mode):
 - Rate and I:E: Identical to the settings in Table 4-2
 - Ttotal: Total breath cycle time
 - Tinsp: Duration of inspiratory phase, including any Pause
 - Texp: Duration of expiratory phase
 - Pause: Duration of pause or plateau
- Calculated MinVol and Vt (if ASV is active) (Figure 4-6)

You must review and confirm these settings, or the mode change will not be accepted.

Review and confirm the control settings as follows:

1. If you need to adjust a control setting, select it, then activate it. Adjust the value, then activate it. Repeat for any other desired parameters.
2. **Confirm** the entire selection.
3. If apnea backup ventilation is active, the message **Check backup controls** is displayed. Check the active settings for apnea backup ventilation by opening the **Controls** window and then following the instructions in Section 4.4.2.

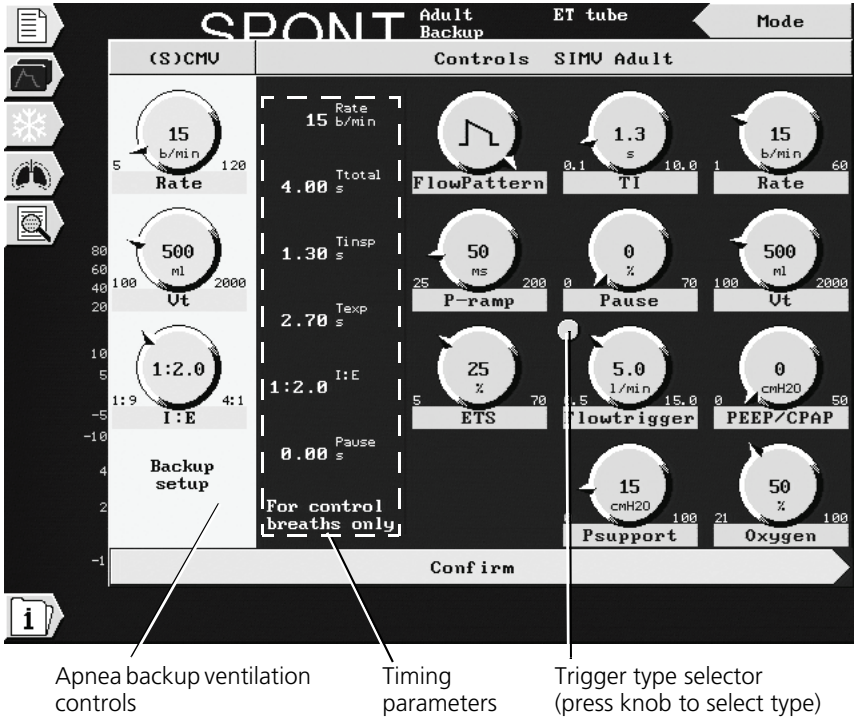


Figure 4-5. Controls window after mode change

Calculated
MinVol
and Vt

Controls

ASV Adult

17

Rate

b/min

7.0

MinVol

l/min

407

Vt

ml

70

kg

100

%

10

200

Body Wt

25

350

%MinVol

3.53

Ttotal

s

1.74

Tinsp

s

1.79

Texp

s

1:1.0

I:E

Pause

s

For control

breaths only

50

ms

25

200

P-ramp

25

%

5.0

l/min

0

cmH2O

50

%

5

70

ETS

0.5

15.0

Flowtrigger

0

50

PEEP/CPAP

21

100

Oxygen

Close

Figure 4-6. ASV mode controls window

4.7.2 Adjusting control settings without mode change

NOTE:

You can also change four of the most often-adjusted control settings from the basic screen without opening the **Controls** window. You simply select the parameter from the right-hand side of the screen, activate it, and adjust the value, then activate it. The adjusted value is then in effect.

Change the control settings at any time as follows:

1. Open the **Controls** window.
2. Select a parameter, then activate it. Adjust the value, then activate it. The change takes effect immediately. Repeat for any other desired parameters.
3. Close the window.

Table 4-2. Control settings and their definitions

Setting (unit)	Definition
%MinVol (%)	Percentage of minute volume to be delivered; regarded as the intended support level of ventilation. The GALILEO uses the %MinVol and the Body Wt setting to calculate the target minute ventilation. When you adjust %MinVol, HAMILTON MEDICAL recommends you start with 100% (100 ml/min/kg body weight for adults and 200 ml/min/kg body weight for pediatric patients), and adjust it as necessary. Applies in ASV mode (see Appendix D).
%TI (%)*	Time to deliver the required gas (time to reach the operator-set Vt or Pcontrol value), as a percentage of the total breath cycle. Applies to mandatory breaths, if the ventilator is so configured.

* Refer to Appendix H for details on breath timing profiles in the GALILEO.

Table 4-2. Control settings and their definitions (continued)

Setting (unit)	Definition
Body Wt (kg)	Ideal body weight (IBW) of patient (see Table D-6 and Table D-7). It is used to calculate the safety limits for the rate and tidal volume in the ASV mode. Applies in ASV mode.
ETS (%)	Expiratory trigger sensitivity. The percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation. Applies to spontaneous breaths.
Flow-Pattern	Flow pattern for gas delivery. This is not affected by patient back pressure or other limitations as long as the peak inspiratory flow or pressure limit is not exceeded. Applies to volume-controlled mandatory breaths.
Flowtrigger (l/min)	The patient's inspiratory flow that triggers the ventilator to deliver a breath. When the Flowtrigger is selected, the GALILEO generates a continuous and constant base flow from the inspiratory outlet to the expiratory outlet during the later part of exhalation. Base flow is essential for flow trigger. This base flow ranges from 4 and 30 l/min, as follows: • Minimal base flow is 10 l/min in adult modes and 4 l/min in pediatric & neonatal modes • Base flow = 2 x flow trigger sensitivity setting in l/min if the product is greater than the minimal base flow. Applies to all breaths in all modes, if selected. NOTE: If autotriggering occurs, first check the patient, breathing circuit, and GALILEO as possible causes before decreasing the trigger sensitivity.
I:E*	Ratio of inspiratory time to expiratory time. Applies to mandatory breaths, if the ventilator is so configured.
Oxygen (%)	Oxygen concentration to be delivered. Applies to all breaths in all modes.

* Refer to Appendix H for details on breath timing profiles in the GALILEO.

Table 4-2. Control settings and their definitions (continued)

Setting (unit)	Definition
Pause (%) [*]	Inspiratory pause or plateau, as a percentage of total breath cycle time. After the required gas is delivered (after the operator-set Vt is reached), gas remains in the lungs and exhalation is blocked during the Pause time. The use of a Pause increases the residence time of gas in the patient's lungs. Applies to volume-controlled mandatory breaths.
Pcontrol (cmH ₂ O)	Pressure (above PEEP/CPAP) to be applied during the inspiratory phase. Applies to mandatory breaths in P-CMV (P-A/C) and P-SIMV.
Peak Flow (l/min) [*]	Peak (maximum) inspiratory flow. It directly influences breath timing. Applies to volume-controlled mandatory breaths, if the ventilator is so configured.
PEEP/CPAP (cmH ₂ O)	PEEP (positive end expiratory pressure) and CPAP (continuous positive airway pressure), baseline pressures applied during the expiratory phase. Applies to all breaths in all modes.
P high (cmH ₂ O)	High positive airway pressure level. P high setting is <i>total</i> desired airway pressure, including P low. Applies to all breaths in DuoPAP and APRV modes.
P low (cmH ₂ O)	Low positive airway pressure level. Applies to all breaths in APRV mode.
P-ramp (ms)	Pressure ramp. Time required for inspiratory pressure to rise to the set (target) pressure. Applies to breaths in pressure modes. NOTE: If airway resistance is high and the P-ramp is short, you may see pressure overshooting during early inspiration. In this case, lengthen the P-ramp.

^{*} Refer to Appendix H for details on breath timing profiles in the GALILEO.

Table 4-2. Control settings and their definitions (continued)

Setting (unit)	Definition
Psupport (cmH ₂ O)	Pressure (above PEEP/CPAP) to be applied to a patient-triggered breath during the inspiratory phase. Applies to spontaneous breaths in SIMV, P-SIMV, SPONT, APVsimv, DuoPAP, APRV, and NIV modes.
P-trigger (cmH ₂ O)	Pressure trigger. The pressure drop below PEEP/CPAP required to begin a patient-initiated breath. Applies to all breaths in all modes, if selected. NOTE: If autotriggering occurs, first check the patient, breathing circuit, and GALILEO for possible causes before decreasing the trigger sensitivity.
Rate (b/min)	Respiratory frequency or number of breaths per minute. Applies to mandatory breaths in (S)CMV (A/C), P-CMV (P-A/C), SIMV, P-SIMV, APVsimv, and DuoPAP modes.
TI (s)*	Time to deliver the required gas (time to reach the operator-set Vt or Pcontrol value), in seconds. Applies to mandatory breaths, if the ventilator is so configured.
T high (s)	Duration of high airway pressure level. Applies to all breaths in DuoPAP and APRV modes.
Ti max (s)*	Maximum inspiratory time. Applies to spontaneous breaths in infant and pediatric modes plus NIV.
Tip (s)*	Inspiratory pause or plateau, in seconds. After the required gas is delivered (after the operator-set Vt is reached), gas remains in the lungs and exhalation is blocked during the Tip time. The use of a Tip increases the residence time of gas in the patient's lungs. Applies to volume-controlled mandatory breaths, if the ventilator is so configured.

* Refer to Appendix H for details on breath timing profiles in the GALILEO.

Table 4-2. Control settings and their definitions (continued)

Setting (unit)	Definition
T low (s)	Duration of low airway pressure level. Applies to all breaths in APRV mode.
Trigger off	Prevents the ventilator from recognizing a patient trigger. Applies to all breaths in (S)CMV (A/C), P-CMV (P-A/C), and APVcmv, if selected. WARNING To minimize patient-ventilator dyssynchrony, never set the trigger off for spontaneously breathing patients without sound clinical reasons.
Vt (ml)	Tidal volume delivered during inspiration. Applies to volume-controlled mandatory breaths.
Vtarget (ml)	Target tidal volume to be delivered during inspiration. The GALILEO meets the Vtarget by adjusting the inspiratory pressure by 1 cmH ₂ O per breath. Applies to breaths in APVcmv and APVsimv modes.

* Refer to Appendix H for details on breath timing profiles in the GALILEO.

4.8 Setting alarm limits

WARNING

To prevent possible patient injury, make sure the alarm limits are appropriately set before you place the patient on the GALILEO.

You can set all alarms quickly using the Auto alarm function, but the settings may not be appropriate under all clinical conditions. HAMILTON MEDICAL recommends that you set the alarms manually when possible. When you do use the Auto alarm function, check the appropriateness of these settings at the earliest opportunity.

NOTE:

- If the ventilator is in the ASV, APVcmv, or APVsimv mode, be sure the high Pressure alarm is properly set. This alarm provides a safety pressure limit for the GALILEO to appropriately adjust the inspiratory pressure necessary to achieve the target tidal volume. The maximum available inspiratory pressure is normally 10 cmH₂O below the high Pressure limit, indicated by a blue bar on the pressure curve display. Set the high Pressure limit to a safe value (e.g., 45 cmH₂O, which limits the pressure target to a maximum of 35 cmH₂O). If the high Pressure alarm is set too low, there may not be enough margin for the GALILEO to adjust its inspiratory pressure in order to deliver the target tidal volume.
 - You can selectively enable or disable 8 of the 10 adjustable alarms during configuration (see Appendix H). At the minimum, the high Pressure, low ExpMinVol, and Apnea alarms are always active.
 - The green numbers to the left of the alarm columns refer to currently measured values. The red numbers and associated column fill refer to current alarm setting values. The range of each alarm is depicted in white numbers at the end of each column.
-

You can access the **Alarms** window and change alarm settings at any time, without affecting ventilation.

The GALILEO offers two alarm-setting options:

- You can individually set alarm limits. Table 4-3 is an alphabetical list of the settings and definitions.
- Using the Auto alarm function, you can automatically set all alarm limits. Table A-11 lists the Auto alarm settings.

Review and adjust the alarm limits as follows:

1. Open the **Alarms** window (Figure 4-7).
2. To individually set a parameter, select it, then activate it. Adjust the value, then activate it. Repeat for any other desired parameters.
3. To select the Auto alarm function, select **Auto**, then activate it.
4. **Close** the window to confirm the selection.

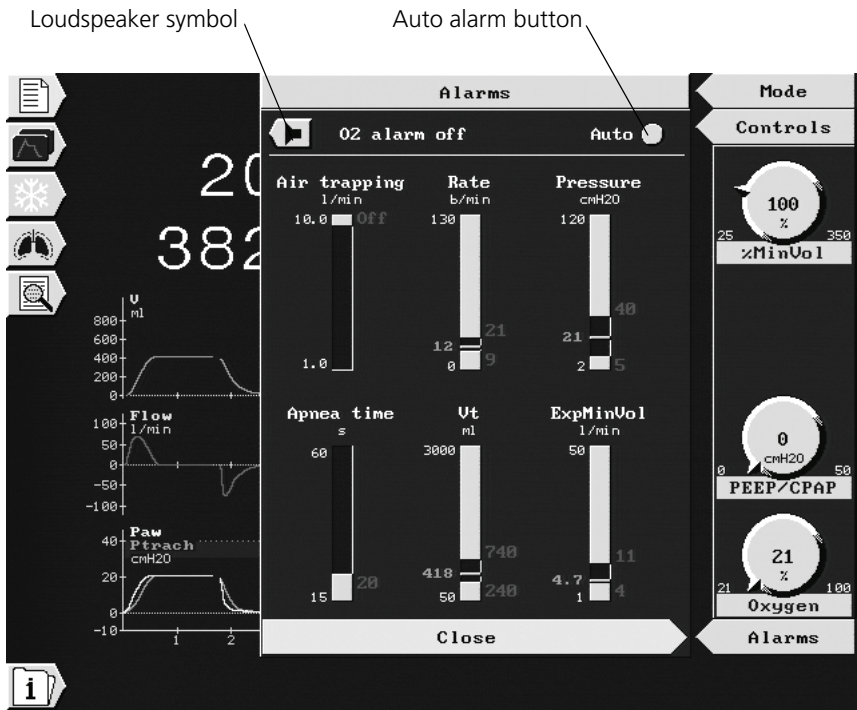


Figure 4-7. Alarms window

4.9 Adjusting alarm loudness

NOTE:

- If the alarm loudness was set to < 5 before the ventilator was powered off, the loudness setting will default to 5 when the GALILEO is powered on.
- If you decrease the alarm loudness during the night shift, do not forget to return it to its daytime setting!

Adjust the alarm loudness as follows:

1. Open the **Alarms** window (Figure 4-7).
2. Select the loudspeaker symbol, then activate it to open the **Alarm loudness** window (Figure 4-8).

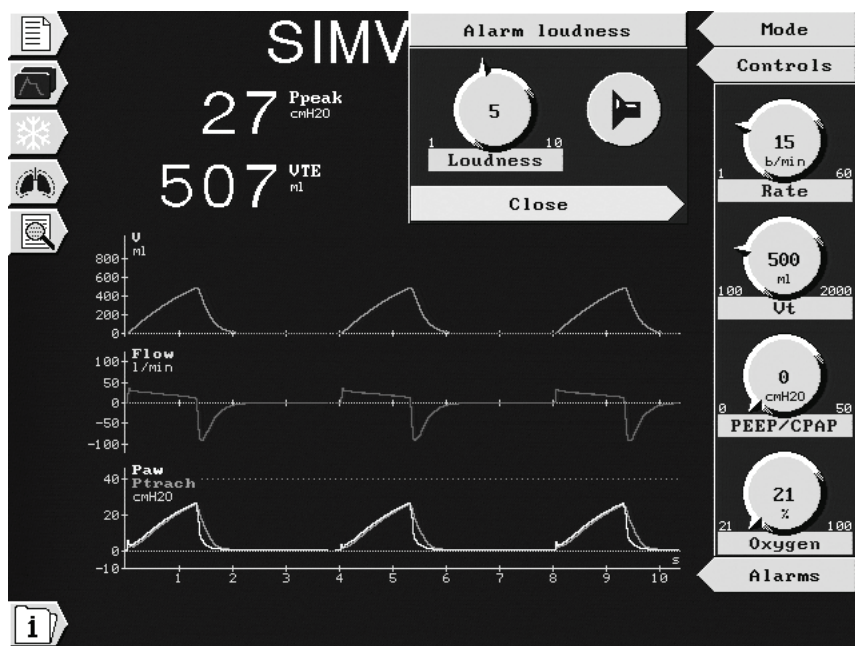


Figure 4-8. Alarm loudness window

3. Select the **Loudness** knob, then activate it. Adjust the loudness value, then activate it. Select the right-hand test knob, then activate it to test the loudness.
4. Repeat the process as required.
5. **Close** the window to confirm the selection.

Table 4-3. Alarm limit settings and definitions

Setting (unit)	Definition
Air trapping (l/min)	The maximum end expiratory flow (Exp Flow) allowed for two consecutive breaths. A medium-priority alarm is annunciated if the set end expiratory flow is exceeded. Air trapping is a sensitive indicator of AutoPEEP.
Apnea time (s)	The maximum time allowed from the beginning of one inspiration to the beginning of the next inspiration. If the patient does not trigger a breath during this time, an alarm is annunciated. Apnea backup ventilation will begin, if enabled. The Apnea alarm is suppressed under these conditions: • When the ventilator is in the ambient state, standby, or any of these modes is active: (S)CMV (A/C), P-CMV (P-A/C), APVcmv, or ASV. • During Flow Sensor calibration or the tightness test If apnea backup ventilation is not enabled, apnea is detected, and the alarm silence is active, the alarm silence is terminated immediately.
ExpMinVol (low and high) (l/min)	Low and high expiratory minute volume (ExpMinVol). If either limit is reached, a high-priority alarm is annunciated. NOTE: For infants, you can set the ExpMinVol alarm to Off . If you do set the ExpMinVol alarm to Off , the pressure alarms become critical, so pay close attention to them and set the low Pressure alarm to an appropriately sensitive level.

Table 4-3. Alarm limit settings and definitions (continued)

Setting (unit)	Definition
Pressure (low and high) (cmH ₂ O)	Low and high monitored pressures at the patient airway (Ppeak). If either limit is reached, a high-priority alarm is annunciated. In addition, if the high Pressure limit is reached, the GALILEO immediately stops gas flow to the patient and relieves pressure until pressure falls to the PEEP/CPAP level. If the airway pressure continues to rise above 120 cmH₂O, the mechanical overpressure relief valve opens and the ventilator enters the ambient state. When the GALILEO is in the ASV, APVcmv, or APVsimv mode, the ventilator uses the high Pressure limit as a safety boundary for its inspiratory pressure adjustment. Normally ASV does not apply inspiratory pressures higher than 10 cmH₂O below the high Pressure limit. An exception is sigh breaths, when ASV may apply inspiratory pressure 3 cmH₂O below the high Pressure limit.
Rate (low and high) (b/min)	Low and high monitored total breath rate (fTotal), including both spontaneous and mandatory breaths. If either limit is reached, a medium-priority alarm is annunciated. NOTE: Respiratory rate monitoring on the GALILEO requires breath delivery followed by detection of expiratory flow at the proximal Flow Sensor.
Vt (low and high) (ml)	Low and high monitored tidal volume (Vt), for two consecutive breaths. If either limit is reached, a medium-priority alarm is annunciated.

5 Neonate and infant ventilation details

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WARNING

To prevent possible patient injury, make sure the ventilator is set up correctly for the infant patient. The `Infant` patient age group must be selected through the `Additions` window. The ventilator must have the appropriate breathing circuit parts, including the infant Flow Sensor, as described in Section 2. *Make sure the Flow Sensor calibration is performed before you use the ventilator on the infant.*

NOTE:

For patients with bodyweights at the high end of the infant setting range (> 7 kg), you may want to select the pediatric patient type. This prevents you from having to change circuits and calibrate the flow sensor should you later decide that your patient requires more support.

You can use the GALILEO to ventilate neonate and infant patients weighing up to 10 kg. Although the procedure for ventilating infants is almost identical to that for ventilating other patients, there are some important differences. This section points out these differences, and is intended to supplement the rest of the manual.

5.1 Breathing circuit

Use an infant breathing circuit with 10 mm ID tubes to ventilate your infant patient. Do not use an adult breathing circuit (22 mm ID breathing tubes) or a pediatric breathing circuit (15 mm ID breathing tubes).

A heating wire may noticeably increase the inspiratory resistance of the infant breathing circuit.

5.2 Flow Sensor

CAUTION

If you plan to change the patient age group from infant to pediatric, you must first change and calibrate the Flow Sensor. The infant Flow Sensor can only be used when the infant patient age group is selected. It cannot be used in pediatric applications.

Use a HAMILTON MEDICAL infant Flow Sensor to ventilate your infant patient. Do not use a pediatric/adult Flow Sensor. The infant Flow Sensor has a dead space of 1.3 ml.

Calibrate the infant Flow Sensor between patients, after installing a new Flow Sensor, or whenever the **Flow Sensor cal. needed** alarm is activated. Unlike for the pediatric/adult Flow Sensor calibration, you do *not* turn the infant Flow Sensor during calibration. During Flow Sensor calibration, the GALILEO can recognize a mismatch between the set patient age group and the Flow Sensor in use. In response it annunciates a **Wrong Flow Sensor type** alarm.

5.3 Ventilation modes and mode additions

To ventilate infant patients, you must first select and activate the **Infant** patient age group.

All infant modes available in the GALILEO are pressure modes. These include: P-CMV (P-A/C), APVcmv, APVsimv, DuoPAP, APRV, and SPONT. The standard mode setting is P-CMV (P-A/C). Volume-controlled modes, including (S)CMV (A/C) and SIMV, are not available. Adaptive support ventilation (ASV) is not available. Noninvasive ventilation (NIV) is not available.

NOTE:

- The GALILEO has several ventilation modes in neonatal & infant application. APVcmv and APVsimv modes should be used in the patients of 2 kg or greater. The rest modes do not have the limit.
 - The tidal volume is tiny in neonates and infants. Increased total dead space leads directly to decreased alveolar ventilation. The operators should
a) avoid installing anything at the artificial airway, e.g. HME, mainstream CO2 probe, Flex tube, etc.
and b) adjust ventilator settings if the item(s) is clinically required.
 - Because infant ET tubes normally do not have a cuff, leakage can be significant (that is, VLeak can be much greater than the measured expiratory tidal volume (VTE)). Check the VLeak parameter in the monitoring window from time to time; the leak may not be predictable.
-

5.4 Controls

The following controls require special consideration when setting up the ventilator for an infant patient.

Table A-5 lists standard settings applicable to infants. Table A-6 lists the control settings applicable to all modes and patient age groups.

5.4.1 Ti max

Ti max (maximum inspiratory time) is set for spontaneous breaths, in P-SIMV, APVsimv, SPONT, DuoPAP, and APRV modes. For all patient age groups, the switchover from inspiration to exhalation in spontaneous breaths is normally controlled by the ETS (expiratory trigger sensitivity). If gas leakage is significant, however, the set ETS may never be reached. The Ti max setting provides a backup so inspiration can be terminated. The GALILEO switches over to exhalation when the set Ti max is reached.

5.4.2 Flowtrigger

The default trigger type for infants is flow triggering.

In a tight patient breathing circuit, the flow baseline is zero. If there is significant gas leakage, however, the delivered flow baseline rises to compensate for the leak. If the leak flow is higher than the Flowtrigger setting, autotriggering occurs. To solve the problem, you can raise the Flowtrigger setting (that is, decrease the sensitivity) until the autotriggering stops.

For example, let's say you set the Flowtrigger initially to 0.5 l/min, but the leak flow from the patient is 2 l/min, so autotriggering occurs. If you raise the Flowtrigger setting to 2.5 l/min, autotriggering stops. The patient actually triggers breaths at 0.5 l/min, because $2.5 \text{ l/min} - 2.0 \text{ l/min (new baseline)} = 0.5 \text{ l/min}$.

Check the patient and adjust the Flowtrigger from time to time; the leak flow may vary due to change in patient position.

5.4.3 P-ramp

If an infant patient has stiff lungs (for example, RDS), be careful not to set a short P-ramp (pressure rise time). A very short P-ramp in this case may cause pressure overshoot.

5.5 Testing and calibration

Just as you would do for any patient, you must run the preoperational test described in Section 3.3 before placing your infant patient on the ventilator. This test includes a test for leak-tightness of the breathing circuit, calibration of the infant Flow Sensor, and a system test of the GALILEO geared for an infant. The preoperational test requires an infant lung model.

5.6 Others

The optional integrated nebulizer is suppressed if the nebulizer volume is greater than 50% of the total delivered volume. In infant application, the internal pneumatic nebulizer is often suppressed due to tiny tidal volume. If the nebulization is strongly indicated for clinical reasons, consider to use an external ultrasonic nebulizer, e.g., Aeronneb.

Be aware that when the 100% O₂ mode is selected, oxygenation will continue for 2 min unless you terminate it by pressing the 100% O₂ key again.

The maximum inspiratory or expiratory breath hold time in infant modes is 3 s, compared to 10 s in adult or pediatric modes.

6 Monitoring

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6.1 Accessing patient data

WARNING

GALILEO's oxygen monitoring function can be disabled during ventilator configuration. To prevent possible patient injury due to nonfunctional alarms and monitoring, however, HAMILTON MEDICAL recommends that oxygen monitoring always be enabled.

NOTE:

To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external monitor that complies with ISO 7767.

During ventilation, you can view patient data on the screen (Figure 6-1). Using the M-knob, you can also access the monitoring windows any time without affecting breath delivery.

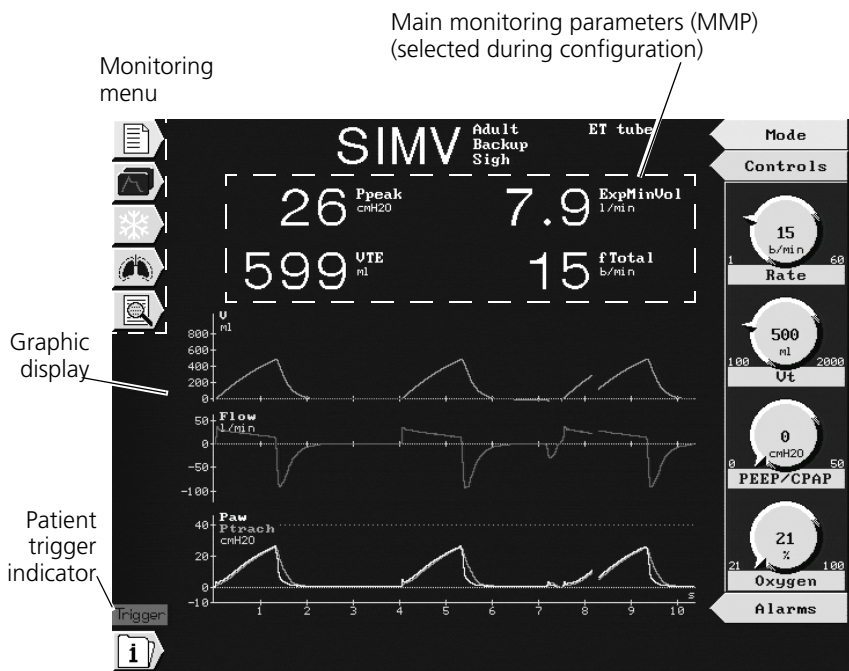


Figure 6-1. Basic screen

6.2 Monitoring menu

The monitoring menu (Figure 6-2) lets you open monitoring windows to view more numeric data or configure the graphic display differently.

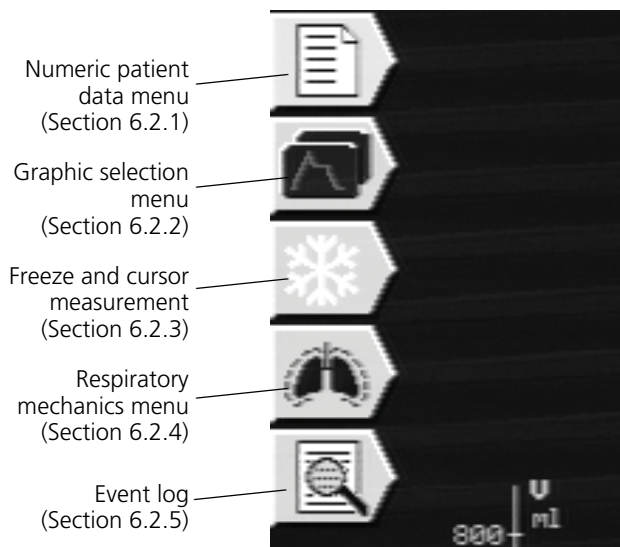


Figure 6-2. Monitoring menu

Use the navigation map in Figure 6-3 to help locate the desired monitoring function. To select a menu item, turn the M-knob to select the symbol, then press the knob to see another menu or to activate the selection.

		Shows 26 monitored parameters
		Shows ASV target and monitored parameters (only when ASV mode is active)
		Activates airway or auxiliary pressure-based calculations of some parameters
		Selects and displays real-time waveforms
		Selects and displays real-time loop
		Selects and displays trend curves
		Displays ASV target graphic screen (only when ASV mode is active)
		Freezes running waveforms or trends and activates cursor measurement
		Selects and activates inspiratory or expiratory hold
		Selects the P/V Tool to perform a pressure/volume curve maneuver
		Selects the P/V Tool 2 to perform a pressure/volume curve maneuver
		Opens Event log to show up to 1000 events, including alarms and settings changes

Figure 6-3. Navigating the monitoring menu

6.2.1 Numeric patient data menu

From the monitoring menu, select the numeric patient data symbol. Then, from the numeric patient data menu (Figure 6-4), select and activate the desired menu item.

Table 6-1 describes the monitored parameters.

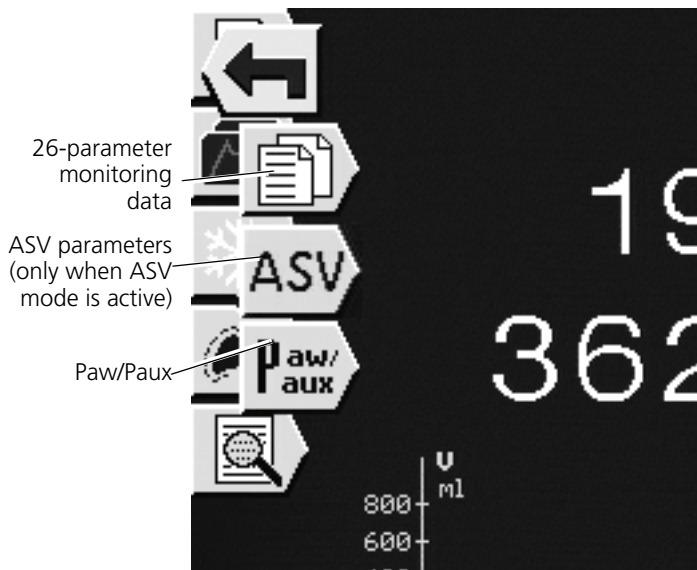


Figure 6-4. Menu for the numeric patient display

6.2.1.1 Viewing 26 monitored parameters

View 26 monitored parameters, as shown in Figure 6-5. The thin black lines on the screen show how the parameters are clustered by type. Hash marks in the window indicate conditions are not right for proper or accurate measurement.

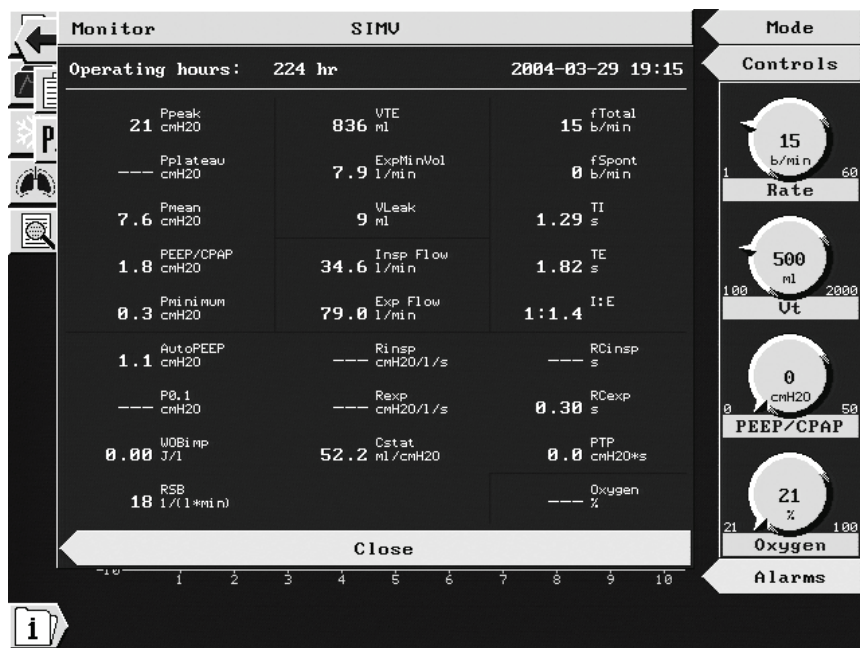


Figure 6-5. 26-parameter monitoring window

6.2.1.2 Viewing ASV numeric parameters

The **ASV** monitored parameter window (Figure D-4), which is accessible only in the ASV mode, provides numeric target and actual parameters for tidal volume, frequency, pressure, and minute ventilation.

To open the **ASV** monitored parameter window, select the ASV symbol. See Appendix D for detailed information on ASV, including how to interpret the data in the window.

6.2.1.3 Selecting pressure input (Paw or Paux) for numeric patient data

NOTE:

When you select the Paux input through the numeric patient data menu, the auxiliary pressure is used as an input in numeric pressure measurements. To display the auxiliary pressure as a curve or in a loop, you must separately assign it through the graphic selection menu.

The GALILEO uses the airway pressure (Paw) as its standard pressure input. You can reassign the GALILEO's pressure input, so that monitored numeric parameters are based on a pressure from a different site, such as the carina. This auxiliary pressure input can be particularly useful when conducting scientific and clinical studies.

To change the pressure source for monitored data, from the numeric patient data menu select the Paw/Paux symbol. Then, from the Paw/Paux menu (Figure 6-6), select Paw or Paux, then activate it.

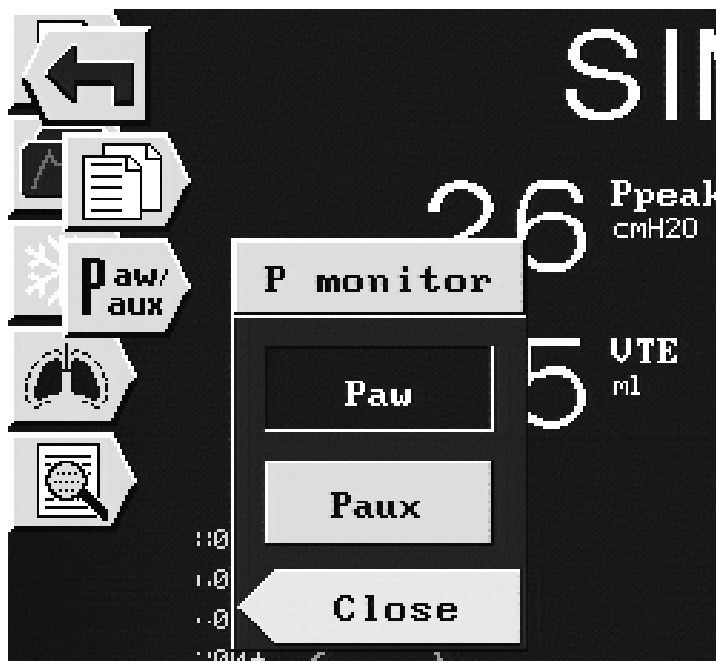


Figure 6-6. P monitor menu

When the Paux pressure input is active, Paux is displayed in the upper right-hand corner of the monitoring window, and the color of the pressure-based parameters changes to orange. This signifies that the parameters are based on the Paux input. These pressure-based parameters are as follows:

Ppeak	Rinsp	RCinsp
Pplateau	Rexp	PTP
Pmean	Cstat	
PEEP/CPAP		
Pminimum		
AutoPEEP		
P0.1		
WOBimp		

To use the auxiliary pressure input, you must connect the site to the ventilator through the Paux connector.

6.2.2 Graphic selection menu

From the monitoring menu, select the graphic selection symbol. Then, from the graphic selection menu (Figure 6-7), select the desired menu item, then activate it.

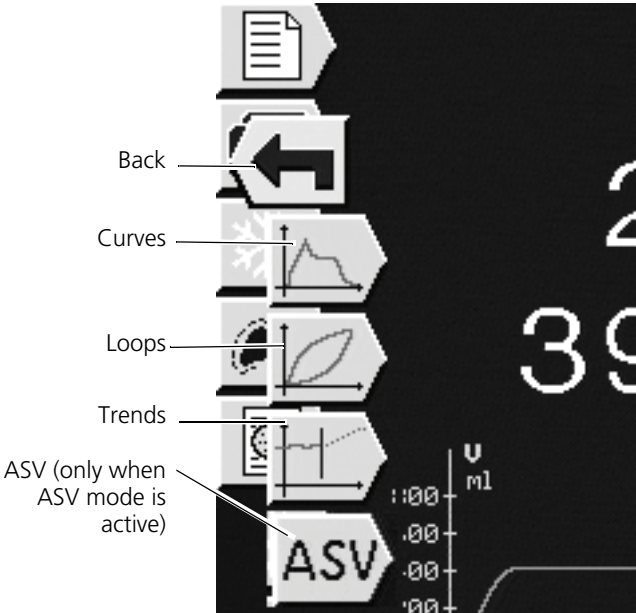


Figure 6-7. Graphic selection menu

6.2.2.1 Selecting curves

You can choose to show real-time patient data as one to three curves. The curves show pressure (either airway or auxiliary), flow, or volume plotted as a function of time.

Select the types of curve by opening the **Curves** menu (Figure 6-8), then selecting and activating the desired parameters. **Close** the menu to confirm the selection.

NOTE:

- If three parameters are highlighted and you want to change one parameter, you must deselect one first.
 - The GALILEO may scale curves differently, based on the range of values to be displayed. For example, the pressure scale may vary from one pressure/time curve to another pressure/time curve.
 - If TRC is activated, an additional calculated carina pressure curve is shown.
-

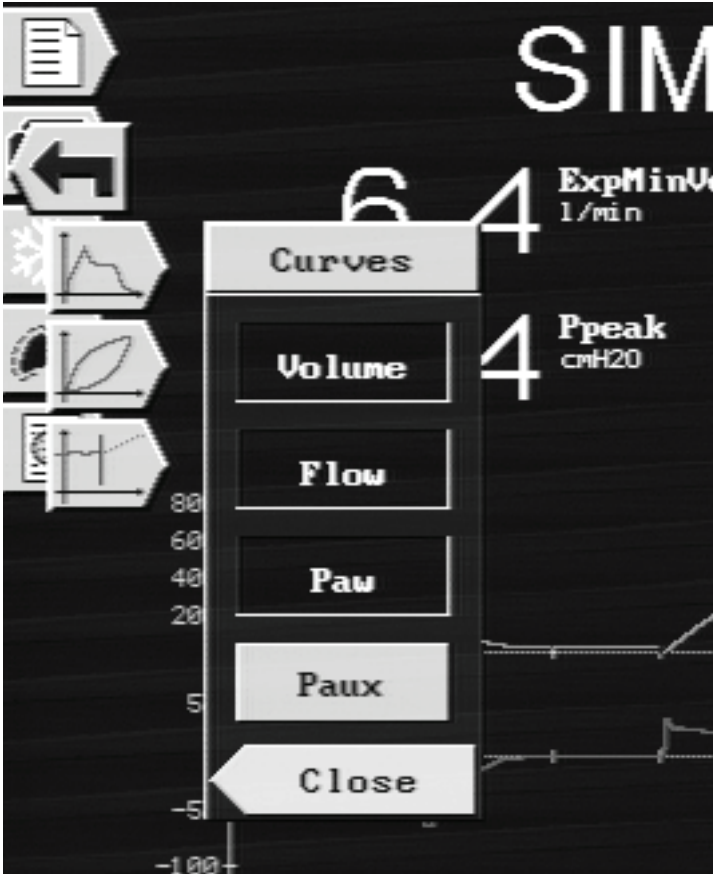


Figure 6-8. Curves menu

6.2.2.2 Selecting a loop

You can choose to show real-time patient data as a loop.

To enable and set up the loop display, open the **Loops** menu (Figure 6-9), then select and activate the desired X and Y axis parameters. **Close** the menu to confirm the selection. The loop will be displayed (Figure 6-10).

NOTE:

- When **Paw/Paux** is selected, both these values are displayed together, plotted against the second parameter. This lets you view patient pressures at two distinct points. Plotting both pressures against volume lets you view P/V loops together on the selected axis. This way you can compare a system view (Paw/V) against the more classic P/V loop (Paux/V). Resistance caused by the ET tube, HME, breathing circuit, exhalation assembly, etc., as opposed to the patient's airway resistance and compliance, becomes obvious. Other important distinctions such as WOB may be seen from the Paux/V loop.
 - The GALILEO may scale the X and Y axes for loops differently, based on the range of values to be displayed. For example, the pressure scale (X axis) may vary from one pressure/volume loop to another pressure/volume loop.
-

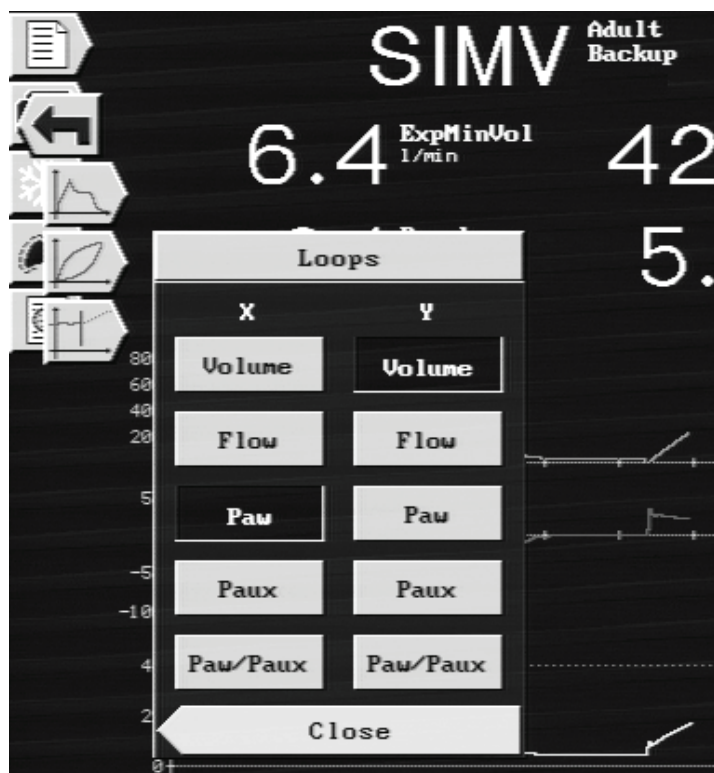


Figure 6-9. Loops menu

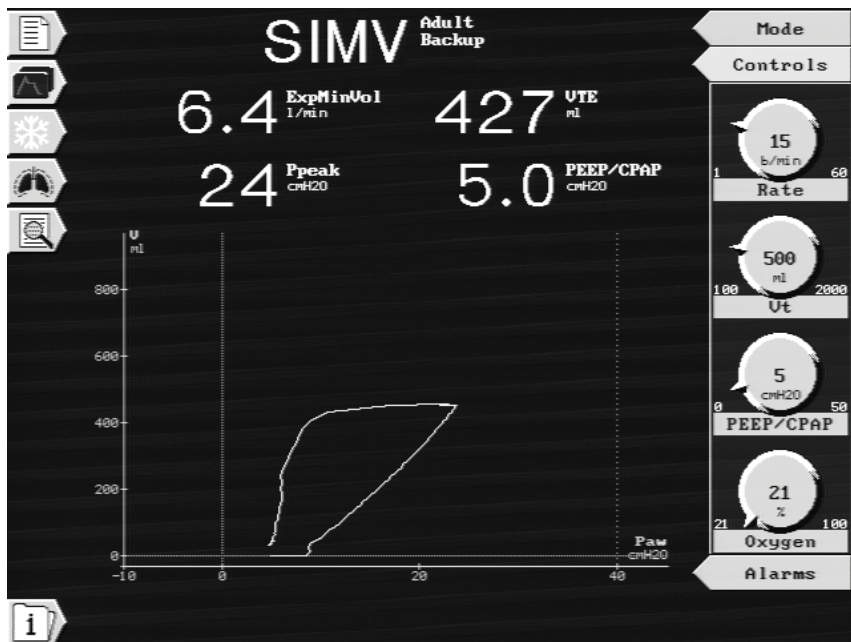


Figure 6-10. Loop display

6.2.2.3 Selecting trends

NOTE:

In setting up trends, you can choose among the monitored parameters shown in the 26-parameter monitoring window with these additions:

- To trend Ppeak, Pmean, and PEEP/CPAP, select Pcombi; this causes all pressure values to be trended together.
 - To trend fTotal and fControl, select fcombi; this causes both rate values to be trended together.
 - You can also trend the Pinsp parameter.
-

You can choose to show up to three monitored parameters as 1, 12, or 24-hour trends. To enable and set up the trend display, open the **Trend parameter selection** window (Figure 6-11), then select and activate up to three parameters. **Close** the window to confirm the selection. You will see the trend displays (Figure 6-12), including all data since you switched on the ventilator or for the past 1, 12, or 24 hours. The number displayed to the right of the curve is a mean or median value.

From the time you switch on power to the GALILEO, the GALILEO continually stores the monitored parameters in its memory, so you have access to any of this data, even after standby. The data disappears from the GALILEO's memory when power is switched off.

The freeze and cursor measurement function (Section 6.2.2.3) may also be used to examine points on trend curves. When trends are frozen, the time axis shows time relative to the present.

Trend parameter selection				
Pressure	Pcombi cmH2O	Ppeak cmH2O	Pmean cmH2O	PEEP/CPAP cmH2O
	Pplateau cmH2O	Pminimum cmH2O	AutoPEEP cmH2O	Pinsp cmH2O
Volume	ExpMinVol l/min	UTE ml	ULeak ml	
Peak flow	Exp Flow l/min	Insp Flow l/min		
Rate	fcombi b/min	fTotal b/min	fSpont b/min	
Time	TI s	TE s	I:E	
	RCinsp s	RCexp s		
R & C	Cstat ml/cmH2O	Rinsp cmH2O/l/s	Rexp cmH2O/l/s	
Others	P0.1 cmH2O	WOBimp J/l	PTP cmH2O*s	RSB 1/(l*min)
	Oxygen %			
1 hr 12 hr 24 hr				

Mode

Controls

Rate

Vt

PEEP/CPAP

Oxygen

Alarms

Close

i

Figure 6-11. Trend parameter selection window

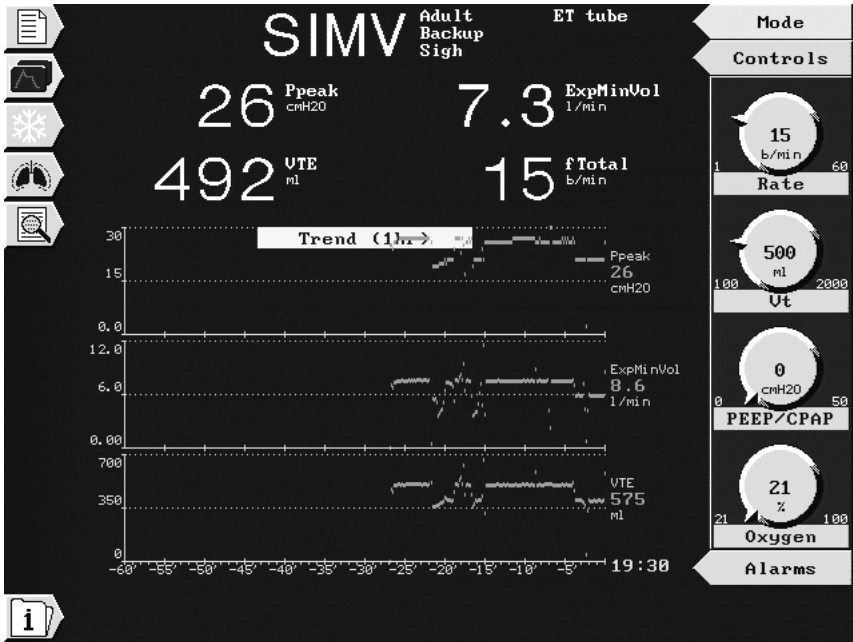


Figure 6-12. Trend displays

6.2.2.4 Viewing the ASV target graphics screen

The ASV target graphics screen (Figure D-3), which is accessible only in the ASV mode, shows how the adaptive lung controller moves toward its targets. It shows both the target and actual parameters for tidal volume, frequency, pressure, and minute ventilation.

To display the ASV target graphics screen, select the ASV symbol. See Appendix D for detailed information on ASV, including how to interpret the data in the screen.

6.2.3 Freeze and cursor measurement

NOTE:

- The freeze function is terminated if you press the M-knob or if you do not move the cursor for 30 s.
 - When a curve is frozen, the time axis shows time relative to the present.
-

This function lets you freeze the display of real-time or trend curves, so that you can view the curves for an extended period of time. It also lets you determine the numeric value for points on a curve. The freeze function is particularly useful when you perform a breath hold maneuver. The screen automatically freezes following a successful inspiratory or expiratory hold maneuver. The function is selectable only when real-time or trend curves are currently on display.

To freeze the curves, select the freeze and cursor measurement symbol from the monitoring menu. Activate the selection by pressing the M-knob. This freezes the curves (Figure 6-13).

To read the numeric value at a point on the curve, turn the M-knob. You can read the value to the right of the curve.

Press the M-knob to terminate the function.

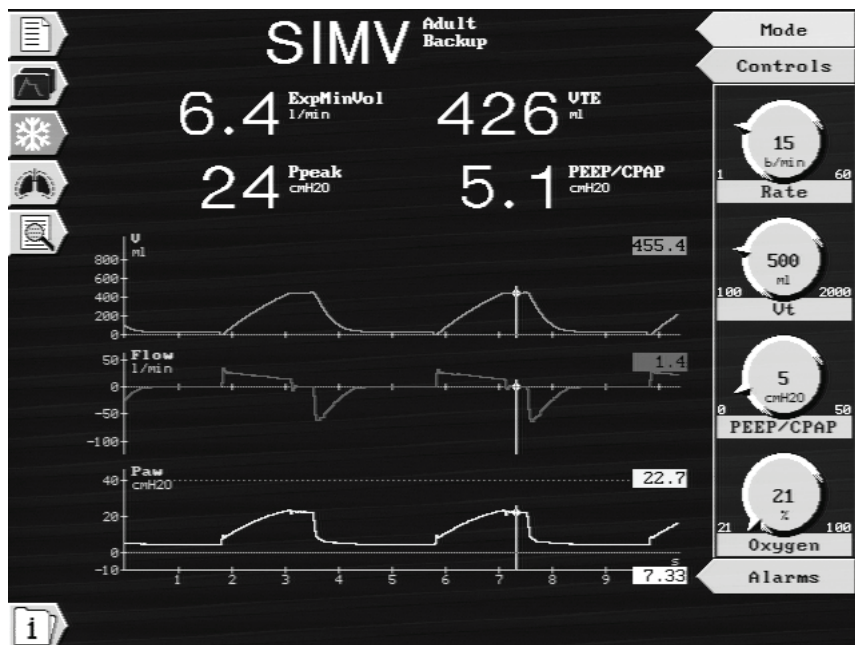


Figure 6-13. Freeze and cursor screen

6.2.4 Respiratory mechanics menu

From the monitoring menu, select the maneuvers symbol. Then, from the respiratory mechanics menu (Figure 6-14), select the desired menu item, then activate it.

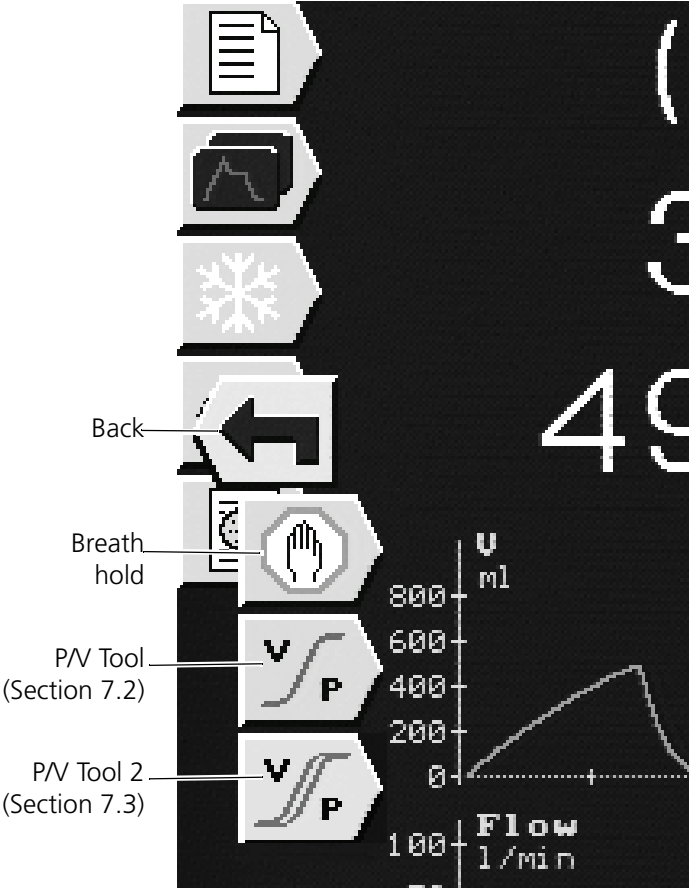


Figure 6-14. Respiratory mechanics menu

6.2.4.1 Breath hold function

WARNING

The GALILEO does not provide ventilation during breath hold maneuvers.

The breath hold function lets you stop the ventilator's breathing cycle at the end of inspiration or exhalation, for a maximum of 10 s (adult and pediatric patients) or 3 s (infant patients). The primary application of the breath hold is to measure lung mechanics in the classical way.

To perform the breath hold maneuver, select the breath hold symbol from the monitoring menu. Then, from the breath hold menu (Figure 6-15), select an inspiratory or expiratory hold (**Insp hold** or **Exp hold**). Activate the selection by pressing the knob. When the pressure curve flattens, deactivate the hold maneuver by pressing the knob again. **Close** the menu. The freeze function is activated automatically.

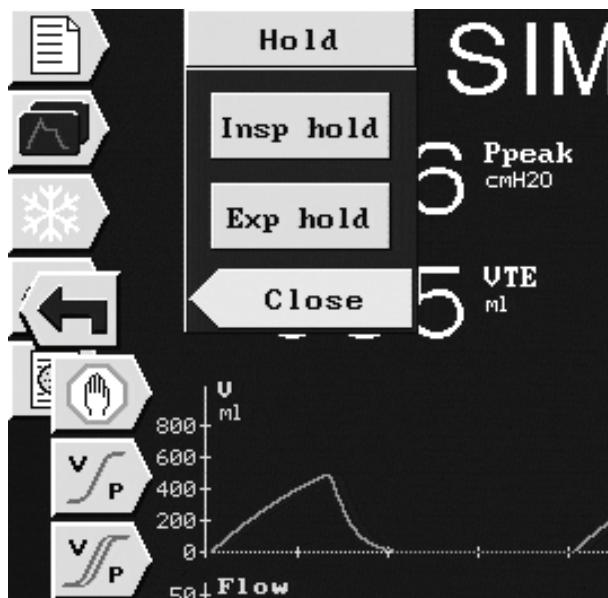


Figure 6-15. Breath hold menu

You can terminate a pending hold by closing the window. You can terminate an active hold by pressing the M-knob during the hold cycle.

Example: Perform a manual AutoPEEP assessment maneuver as follows:

1. Make sure the Paw curve is displayed.
2. Open the breath hold menu.
3. Wait until the Paw curve plot restarts from the left-hand side.
4. Wait for the next inspiration.
5. Activate **Exp hold** and immediately select **Close** without activating it, that is, without pressing the M-knob.
6. Observe the patient's Paw during the subsequent obstructed exhalation phase.
7. Measure AutoPEEP by moving the cursor with the M-knob (for details about the freeze and cursor measurement, see Section 6.2.3).

6.2.5 Event log

The **Event log** (Figure 6-16) contains data about clinically relevant ventilator occurrences, including alarms, setting changes, calibrations, maneuvers, and special functions since the GALILEO was powered on. The date, time, and a unique ID for event classification are included. A more extensive log including technical and configuration information is available to service technicians.

To open the log, select the Event log symbol from the monitoring menu. Activate the selection by pressing the M-knob. The most recent event is at the top. Turn the knob repeatedly to scroll up or down as desired. **Close** the log when finished.

NOTE:

The GALILEO event log can contain maximally 1'000 events. If the total number exceeds the limit, only the latest 1'000 events are recorded, i.e. the older events are deleted.

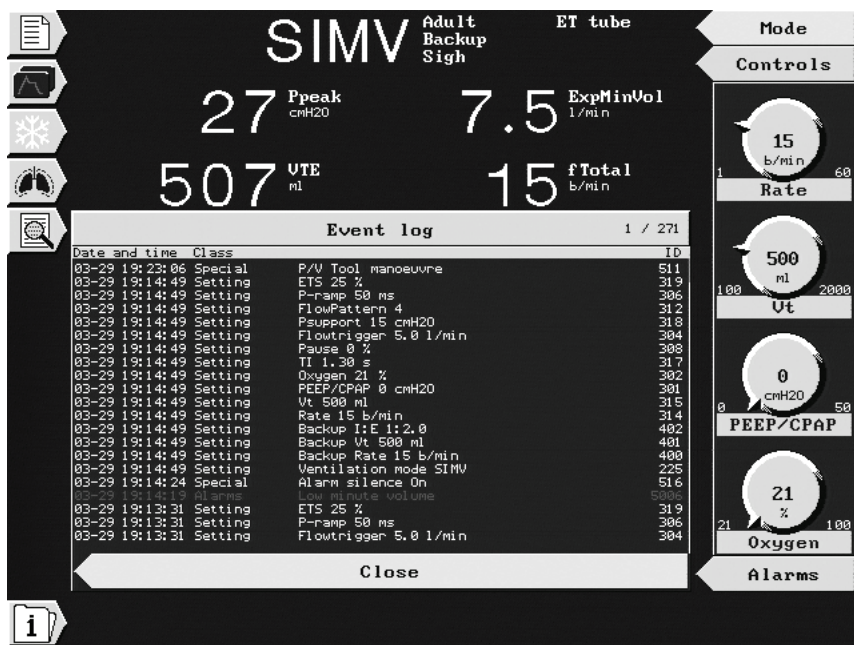


Figure 6-16. Event log

6.3 Monitored parameters

NOTE:

The GALILEO automatically measures inspiratory and expiratory resistance (R_{insp} and R_{exp}), compliance (C_{stat}), and AutoPEEP breath by breath, during mandatory and spontaneous breaths in all modes, without interruption in ventilation. To obtain these measurements, the GALILEO uses a statistical technique called the least squares fitting (LSF) method. This method is applied on a breath-by-breath basis, without the need for special inspiratory flow patterns and occlusion maneuvers, provided that the patient is relaxed or nearly relaxed.

Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. The more active the patient, the less accurate the measurements. To minimize patient participation during these measurements, you may want to increase P_{support} by 10 cmH₂O. After completion, return this control to its former setting.

Table 6-1 is an alphabetical list of the GALILEO's monitored parameters. All can be viewed in the 26-parameter monitoring window (Figure 6-5). The display of monitored parameters is updated every breath.

Table 6-1. Monitored parameters

Parameter (unit)	Definition
AutoPEEP (cmH ₂ O)	The difference between the measured and set PEEP. AutoPEEP is the abnormal pressure generated by air “trapped” in the alveoli due to inadequate lung emptying. Ideally, it should be zero. AutoPEEP is calculated using the LSF method applied to the entire breath. When AutoPEEP is present, volutrauma or barotrauma might develop. In active patients, AutoPEEP may present an extra workload to the patient. AutoPEEP or air trapping results when the expiratory phase is too short. The expiratory phase might be too short under these conditions: • Delivered tidal volume too large • Expiratory time too short or respiratory rate too high • Circuit impedance too high or expiratory airway obstruction • Peak expiratory flow too low WARNING The GALILEO’s automatic measurement of AutoPEEP is accurate only in patients without small airway collapse. Do not use this measurement to quantify hyperinflation in COPD patients. Refer to Section 6.2.4.1 for manual AutoPEEP measurement.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
Cstat (ml/cmH ₂ O)	Static compliance of the respiratory system, including lung and chest wall compliances. It is calculated using the LSF method applied to the entire breath. Cstat can help diagnose changes in elastic characteristics of the patient's lungs. NOTE: Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH₂O. After completion, return this control to its former setting.
Exp Flow (l/min)	Peak expiratory flow.
ExpMinVol (l/min)	Expiratory minute volume. The moving average of the monitored expiratory volume per minute, over the last 8 breaths.
fSpont (b/min)	Spontaneous breath frequency. The moving average of spontaneous breaths per minute, over the last 8 spontaneous breaths. An increased fSpont may indicate that the patient is compensating for a low compliance. This may indicate ventilatory fatigue due to imposed work of breathing.
fTotal (b/min)	Total breathing frequency. The moving average of the patient's total breathing frequency over the last 8 breaths, including both mandatory and spontaneous breaths. When the patient triggers or the user initiates a breath, fTotal may be higher than the Rate setting. NOTE: Respiratory rate monitoring on the GALILEO requires breath delivery followed by detection of expiratory flow at the proximal Flow Sensor.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
I:E	Inspiratory:expiratory ratio. Ratio of the patient's inspiratory time to his expiratory time. This includes both mandatory and spontaneous breaths. I:E may differ from the set I:E ratio if the patient breathes spontaneously.
Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mechanical.
Oxygen (%)	Oxygen concentration of the delivered gas. It is measured by the oxygen cell in the inspiratory pneumatics. This parameter is not displayed if the oxygen supply is not connected, the oxygen cell is not installed or is defective, or if O2 measurement is configured off.
P0.1 (cmH ₂ O)	Airway occlusion pressure. The maximal slope of the airway pressure drop during the first 100 ms when the airway is occluded. P0.1 indicates the patient's respiratory drive and efforts. It applies to patient-triggered breaths with pressure trigger only. A P0.1 value of -3 cmH₂O indicates a strong inspiratory effort, and a value of -5 cmH₂O, an excessive effort., possibly because the patient is "air hungry" (peak inspiratory flow or total ventilatory support is inadequate) or has an excessive drive. If P0.1 is too low... • Increase Psupport or Pcontrol settings • Increase %MinVol if in ASV mode • Switch to a pressure mode: SPONT, ASV, P-CMV (P-A/C), or P-SIMV • Shorten P-ramp time NOTE: Due to changes in pneumatic impedance, P0.1 values may vary with different settings of the Trigger function. Best results are obtained with a pressure trigger.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
PEEP/CPAP (cmH ₂ O)	Monitored PEEP (positive end expiratory pressure)/CPAP (continuous positive airway pressure). The airway pressure at the end of exhalation. Measured PEEP/CPAP may differ slightly from set PEEP/CPAP, especially in actively breathing patients.
Pmean (cmH ₂ O)	Mean airway pressure. Δ (Ppeak - PEEP/CPAP) averaged over the breath cycle. The displayed value is the moving average during the last 8 breath cycles. Pmean is an important indicator of the possible impact of applied positive pressure on hemodynamics and surrounding organs.
Pminimum (cmH ₂ O)	Minimum airway pressure during the breath cycle. Pminimum may be lower than the PEEP/CPAP if TRC is active or if the patient is making strong inspiratory efforts.
Ppeak (cmH ₂ O)	Peak airway pressure. The highest pressure during the previous breath cycle. It is influenced by airway resistance and compliance. It may be higher than expected due to the GALILEO's breathing circuit compensation. It may differ noticeably from alveolar pressure if airway flow is high.
Pplateau (cmH ₂ O)	Plateau or end-inspiratory pressure. The pressure measured at the end of inspiration when flow is or is close to zero. Pplateau is displayed under these conditions: • In volume modes when the set Pause is greater than zero. • In non-volume modes when the end-inspiratory pressure is very stable (pressure change < 1 cmH₂O over 100 ms). Pplateau reflects the end-inspiratory lung compliance. It is a rough representation of alveolar pressure.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
PTP (cmH ₂ O*s)	Inspiratory pressure time product. The measured pressure drop multiplied by the time interval until the PEEP/CPAP level is reached during inspiration. The area of the patient-created pressure drop (below PEEP/CPAP) as a function of time. Both PTP and WOBimp indicate work by the patient to trigger the GALILEO. The work depends on • the intensity of the patient's effort, • the trigger type and sensitivity, and • the volume and resistance of the breathing circuit. PTP and WOBimp are valid for patient-initiated breaths only. Neither PTP nor WOBimp indicates total patient work, because the work resulting from the endotracheal tube and the total respiratory system is excluded. But they are good indicators of how well the ventilator is adapted to the patient. If PTP and WOBimp values increase... • Check and remove water in tubes • Switch to flow trigger • Increase trigger sensitivity • Switch to a pressure mode: SPONT, ASV, P-CMV (P-A/C), or P-SIMV • Shorten P-ramp time

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition										
RCexp (s)	Expiratory time constant. The rate at which the lungs empty, as follows: <table> <tr> <th>Actual TE</th><th>% emptying</th></tr> <tr> <td>1 x RCexp</td><td>63%</td></tr> <tr> <td>2 x RCexp</td><td>86.5%</td></tr> <tr> <td>3 x RCexp</td><td>95%</td></tr> <tr> <td>4 x RCexp</td><td>98%</td></tr> </table> RCexp is calculated from 75% VTE and the flow at 75% Vt. ASV uses RCexp in its calculations. In adults, an RCexp value above 1.2 s indicates airway obstruction, and a value below 0.5 s indicates a severe restrictive disease. Use RCexp to set optimal TE (Goal: TE $\geq$ 3 x RCexp): • In passive patients: Adjust rate and I:E. • In active patients: Increase Psupport and/or ETS to achieve a longer TE. These actions may reduce the incidence of AutoPEEP.	Actual TE	% emptying	1 x RCexp	63%	2 x RCexp	86.5%	3 x RCexp	95%	4 x RCexp	98%
Actual TE	% emptying										
1 x RCexp	63%										
2 x RCexp	86.5%										
3 x RCexp	95%										
4 x RCexp	98%										
RCinsp (s)	Inspiratory time constant. It is calculated from the product of Rinsp and Cstat and defines the lung filling time. RCinsp is calculated using the LSF method. An inspiratory time shorter than 2 x RCinsp indicates disequilibrium between ventilator pressure and alveolar pressure and may result in inadequate inspiration. NOTE: Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH₂O. After completion, return this control to its former setting.										

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
Rexp (cmH ₂ O/(l/s))	Resistance to expiratory flow caused by the endotracheal tube and major airways during exhalation. It is calculated using the LSF method applied to the expiratory phase. NOTE: Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase P_{support} by 10 cmH₂O. After completion, return this control to its former setting.
Rinsp (cmH ₂ O/(l/s))	Resistance to inspiratory flow caused by the endotracheal tube and the patient's airways, during inspiration. It is calculated using the LSF method applied to the inspiratory phase. NOTE: Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase P_{support} by 10 cmH₂O. After completion, return this control to its former setting.
RSB (1/(min x l))	Rapid shallow breathing index. The total breathing frequency (f_{Total}) divided by the exhaled tidal volume (VTE). It has significance for spontaneously breathing patients only. Because a patient with dyspnea typically takes faster, shallower breaths than a nondyspneic patient, RSB is high in the dyspneic patient and low in the nondyspneic person. RSB is often used clinically as an indicator to judge whether a ventilated patient is ready for weaning.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
TE (s)	Expiratory time. In mandatory breaths, TE is measured from the start of exhalation until the set time has elapsed for the switchover to inspiration. In spontaneous breaths, TE is measured from the start of exhalation, as dictated by the ETS setting, until the patient triggers the next inspiration. TE may differ from the set expiratory time if the patient breathes spontaneously.
TI (s)	Inspiratory time. In mandatory breaths, TI is measured from the start of breath delivery until the set time has elapsed for the switchover to exhalation. In spontaneous breaths, TI is measured from the patient trigger until the flow falls to the ETS setting, for the switchover to exhalation. TI may differ from the set inspiratory time if the patient breathes spontaneously.
VLeak (ml)	Leakage volume. The difference between the inspiratory tidal volume (VTI) and the expiratory tidal volume (VTE) measured at the Flow Sensor and averaged over the past 8 breaths. VLeak can indicate leaks on the patient side of the Flow Sensor (endotracheal tube, chest tube). It does not include leakage between the ventilator and Flow Sensor.

Table 6-1. Monitored parameters (continued)

Parameter (unit)	Definition
VTE (ml)	Expiratory tidal volume. The volume exhaled by the patient. It is determined from the Flow Sensor measurement, so it does not show any volume added due to compression or lost due to leaks in the breathing circuit. If there is a gas leak at patient side, the displayed VTE may be less than the tidal volume the patient actually receives.
WOBimp (J/l)	Work of breathing imposed by the inspiratory valve, tubing, and humidifier. It is airway pressure integrated over inspiratory volume until pressure exceeds the PEEP/CPAP level. In the dynamic pressure/volume loop, WOBimp is the area below PEEP/CPAP. This is created exclusively by the patient; thus WOBimp is valid for patient-initiated breaths only. If based on Paw, WOBimp indicates the work required of the patient to be on a ventilator. It does not include work resulting from the endotracheal tube and the total respiratory system. If based on endotracheal pressure using Paux, WOBimp includes work resulting from the endotracheal tube. The significance of WOBimp is similar to that of PTP. For more information, see the description of the PTP parameter in this table.

7 P/V Tool maneuvers

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7.1 Introduction

7.1.1 Overview

The GALILEO Gold offers two respiratory mechanics maneuvers, the P/V Tool and the P/V Tool 2, to record a quasi-static P/V (pressure/volume) curve at the bedside. The P/V Tool records the inflation limb of the curve, while the P/V Tool 2 records both the inflation and deflation limbs.

This curve, generated with very low flow, can provide the clinician with valuable and objective information about the respiratory system mechanics. The information may be useful for clinical diagnosis as well as for optimization of ventilator settings. A cursor function permits graphical analysis of the curve, including identification of inflection points and “visual curve fitting” to determine the linear compliance.

The maneuvers employ an adjustable pressure ramp in which airway pressure is slowly increased to an upper level and, in the P/V Tool 2, then decreased to a lower level.

The P/V Tool maneuvers require no disconnection of the breathing circuit and no patient setting changes. You can resume normal ventilation at any time.

7.1.2 Differences between the P/V Tool and the P/V Tool 2

The P/V Tool 2 expands on the capabilities of the P/V Tool in these ways:

- In addition to the inflation limb, it also shows the deflation limb.
- You can display data in additional forms, including not only the conventional pressure/volume curve, but also a pressure/flow curve or a transpulmonary curve.
- You can start the maneuver from an operator-set pressure.
- You can add a pause at **P_{top}**, between the inflation and deflation limbs.
- You can set the end pressure.

7.1.3 Indications for use

As long as the required conditions are met and no contraindications exist, the P/V Tool maneuvers may be performed on any patient.

The P/V Tool maneuvers are particularly valuable for use with restrictive lung “stiff lung” diseases (for example, ALI or ARDS patients).

Be careful when performing the P/V Tool maneuvers on patients with obstructive “soft lung” diseases (for example, COPD). Set **P_{top}** low to prevent generation of excessive volumes.

7.1.4 Contraindications for use

- Patients who are breathing spontaneously
- Patients with unstable cardiovascular dynamics
- Patients with confirmed or suspected intracranial hypertension
- Patients who cannot tolerate high intrapulmonary pressure for other reasons
- Patients vulnerable to baro- or volutrauma
- Leaks in the system (patient and/or breathing circuit)

7.1.5 Required conditions for use

Make sure the following conditions are met before attempting a P/V Tool maneuver.

- The patient must be intubated and ventilated but not breathing spontaneously. Some patients may require heavy sedation or neuromuscular blockade to prevent spontaneous breathing efforts.
- There must be no gas leak throughout the entire system composed of the ventilator, the breathing circuit, and the ventilated patient.
- Nebulization must be deactivated.

- The Flow Sensor must perform optimally.
- Total respiratory system compliance must be a minimum of 5 ml/cmH₂O. (The P/V Tool maneuvers do not function correctly with the IngMar neonatal lung model.)

7.2 P/V Tool

7.2.1 How the P/V Tool works

Once a P/V Tool maneuver is activated, the following sequence occurs:

1. The exhalation phase of the current control breath is prolonged, and airway pressure is reduced to zero to ensure complete lung emptying.
2. The breathing circuit is pressurized to a predefined peak pressure (**P_{top}**) at the operator-set **Ramp speed**. Real-time pressure and pressure-induced volume values are plotted.
3. Pressure is released to the PEEP level. Normal control ventilation resumes. The window remains open with the curve frozen for analysis.

7.2.2 Procedure

WARNING

- **Be careful when using the P/V Tool maneuver on patients with severe obstructive pulmonary disease, because it can generate excessive volumes.**
 - **To prevent possible patient discomfort and erroneous readings, do not attempt to use the P/V Tool on an active patient. If the patient becomes active during the maneuver, manually abort the maneuver by pressing Start/Stop.**
-

NOTE:

- To ensure that the P/V Tool maneuver yields meaningful data, it is recommended that you perform a Flow Sensor calibration and tightness test before performing it.
 - The P/V Tool is inactive in SPONT and NIV modes and during apnea backup.
 - The P/V Tool remains inactive for 5 breaths after a prior P/V Tool maneuver.
 - The P/V Tool is inactive during, and for 5 breaths after, nebulization.
 - During the maneuver, all alarms except supply and technical failures are suppressed.
-

Perform the P/V Tool maneuver as follows:

1. From the monitoring menu, select the respiratory mechanics symbol. Then, from the respiratory mechanics menu select the P/V Tool symbol, then activate it. The P/V Tool information window will be displayed (Figure 7-1).

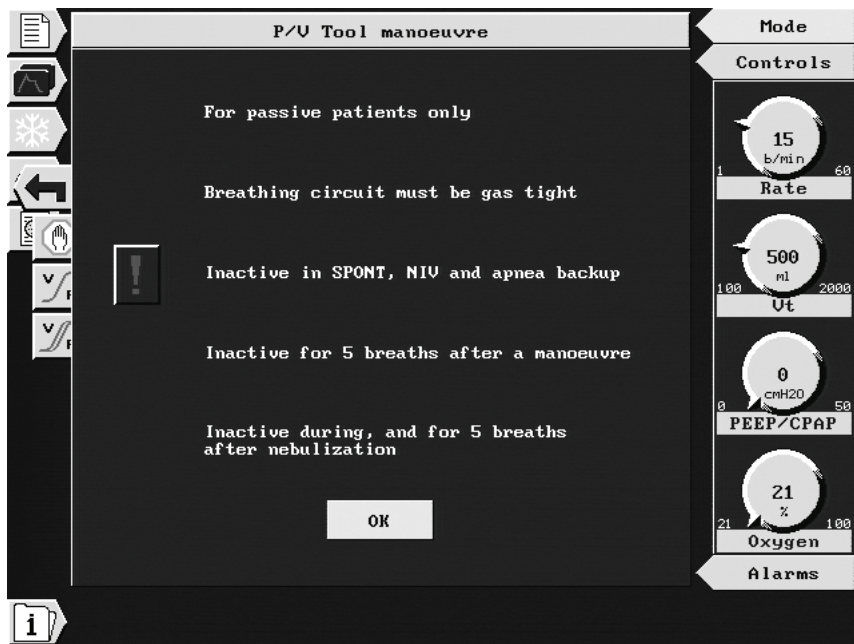
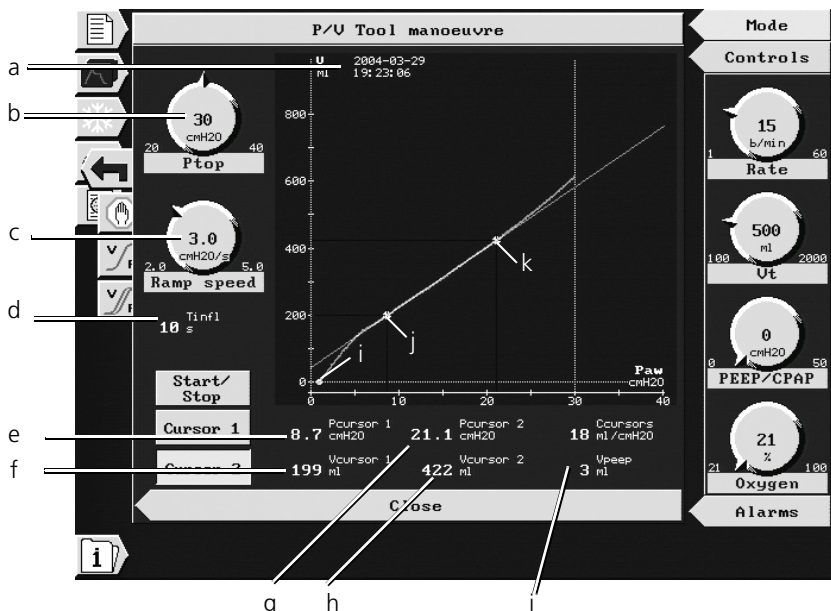


Figure 7-1. P/V Tool information window

2. Select and activate **OK** to continue. The P/V Tool window will open (Figure 7-2).



- a. Manoeuvre date and start time
- b. **Ptop** - Maximum pressure to be applied.
- c. **Ramp speed** - Rate of change of pressure.
- d. **Tinfl** - Inflation time.
- e. **Pcursor 1** - Pressure at cursor 1.
- f. **Vcursor 1** - Volume at cursor 1.
- g. **Pcursor 2** - Pressure at cursor 2.
- h. **Vcursor 2** - Volume at cursor 2.
- i. **Vpeep** - PEEP volume.
- j. Cursor 1
- k. Cursor 2.

Figure 7-2. P/V Tool window

3. Select and activate the **P_{top}** control. Adjust the desired upper pressure to be delivered, then activate by pressing the knob. Repeat for the **Ramp speed** control. The calculated inflation time will be displayed as **T_{infl}**.

NOTE:

- Make sure the high Pressure alarm setting is at least (**P_{top}** + 5 cmH₂O); otherwise, the maneuver may be aborted.
 - If the compliance is normal to higher than normal, use a lower **Ramp speed** setting. If the compliance is lower, you may select a higher **Ramp speed** setting.
 - For COPD patients it is suggested you set **P_{top}** to 30 cmH₂O and the **Ramp speed** to 2 cmH₂O/s.
-

4. Select and activate **Start/Stop** to start the maneuver. Observe the curve and the PEEP volume (**V_{peep}**) value displayed below it.

NOTE:

Once you initiate a P/V Tool maneuver, you can terminate it any time by pressing the M-knob or **Start/Stop**.

5. When the maneuver is finished, the window remains open with the curve displayed for approximately 1 min. To examine points on the curve, select and activate **Cursor 1**; then turn the M-knob to locate a point on the curve where you suspect the low inflection point is located (Figure 7-3). Deactivate **Cursor 1**.

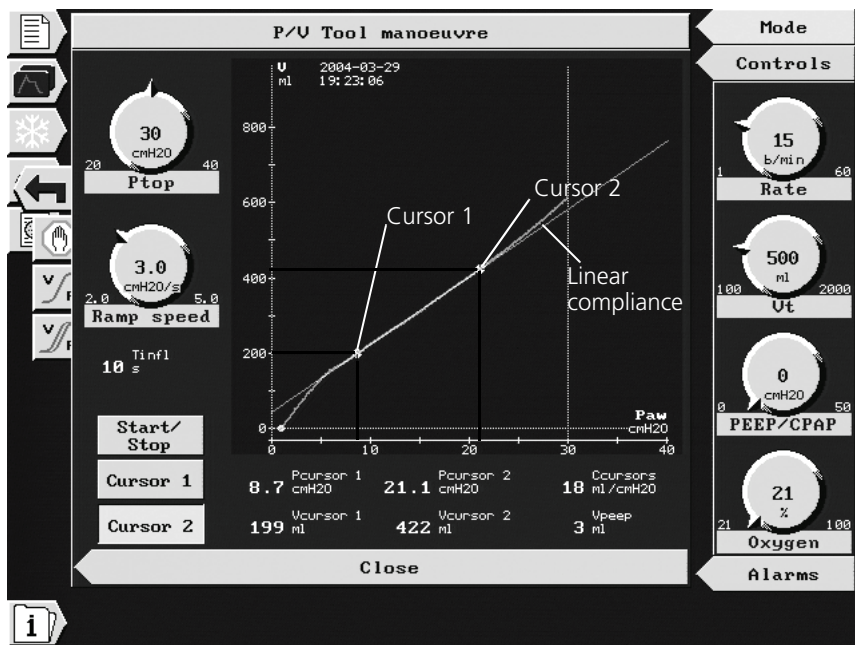


Figure 7-3. P/V Tool cursor measurement

6. Select and activate **Cursor 2**; then turn the M-knob to locate a point on the curve where you suspect the upper inflection point is located. Deactivate **Cursor 2**.
7. A straight line (linear compliance) is automatically drawn between the two cursor points. Adjust the cursors for the "best visual fit" -- that is, so that the straight line lies on the longest and steepest linear segment of the curve. The cursor pressure (**Pcursor**) and cursor volume (**Vcursor**) values will be displayed below. See Section 7.3.2.5 for help in interpreting the curve.
8. **Close** the window to return to the basic screen. This returns P/V Tool settings to their defaults.
9. Reopen the P/V Tool window at any time to re-examine the curve. The curve remains available for later observation until the maneuver is repeated.

7.3 P/V Tool 2

7.3.1 How the P/V Tool 2 works

The P/V Tool 2 records the pressure-volume relation of the lungs at close to zero flow. It follows this sequence:

1. **Maneuver initiation.** The operator initiates the maneuver by pressing **Start/Stop**.
2. **Prolonged exhalation.** The exhalation phase of the current control breath is prolonged, and pressure is reduced to the operator-set **P_{start}** level. The exhalation lasts 10 x **RC_{exp}**, or a minimum of 6 s and a maximum of 15 s.
3. **Linear pressure increase (inflation limb).** The breathing circuit is pressurized linearly to the operator-set **P_{top}** pressure at the operator-set **Ramp speed**. Resultant volume changes are recorded.
4. **Pause at P_{top}.** When the pressure reaches **P_{top}**, any operator-set **T_{pause}** is performed. The inspiratory and expiratory valves are closed during the pause.
5. **Linear pressure decrease (deflation limb).** Pressure is released linearly to the operator-set **End PEEP** level. The **Ramp speed** defines the rate of pressure decrease.
6. **Ventilation resumes at new PEEP (End PEEP).** Ventilation resumes when **End PEEP** is reached. The P/V Tool 2 window remains open with the curve frozen for analysis.

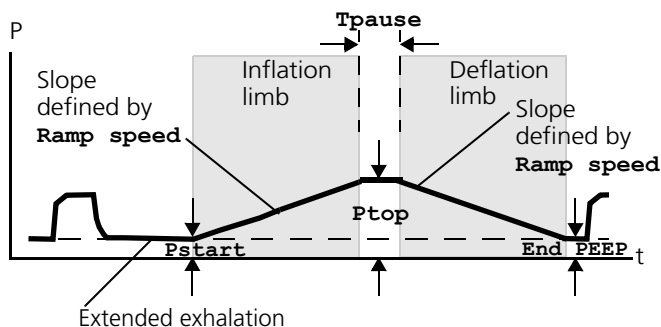


Figure 7-4. How the P/V Tool 2 works

7.3.2 Procedure

WARNING

- The P/V Tool 2 can apply high pressures for extended periods of time.
 - Be careful when using the P/V Tool 2 maneuver on patients with severe chronic obstructive pulmonary disease, because it can generate excessive volumes.
 - To prevent possible patient discomfort and erroneous readings, do not attempt to use the P/V Tool 2 on an active patient.
-

NOTE:

- Meaningful data from the P/V Tool 2 maneuver requires that there be no gas leak on the patient side of the Flow Sensor and that the Flow Sensor perform well at very low flows. Always perform the tightness test and the Flow Sensor calibration before using the P/V Tool 2; however, If you have doubts about the validity of the resulting data, also perform the breathing circuit and Flow Sensor test described in Section 7.3.2.8.
 - The P/V Tool 2 is inactive in SPONT and NIV modes and during apnea backup.
 - The P/V Tool 2 remains inactive for 5 breaths after a prior P/V Tool 2 maneuver.
 - The P/V Tool 2 is inactive during, and for 5 breaths after, nebulization.
 - If the **P_{top}** setting is greater than the high **Pressure** alarm setting, the high pressure alarm threshold becomes **P_{top}** + 5 cmH₂O. It overrides the operator-set alarm threshold.
 - During the maneuver, all alarms except supply and technical failures are suppressed.
-

7.3.2.1 Accessing the P/V Tool 2

1. From the monitoring menu, select the respiratory mechanics symbol. Then, from the respiratory mechanics menu select the P/V Tool 2 symbol, then activate it. The P/V Tool 2 information window opens (Figure 7-5). Read it carefully.

NOTE:

Pay attention to the remarks summarized in the P/V Tool 2 information window:

- For passive patients only
 - Inactive in SPONT, NIV and apnea backup
 - Breathing circuit must be gas tight
 - Inactive for 5 breaths after a maneuver
 - Inactive during, and for 5 breaths after, nebulization
 - Inactive while **Flow Sensor cal. needed** is displayed
 - Reconfirmation is required if the setting exceeds critical limits
 - The quality of information obtained depends on the quality of Flow Sensor!
-

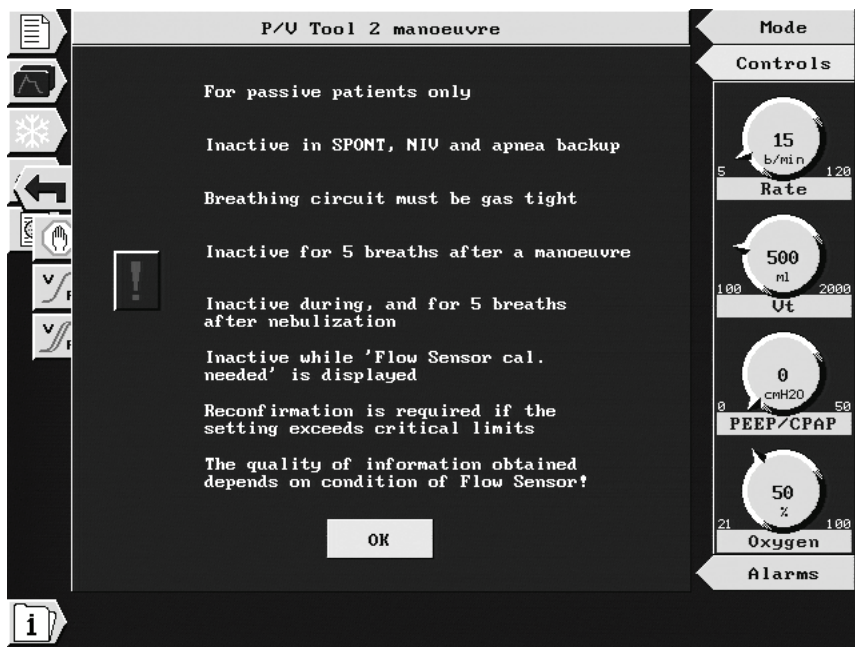


Figure 7-5. P/V Tool 2 information window

2. Select and activate **OK** to continue. The P/V Tool 2 window will open (Figure 7-6).

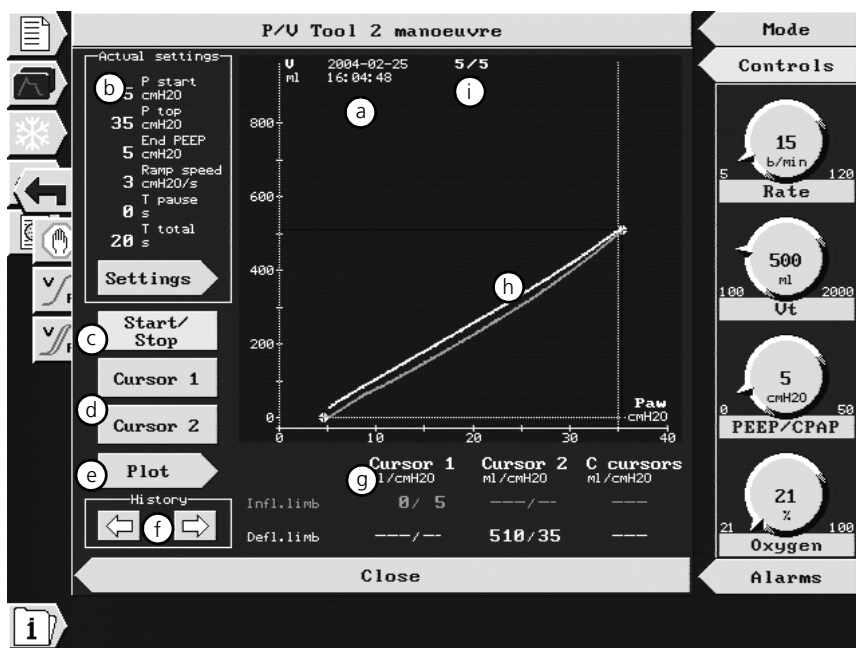


Figure 7-6. P/V Tool 2 window

Item	Description
a	Maneuver date and start time
b	Current settings box. Shows the currently active P/V Tool 2 control settings. You can change these settings through the Settings arrow, which opens the P/V Tool 2 settings window (Figure 7-7).
c	Start/Stop . Starts maneuver or ends it at any time.
d	Cursor 1 and Cursor 2 . Each cursor simultaneously selects two points, one on the inflation and one on the deflation limb. The points are vertically aligned. Using both cursors you can determine the linear compliance by obtaining a “best visual fit.” Data about these points is also displayed.

Item	Description
e	Plot type. Opens a menu so you change the type of curve displayed (Figure 7-9).
f	History. Lets you scroll through stored P/V Tool 2 curves.
g	Numerical data. The Cursor x column shows the values for the points on the inflation limb (Infl limb) and deflation limb (Defl limb) of the curve. The Cursors column shows the calculated compliance in ml/cmH ₂ O for a straight line that connects the cursor points.
h	Curve, in this case a pressure/volume curve that includes both inflation and deflation limbs
i	Plot number/Total number of stored plots

7.3.2.2 Changing control settings

1. From the **P/V Tool 2** window, select the **Settings** arrow, then activate it. The **P/V Tool 2 settings** window opens (Figure 7-7).

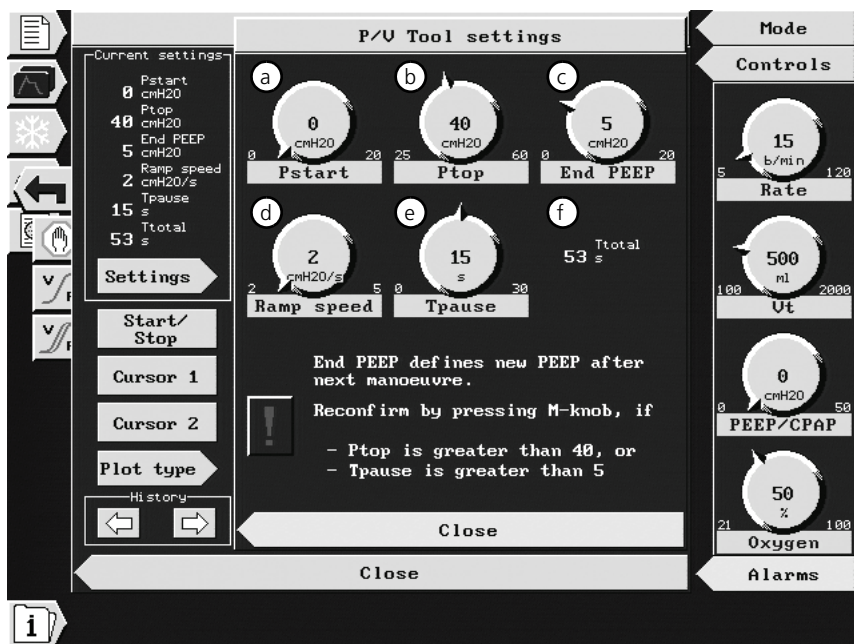


Figure 7-7. P/V Tool 2 settings window

Item	Description*
a	Pstart . PEEP to be applied at start of maneuver.
b	Ptop . Maximum pressure to be applied.
c	End PEEP . PEEP to be applied at end of deflation limb.
d	Ramp speed . Rate of change of pressure.
e	Tpause . Length of pause between inflation and deflation limbs.
f	Ttotal . Total maneuver time, calculated.

*See Table A-8 for a list of setting ranges, standard settings, and resolutions.

-
2. Select a parameter, then activate it. Adjust the value, then activate it. Repeat for any other desired parameters. The calculated inflation time is displayed as **Ttotal**.

If you try to set **Ptop** to greater than 40 cmH₂O or **Tpause** greater than 5 s, you must reconfirm your intention by pressing the M-knob.

3. **Close** the **P/V Tool 2 settings** window to confirm the entire selection.

If you set **End PEEP** to a value different from the current PEEP/CPAP, you will see a confirmation window (Figure 7-8). Select **No** if you don't want to change PEEP/CPAP after the maneuver. Select **Yes** if you do want to change PEEP/CPAP from its current level to the **End PEEP** level. **Close** the **Confirm PEEP change** window to confirm.

NOTE:

- If the compliance is normal to higher than normal, use a lower **Ramp speed** setting. If the compliance is lower, you may select a higher **Ramp speed** setting.
 - For COPD patients it is suggested you set **Ptop** to 30 cmH₂O and the **Ramp speed** to 2 cmH₂O/s.
 - Because P/V Tool 2, unlike P/V Tool, lets you select the maneuver starting pressure, the AutoPEEP volume (Vpeep) is not automatically displayed. To display Vpeep, set **Pstart** to 0 cmH₂O.
-

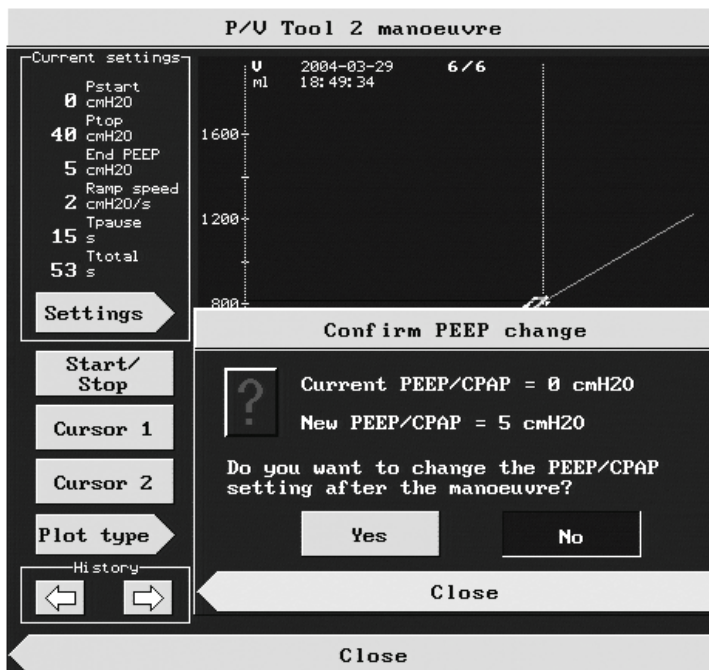


Figure 7-8. Confirm PEEP change window

7.3.2.3 Performing the maneuver

NOTE:

Once you initiate a P/V Tool 2 maneuver, you can terminate it any time by pressing the M-knob or **Start/Stop** again.

Select and activate **Start/Stop** to start the maneuver. When the maneuver is finished, the window remains open with the curve displayed for approximately 1 min, waiting for your input.

7.3.2.4 Using the cursor feature to graphically analyze the plot

You can use the P/V Tool 2 cursors to determine numeric values for points on the curve. Using both cursors, you can also perform a “visual curve fitting” to determine the linear compliance, which is then displayed.

NOTE:

The cursor selects two points simultaneously: one on the inflation limb and one on the deflation limb.

To determine the numeric value at a point on the curve, turn the M-knob. You can read the values at the bottom of the window (Figure 7-10).

To perform a “visual curve fitting” to determine the compliance, do the following:

1. Select and activate **Cursor 1**; then turn the M-knob to select a point on the curve where you suspect the low inflection point is located (Figure 7-9). Deactivate **Cursor 1**.
2. Select and activate **Cursor 2**; then turn the M-knob to locate a point on the curve where you suspect the upper inflection point is located. Deactivate **Cursor 2**.
3. Two straight lines (linear compliance) are automatically drawn, each connecting the cursors on the inflation or deflation limb. Adjust the cursors for the “best visual fit” -- that is, so that the straight lines lie on the longest and steepest linear segment of the curve. Pressure and volume/flow values are displayed at the bottom of the window along with the calculated compliances (Figure 7-10).
4. **Close** the window to return to the basic screen. This returns P/V Tool 2 settings to their defaults.
5. Reopen the P/V Tool 2 window at any time to re-examine the curve. The curve remains available for later observation until the maneuver is repeated. You can also use the History feature (Section 7.3.2.7) to review stored curves.

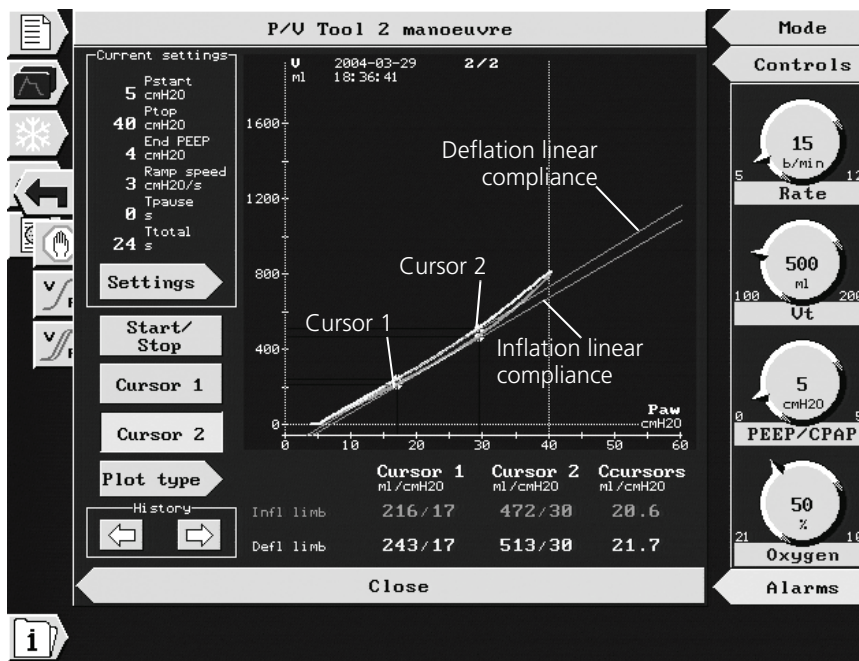


Figure 7-9. Using the cursor function: Creating the linear compliance curve

	Cursor 1 ml / cmH2O	Cursor 2 ml / cmH2O	C cursors ml / cmH2O
Infl.limb	203 / 9	726 / 37	18.2
Defl.limb	251 / 9	775 / 37	18.3

Volume (ml) or flow (l/min) Pressure (cmH₂O) Compliance (ml/cmH₂O)

Figure 7-10. Reading the P/V Tool 2 measurements (shown for P/V plot type)

7.3.2.5 Analyzing the curve

NOTE:

The P/V Tool and P/V Tool 2 are monitoring maneuvers, which provide information that may be used to optimize PEEP and other ventilator settings. This is just one piece of information that must be considered, however, along with hemodynamics and other clinical conditions. It is the clinician's responsibility to appropriately interpret and apply this information in patient treatment.

A pressure/volume (P/V) curve provides data that can be used to optimize ventilator settings, among others. Figure 7-11 shows some information that you can obtain from a P/V curve.

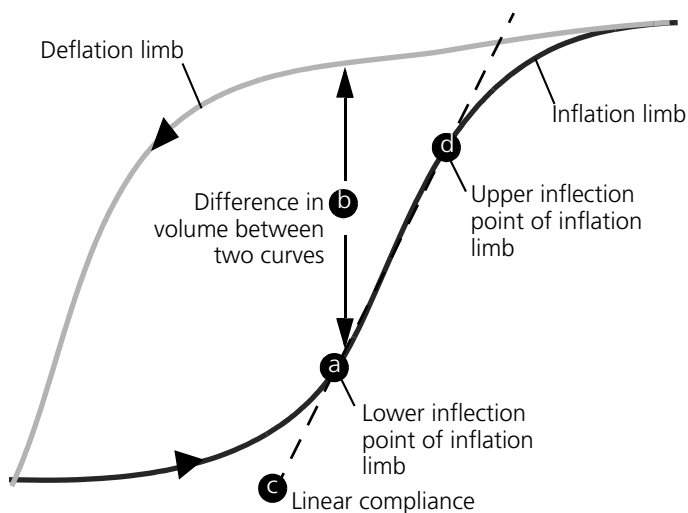


Figure 7-11. Interpreting the P/V curve

The P/V Tool 2 maneuver shows two curves: the inflation P/V curve (in green) and the deflation P/V curve (in yellow and usually shifted to the left). You can obtain the following information from the curve:

- a** The lower inflection point of the inflation limb (LIP_{IN})
- b** The difference in volume between the two limbs (ΔV_{DE-IN})
- c** The linear compliance of the inflation limb (Cl_{IN})
- d** The upper inflection point of the inflation limb (UIP_{IN})

In addition, you can obtain several pieces of information from the deflation limb, such as the PEEP level required to avoid alveoli collapse after a special maneuver to open alveoli (recruitment maneuver). For comprehensive physiological explanations, refer to recent publications¹.

a The lower inflection point of the inflation pressure/volume curve (LIP_{IN})

The LIP_{IN} is the point of maximal curvature below the linear portion of the inflation P/V curve, in other words, the point where the rate of increase in respiratory system compliance is maximal. This point is where alveoli start to open as airway pressure increases. The recommendation is to set positive end expiratory pressure (PEEP) at that level or slightly above².

1. Maggiore SM, Richard JC, Brochard L. What has been learnt from P/V curves in patients with acute lung injury/acute respiratory distress syndrome. *Eur Respir J Suppl.* 2003;42:22s-6s.

2. Tobin MJ. Advances in mechanical ventilation. *N Engl J Med.* 2001;344:1986-96.

b The difference in volume between the two curves (ΔV_{DE-IN})

The difference between the inflation and the deflation limb, also called hysteresis, may have several meanings. Recent publications suggest that in patients with acute lung injury or acute respiratory distress syndrome this hysteresis could indicate the volume that might be gained by increasing PEEP or by using a special maneuver to open alveoli (recruitment maneuver)¹.

c The linear compliance of the inflation pressure/volume curve ($Clin_{IN}$)

This part of the curve is where the maximal compliance is obtained. In that zone, change in volume will require a minimal increase in pressure. The recommendation is to set PEEP and tidal volume to obtain tidal ventilation in that zone².

d The upper inflection point of the inflation pressure/volume curve (UIP_{IN})

The UIP_{IN} is the point of maximal curvature at the end of the linear portion of the inflation PV curve, in other words the point where the rate of decrease in respiratory system compliance is maximal. This point is where all recruitable alveoli are open and start to overinflate. The recommendation is to set the tidal volume in order to obtain a plateau pressure below that point².

1. Hickling KG. The pressure-volume curve is greatly modified by recruitment. A mathematical model of ARDS lungs. Am J Respir Crit Care Med. 1998;158:194-202.

7.3.2.6 Selecting plot type

The P/V Tool 2 lets you display your maneuver data in various forms for flexibility in patient assessment. You can change the plot type before or after the maneuver; or you can change the representation of stored curves while using the **History** feature.

Select the desired type of plot as follows:

1. From the **P/V Tool 2** window, select the **Plot type** arrow, then activate it. The **P/V Tool 2 Plot** menu is displayed (Figure 7-9).
2. Select a plot type, then activate it.
 - **Paw/V** (airway pressure/volume)
 - **Paw/Flow** (Figure 7-10). This curve can be used to check the quality of the maneuver. If flow at any point is outside the range ± 10 l/min, consider reducing the **Ramp speed**.
 - **Paux/V**
 - **Paw-Paux/V**. If you use esophageal pressure as the Paux input, a transpulmonary pressure curve is displayed. This curve shows the compliance of the lungs alone, eliminating the chest wall compliance.
3. **Close** the **P/V Tool 2 Plot** menu to confirm the selection.

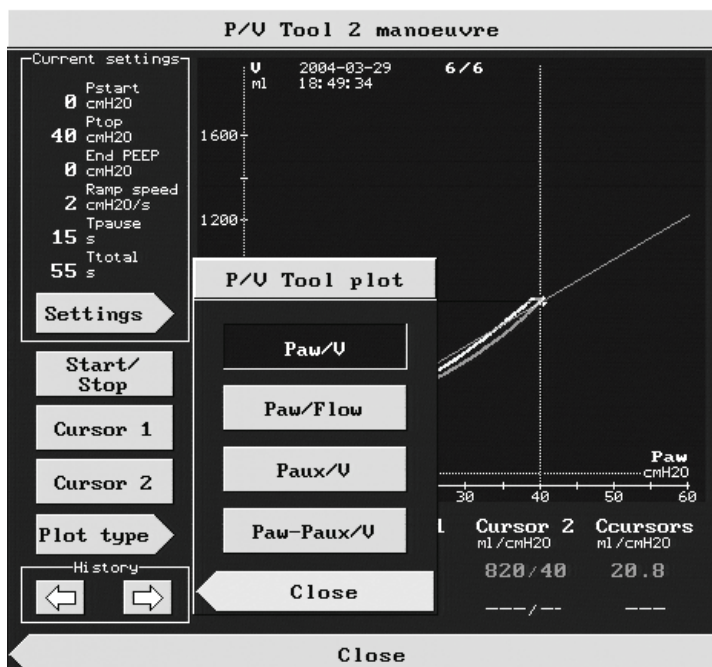


Figure 7-12. P/V Tool 2 Plot menu

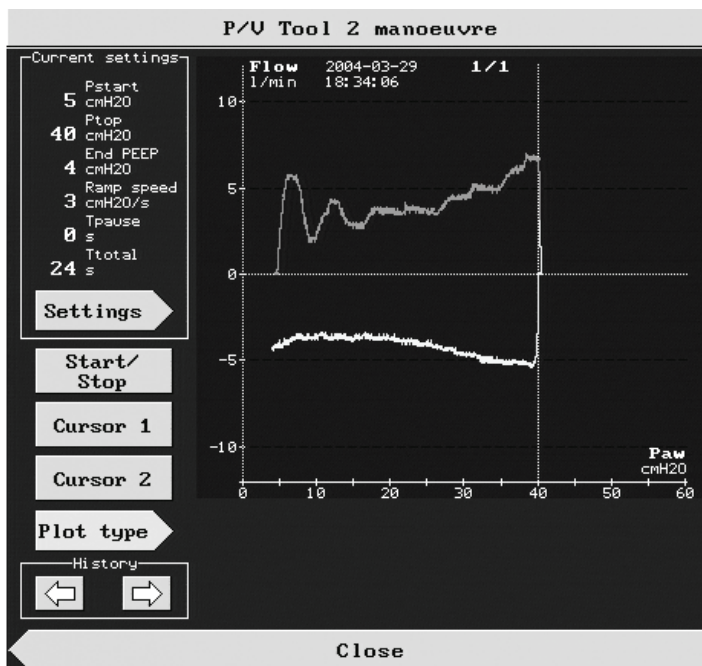


Figure 7-13. Paw/Flow plot

7.3.2.7 Using the History feature to review stored curves

The history features lets you monitor patient change and treatment effectiveness over time. Select and activate the arrows in the **History** box (Figure 7-6) to call up a curve from any of the previous maneuvers. The number of stored curves depends on the storage required to hold them; the number is at least 5.

7.3.2.8 Flow Sensor and breathing circuit check

NOTE:

- This check is recommended only when you want a much higher quality of measurement.
 - Make sure another source of ventilatory support is available during this check. The patient must be disconnected from the ventilator during it.
 - To ensure the validity of this check, you must use the actual parts to be used when performing the P/V Tool 2 maneuver, including the Flow Sensor.
-

When to perform: If you have doubts about the validity of P/V Tool 2 maneuver data.

Required materials:

- Breathing circuit setup to be used for P/V Tool 2, including breathing circuit, Flow Sensor, expiratory membrane and cover
- Adult (2 l) demonstration lung assembly with ET tube (PN 151815) (Figure 7-14)



Figure 7-14. Demonstration lung assembly

Description: Meaningful data from the P/V Tool 2 maneuver requires that there be no gas leak on the patient side (that is, between the Flow Sensor and the patient's respiratory system) and that the Flow Sensor perform well at low flows (that is, < 15 l/min in both directions).

For the purposes of normal ventilation, the tightness test and the Flow Sensor calibration provide assurance that these patient circuit parts will perform adequately. For the purposes of the P/V Tool 2 maneuver, however, the tightness test and the Flow Sensor calibration may not suffice. This is because the P/V Tool 2 maneuver involves very low flows and therefore may not tolerate small leaks or less-than-optimal performance, which would be perfectly adequate for routine ventilation.

Preparation: Connect the ventilator to ac power and air and oxygen supplies. Set the ventilator up as for normal ventilation, complete with appropriate breathing circuit, appropriate Flow Sensor, appropriate demonstration lung or lung model, and expiratory membrane and cover. Switch on power.

Procedure:

1. Run the tightness test and Flow Sensor calibration.
2. Open the **P/V Tool 2** window (Section 7.3.2.1) and then the **P/V Tool 2 settings** window (Section 7.3.2.2). Make the following settings:

Pstart	0 cmH ₂ O
Ptop	40 cmH ₂ O
End PEEP	0 cmH ₂ O
Ramp speed	2 cmH ₂ O
Tpause	15 s
3. **Close** the **P/V Tool 2 settings** window to confirm the entire selection.
4. You will see the **Confirm PEEP change** window (Figure 7-8). Select **No**, then **Close** the window.
5. Select and activate **Start/Stop** to perform a maneuver.

6. Check for gas leakage on the patient side and check Flow Sensor performance at low ramp speed:

- a. Move **Cursor 2** to the left to 35 cmH₂O.
- b. Examine the volume difference between the inflation and deflation limbs, which is where the pause occurred (Figure 6-15). Verify that it is less than 150 ml.

If the volume difference is greater than 150 ml, there is a gas leak between the Flow Sensor and the demonstration lung. Minimize the leak (check the lung, tubes, and connectors), then repeat the maneuver until the volume difference is less than 150 ml.

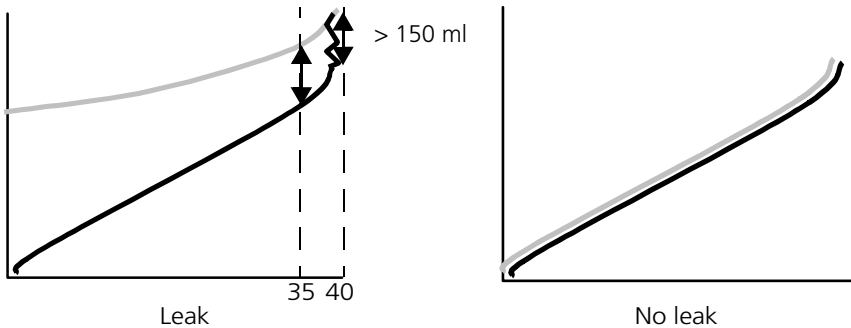


Figure 7-15. Checking for a gas leak between the Flow Sensor and the demonstration lung. Examine the volume difference between the inflation and deflation limbs at P_{top} . An unacceptable leak on the patient side shows up as a volume difference > 150 ml when the pause is applied at P_{top} .

7. Check Flow Sensor performance at high ramp speed:
 - a. Change the **Ramp speed** setting from 2 cmH₂O/s to 5 cmH₂O/s.
 - b. Initiate another maneuver by selecting and activating **Start/Stop**.
 - c. Using the History feature, compare the curves obtained at **Ramp speeds** of 2 and 5 cmH₂O/s. Verify that the inflation and deflation limbs of the two curves are visually (more or less) parallel (Figure 7-16).

If the curves are not parallel, the Flow Sensor may not perform sufficiently to produce meaningful P/V Tool 2 results. Consider using a new Flow Sensor.

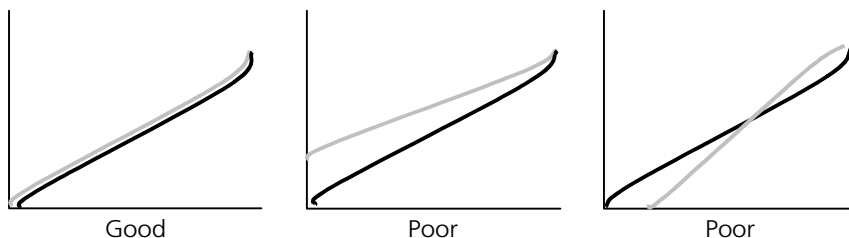


Figure 7-16. Checking Flow Sensor performance. Compare curves obtained at different **Ramp speeds**. Nonparallel curves can indicate insufficient Flow Sensor performance.

7.4 References

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8 Responding to alarms

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8.1 Introduction

The GALILEO's visual and audible alarms notify the operator of problems. These alarms can be categorized as high-, medium-, or low-priority, and technical fault alarms. Each has corresponding visual and audible characteristics (see Table 8-1).

When an alarm condition is detected, an audible alarm sounds and the red indicator on the left side of the alarm silence key blinks. A message is displayed on the bottom (message bar) of the screen. If more than one alarm are active, the alarm messages alternate and the active alarm symbol is displayed.

In addition, if the alarm is serious enough to possibly compromise safe ventilation, the GALILEO is placed into the ambient state. The inspiratory valve is closed and the ambient and expiratory valves are opened, letting the patient breathe room air unassisted.

Information about the alarm is also stored in the Event log (see Section 6.2.5).

NOTE:

- The audible alarm is automatically silenced for 30 s after power on, after the ventilation mode or patient age group is changed, and during calibration procedures.
 - During standby alarms are suppressed.
-

8.2 How to respond to an alarm

WARNING

- To prevent possible patient injury when alarms are active, check the patient for adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.
 - To prevent possible patient injury arising from an equipment malfunction, HAMILTON MEDICAL recommends that you immediately remove any ventilator with a technical fault from use, record the number of the fault, and have the ventilator serviced.
-

NOTE:

- Be aware that an alarm may result from either a clinical condition or an equipment problem.
 - Be aware that one alarm condition can induce multiple alarms. Normally only one or two indicate the root cause of the alarm; the rest are resultant. Your search for the causes of the alarm condition should be assisted by, but not limited to, the alarm messages displayed.
-

Respond to an alarm as follows:

1. Approach the patient immediately. Secure sufficient and effective ventilation for the patient. You may silence the alarm.
2. Correct the alarm condition from the alarm messages, referring to Table 8-2. Alarm messages are displayed in the message bar. If the active alarm symbol is visible on the screen, there are messages in the active alarm buffer. The most recent alarm is at the top; if more than six alarms are active, you will only be able to view the first six detected. This way, the original alarm remains visible.

If the condition that caused the alarms is corrected, the GALILEO automatically resets the alarm. Later, you can see which alarms were reset in the alarm information buffer.

Information about active and reset alarms, along with other clinically significant events, is also stored in the event log.

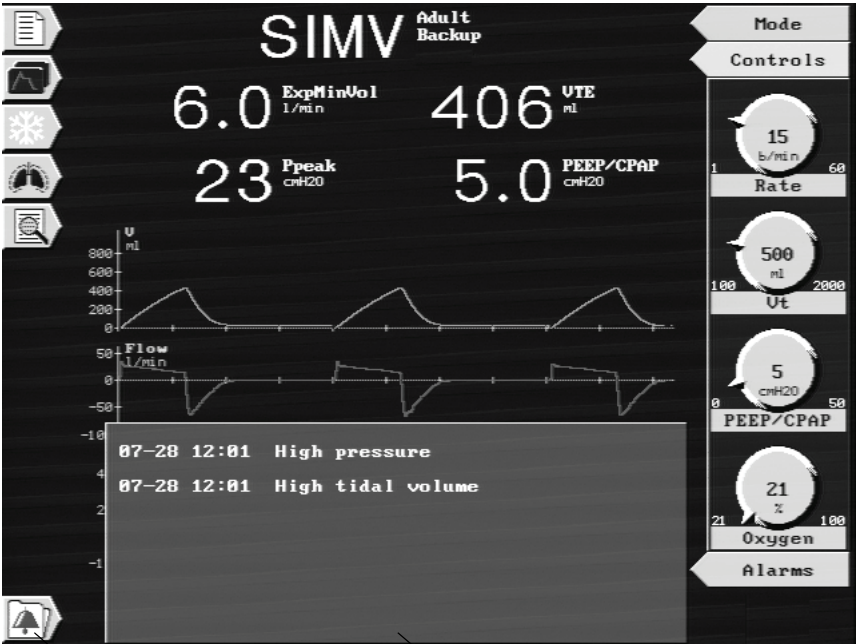
Table 8-1. Alarm categories

Category	Visual alarm	Audible alarm	Action needed
High-priority	Message on red background	A sequence of 5 beeps repeated until the alarm is reset.	The patient's safety is compromised. The problem needs immediate attention from the clinician.
Medium-priority	Message on yellow background	A sequence of 3 beeps repeated periodically.	The problem needs prompt attention from the clinician.
Low-priority	Message on yellow background, typically starting with Check . . .	Two beeps. This is not repeated.	This can indicate a procedure is in progress, a control setting conflict, or the faulty results of a process.
Technical fault	Message on red background	A sequence of 5 beeps repeated until the alarm is reset; <i>or</i> A continuous buzzer tone. This buzzer cannot be silenced.	Provide alternative ventilation. Turn off the ventilator. Have the ventilator serviced.

8.3 Active alarm buffer (red or yellow background)

When the active alarm symbol is displayed (Figure 8-1), one or more alarms are currently active. The associated alarm messages alternate in the message bar. Information about up to six currently active alarms is also stored in the active alarm buffer. This information remains in the buffer as long as the conditions that caused each alarm persist.

To open the buffer, first close any open windows, select the active alarm symbol, and press the M-knob. The most recent alarm is at the top; if more than six alarms are active, you will only be able to view the first six detected. This way, the original alarm remains visible. Pressing the knob again closes the buffer, but does not erase its contents.



Active alarm symbol

Active alarm buffer

Figure 8-1. Active alarm symbol and buffer

8.4 Alarm information buffer (blue background)

When the alarm information symbol is displayed (Figure 8-2), there is data in the alarm information buffer. This buffer contains data about the last six alarms that occurred and were reset.

To open the buffer, first close any open windows, select the alarm information symbol, and press the M-knob. The most recent alarm is at the top. Pressing the knob again closes the buffer, but does not erase its contents.

The alarm information symbol remains displayed unless one or more alarms become active. In this case, the alarm information symbol is removed. An active alarm symbol replaces it if more than one alarm is active. The alarm information symbol is displayed again when the alarms are reset.

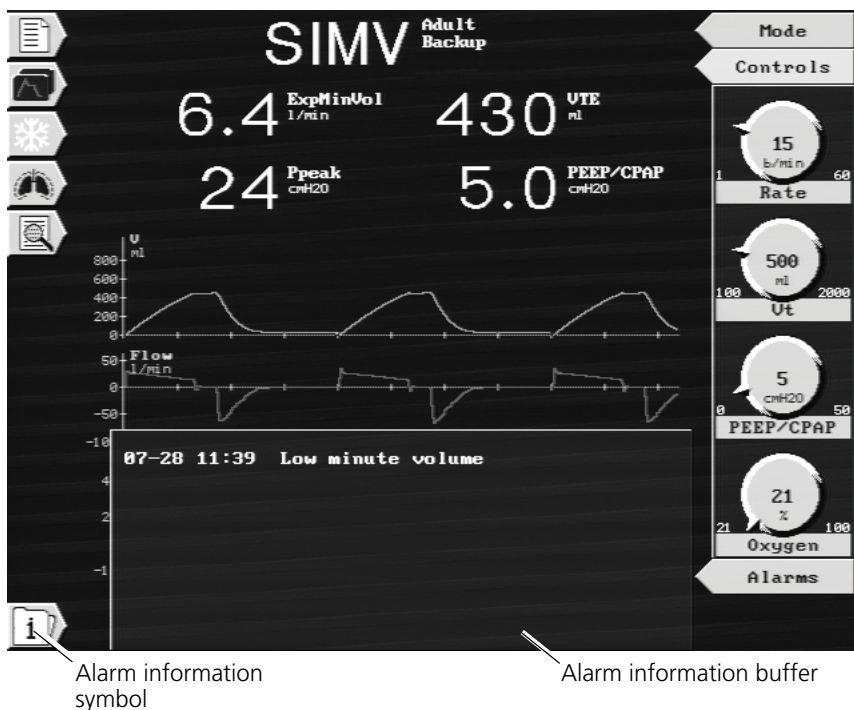


Figure 8-2. Alarm information symbol and buffer

8.5 Alarms and other messages

Table 8-2 is an alphabetical list of the alarm and other messages displayed by the GALILEO, along with their definitions and suggested corrective actions. These corrective actions are sequenced to correct the most probable malfunction or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

Table 8-2. Alarms and other messages

Alarm	Definition	Action needed
Air supply failed	<i>Medium priority.</i> The air supply pressure < 190 kPa (28 psi) or the input flow dropped below 40 l/min. The GALILEO will ventilate the patient with 100% oxygen if the internal pressure can be maintained. (The alarm is not activated when the Oxygen setting is 100%.)	Check air supply. Increase air supply pressure. Consider changing source.
Air trapping	<i>Medium priority.</i> The end-expiratory gas flow is greater than the operator-set limit for two consecutive breaths. The "Air trapping" indicates the presence of "AutoPEEP".	Check the patient. Adjust breath timing controls to increase the expiratory time. Try to reduce the expiratory resistance of the patient's airway.
Apnea	<i>High priority.</i> No patient trigger after the operator-set Apnea Time in SPONT, SIMV, P-SIMV, APVsimv, DuoPAP, or ARV mode.	Check the patient. Consider switching to a mandatory mode or increasing the mandatory rate.
Apnea ventilation	<i>Low priority.</i> No breath delivered for the operator-set apnea time. Apnea backup is on.	Apnea backup ventilation has started. The ventilator is in the corresponding backup mode. Check the control settings for the backup mode.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Apnea ventilation ended	<i>Low priority.</i> Backup mode was reset, and GALILEO is again ventilating in its original support (pre-apnea) mode.	No action required.
APV: Check hi press limit	<i>Low priority.</i> The operator-set high Pressure alarm limit is too low, and the ventilator cannot deliver the Vtarget.	Check the patient. Check the control settings. Consider increasing the high Pressure limit to an appropriate level.
ASV: Cannot meet target	<i>Low priority.</i> The operator-set %MinVol cannot be delivered, possibly because of setting conflicts.	Check the patient. Check the control settings. Consider decreasing the %MinVol setting or increasing the high Pressure alarm limit to an appropriate level. Consider suctioning or other therapy. NOTE: Display the ASV target graphics screen to help troubleshoot this alarm.
ASV: Check hi press limit	<i>Low priority.</i> The operator-set high Pressure alarm limit is too low, and the ventilator cannot deliver the calculated target tidal volume.	Check the patient. Consider suctioning or other therapy. Check the control settings. Consider increasing the high Pressure limit to an appropriate level.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Automatic calibration	<i>User message.</i> Autozeroing of pressure sensors is in progress. Curve display may be interrupted. NOTE: During ventilation the GALILEO periodically performs an autocalibration (autozero) function to “zero” or adjust the device's pressure sensors to a zero value. This is done by periodically applying ambient pressure to the sensor, measuring the pressure, comparing it to the expected ambient pressure, and making an internal correction to remove pressure sensor drift due to temperature changes or other factors. Autocalibration is performed automatically at defined intervals.	No action required.
Calibration faulty	<i>User message.</i> The Flow Sensor calibration could not be performed.	Repeat the calibration. If the message is displayed again, install a new Flow Sensor.
Calibration in progress	<i>User message.</i> A user-initiated calibration is in progress.	Wait.
Check %MinVol	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check %TI	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check backup controls	<i>Low priority.</i> You just activated a mode in which apnea is possible.	Check apnea backup control settings. Adjust as necessary.
Check Body Wt	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Check FlowPattern	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check Flow Sensor tubing	<i>High priority.</i> The Flow Sensor sensing lines are disconnected or occluded. If flow triggering is active, the GALILEO will switch to pressure triggering. The GALILEO automatically returns to flow triggering (if selected) when the alarm condition is eliminated.	Check the Flow Sensor and the sensing lines. Confirm the new setting for pressure triggering, if applicable. Replace the Flow Sensor.
Check Flow Sensor type	<i>High priority.</i> The Flow Sensor in use may not match the selected patient age group. This is detected during ventilation.	Make sure the Flow Sensor is for the appropriate patient age group. Run the Flow Sensor calibration.
Check I:E	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check patient system	<i>User message.</i> The tightness test failed.	Check the circuit connections. Replace leaking parts and repeat the tightness test.
Check Pause	<i>Low priority.</i> The Pause setting is too long in relation to other breath timing parameters.	Confirm the proposed new setting. Adjust other settings as required.
Check P-ramp	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check Peak Flow	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check PEEP/ Pcontrol	<i>Low priority.</i> The PEEP/CPAP setting + the Pcontrol setting > 100 cmH ₂ O.	Confirm the proposed new setting. Adjust other settings as required.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Check PEEP/hi press limit	<i>Low priority.</i> The operator-set high Pressure alarm limit is too low to achieve sufficient ventilation in ASV or the APV modes. The difference between PEEP/CPAP and the high Pressure alarm limit < 10 cmH ₂ O.	Check patient. Check monitored data for adequate ventilation. Check control settings, including high Pressure limit.
Check PEEP/Psupport	<i>Low priority.</i> The PEEP/CPAP setting + the Psupport setting > 100 cmH ₂ O.	Confirm the proposed new setting. Adjust other settings as required.
Check Rate	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check TI	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Check trigger	<i>Low priority.</i> The trigger is off and the operator has attempted to activate a mode allowing spontaneous breathing. The ventilator switches to the selected mode and uses a pressure trigger of - 3 cmH ₂ O. It continues to alarm.	Confirm the P-trigger setting or switch the Flowtrigger on.
Check Vt	<i>Low priority.</i> The desired setting cannot be obtained because of setting conflicts.	Confirm the proposed new setting. Adjust other settings as required.
Confirm mode change first	<i>User message.</i> A mode change was begun, but not completed.	Confirm mode change in Controls window before proceeding.
Disconnect patient	<i>User message.</i> Instruction message during the Flow Sensor calibration and tightness test.	Disconnect the breathing circuit at the patient side of the Flow Sensor.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Disconnection	<i>High priority.</i> A disconnection was detected, but tidal volume is too low (< 200 ml) to determine whether it is on the patient or ventilator side.	Troubleshoot as per Disconnection pat. side or Disconnection vent. side.
Disconnection pat. side	<i>High priority.</i> VTE $<$ than $1/8$ delivered tidal volume for 2 consecutive breaths.	Check the patient. Check the breathing circuit for a disconnection between the patient and the Flow Sensor, or for other large leaks (for example, ET tube, Bronchopleural Fistula).
Disconnection vent. side	<i>High priority.</i> Inspiratory tidal volume $<$ $1/2$ VTE for 2 consecutive breaths.	Check the breathing circuit for a disconnection between the ventilator and the Flow Sensor, or for other large leaks (for example, patient breathing circuit, humidifier). Reconnect and calibrate the Flow Sensor.
Exhalation obstructed	<i>High priority.</i> Proximal airway pressure does not drop during exhalation.	Check the patient. Check the expiratory limb for occlusion. Check the expiratory valve membrane and cover. Check the Flow Sensor tubes for occlusion. Adjust breath timing controls to increase the expiratory time. Contact service.
Exp. valve cal. needed	<i>Low priority.</i> The ventilator does not have correct expiratory valve calibration data	Have the ventilator serviced.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Flow Sensor cal canceled	<i>User message.</i> The user canceled the flow sensor calibration.	No action required.
Flow Sensor cal. needed	<i>Low priority.</i> The ventilator does not have correct calibration data or automatic recalibration of the Flow Sensor is impossible. The flow trigger is disabled, and the pressure trigger is enabled.	Try calibrating the Flow Sensor up to two times. Replace the Flow Sensor.
Flow Sensor calibrated OK	<i>User message.</i> The Flow Sensor calibration was successful.	No action required.
High frequency	<i>Medium priority.</i> The measured fTotal > the set alarm limit.	Check the patient for adequate ventilation (VTE). Check the alarm limits. If the ventilator is in ASV, refer to Section D.2.
High minute volume	<i>High priority.</i> The measured ExpMinVol > the set alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarms.
High oxygen	<i>High priority.</i> Measured Oxygen concentration > (the operator-set Oxygen + 5%). This alarm is disabled if there is a O2 cell missing or O2 cell defective alarm, or if oxygen measurement is configured off.	Calibrate the oxygen cell. Install a new oxygen cell. Troubleshoot the Air supply failed alarm, if present.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
High pressure	<i>High priority.</i> The measured inspiratory pressure > the set alarm limit. The GALILEO immediately stops gas flow to the patient and relieves pressure to the PEEP/CPAP level. If the pressure continues to rise, the mechanical relief valve opens at 120 cmH ₂ O. The ventilator enters the ambient state. This alarm cannot be silenced.	Check the patient. Adjust the high Pressure alarm limit. Check the breathing circuit and Flow Sensor tubes for kinks and occlusions. Provide alternative ventilation once the GALILEO enters the ambient state.
High pressure during sigh	<i>High priority.</i> The measured inspiratory pressure during a sigh > the high Pressure limit. The sigh will only be partly delivered.	Check the patient. Check the breathing circuit. Adjust the high Pressure alarm limit. Consider disabling the sigh function.
High tidal volume	<i>Medium priority.</i> The measured Vt > the set limit for 2 consecutive breaths.	Reduce the Psupport setting. Adjust the high Vt alarm limit.
Initialisation failed	<i>Medium priority.</i> ASV, APVcmv, or APVsimv cannot start, because the test breath results are not acceptable.	Consider increasing the high Pressure limit (the difference between PEEP/CPAP and the high Pressure limit must be > 25 cmH ₂ O). Calibrate the Flow Sensor. Check for leaks. Replace the Flow Sensor. Switch to a conventional pressure mode.
Insert O2 cell	<i>User message.</i> You have enabled oxygen monitoring and/or tried to perform an oxygen cell calibration, but the oxygen cell is missing.	Install oxygen cell and perform the calibration.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Loss of PEEP	<i>Medium priority.</i> Pressure < (PEEP/CPAP - 3 cmH ₂ O) for more than 10 s.	Check the patient. Check the breathing circuit for leaks. Replace the breathing circuit, if necessary.
Low frequency	<i>Medium priority.</i> Measured fTotal < the set limit.	Check the patient. Adjust the fTotal alarm limit. If the ventilator is in ASV, check the %MinVol and Body Wt settings. Consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.
Low internal pressure	<i>High priority.</i> The internal reservoir pressure < 150 cmH ₂ O for more than 3 s and one gas supply registers no pressure. The usual cause is loss of supply pressure. The ventilator enters the ambient state. This alarm cannot be silenced.	Check the gas supply for adequate pressure. Consider using an alternative source of compressed air (for example, VENTILAIR ^{ll}) or oxygen. Have the ventilator serviced.
Low minute volume	<i>High priority.</i> Measured ExpMinVol < the set limit.	Check the patient. Check the breathing circuit. Check and adjust the ventilator settings, including alarms. If the ventilator is in ASV, check the %MinVol and Body Wt settings. Consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Low oxygen	<i>High priority.</i> Measured Oxygen is < (the operator-set Oxygen - 5%). This alarm is disabled if there is a O2 cell missing or O2 cell defective alarm, or if oxygen measurement is configured off.	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary. Calibrate the oxygen cell. Install a new oxygen cell.
Low pressure	<i>High priority.</i> Measured Ppeak < the set limit for 2 consecutive breaths.	Check the patient. Check and adjust the ventilator settings, including alarm limits.
Low tidal volume	<i>Medium priority.</i> Measured VTE < the set limit for 2 consecutive breaths.	Check the patient. Check and adjust the ventilator settings, including alarm limits. Check for leaks and disconnects. If the ventilator is in ASV, consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Maneuver in progress	<i>User message.</i> P/V Tool maneuver is in progress.	Wait.
Maximum compensation	<i>Low priority.</i> VLeak is greater than half of the set VTarget, and the APV controller is compensating the leak at its maximum compensation level. VTE will be lower than VTarget. Applies to the APV modes.	Check for leaks. Suction patient. Check high Pressure limit. Switch to another mode.
MinVol low alarm off	<i>Low priority.</i> The operator-adjustable low ExpMinVol alarm is set to off.	For information only.
No. of breaths not reached	<i>User message.</i> Too few breaths between P/V Tool maneuvers.	Wait until five breaths have been delivered before attempting maneuver again.
O2 cell cal. needed	<i>Low priority.</i> The ventilator does not have correct calibration data, measured Oxygen < 18%, or measured Oxygen > 105%.	Calibrate the oxygen cell. If you are attempting to calibrate the cell, make sure oxygen is connected.
O2 cell calibrated OK	<i>User message.</i> The oxygen cell calibration was successful.	No action required.
O2 cell defective	<i>High priority.</i> The oxygen cell is depleted.	Install a new oxygen cell.
WARNING To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external monitor that complies with ISO 7767.		

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
O2 cell missing	<i>Low priority.</i> There is no signal from the oxygen cell. This is not shown if oxygen monitoring is configured off.	Install an oxygen cell or use an external monitor, according to ISO 7767. If the GALILEO is not configured for oxygen monitoring, have it configured.
Oxygen + air supply failed	<i>High priority.</i> Input pressures of both oxygen and air < 190 kPa (27 psi), or the input flow dropped below 40 l/min. The GALILEO continues to ventilate as long as there is sufficient reservoir pressure to maintain gas flow. If the reservoir pressure drops below 150 cmH ₂ O, the ventilator enters the ambient state. This alarm cannot be silenced.	Provide alternative ventilation. Check air and oxygen supplies, or provide alternative compressed air or oxygen sources to the ventilator (VENTILAIR ^{II} compressor or oxygen cylinder).
Oxygen supply failed	<i>Medium priority.</i> Input pressure of oxygen < 190 kPa (28 psi), or the input flow dropped below 40 l/min. The ventilator continues to function at an oxygen concentration of 21% if the internal pressure can be maintained. Under these conditions, the low Oxygen concentration alarm is disabled.	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary.
Patient system tight	<i>User message.</i> The tightness test was successful.	No action required.
Press MANUAL to resume	<i>User message.</i> Instruction message during ventilation suppression.	Resume ventilation when desired by first reconnecting the patient, then pressing MANUAL.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Pressure not released	<i>High priority.</i> Airway pressure has exceeded the high Pressure limit, and the pressure was not released after 5 s. The ventilator enters the ambient state.	Provide alternative ventilation. Have the ventilator serviced.
TF: xxxx	<i>Technical fault.</i> A hardware or software malfunction was detected. The ventilator may switch to the ambient state, and the patient will breathe room air unassisted. You will hear the high-priority alarm tone, or the continuous-tone buzzer will sound as long as possible. WARNING To prevent possible patient injury arising from an equipment malfunction, HAMILTON MEDICAL recommends that you immediately remove any ventilator with a technical fault from use, record the number of the fault, and have the ventilator serviced.	Provide alternative ventilation. Have the ventilator serviced.
Tighten patient system	<i>User message.</i> Instruction message during tightness test.	Block the patient side of the patient end of the Flow Sensor (a finger covered with an alcohol pad may be used).
Turn Flow Sensor	<i>User message.</i> Instruction message during Flow Sensor calibration.	Reverse the ends of the Flow Sensor so that the blue tube is closest to the Y-piece.

Table 8-2. Alarms and other messages (continued)

Alarm	Definition	Action needed
Turn the Flow Sensor	<i>Medium priority.</i> The Flow Sensor connections are reversed. The flow trigger is turned off and the GALILEO switches to a pressure trigger.	Rotate the Flow Sensor. The blue sensing line is close to the patient and must be attached to the blue connector. The colorless sensing line is close to the ventilator and must be attached to the white connector.
Ventilation suppressed	<i>User message.</i> Ventilation suppression is active, and ventilator settings are being maintained, although the GALILEO is not delivering breaths.	Resume ventilation when desired by first reconnecting the patient, then pressing MANUAL.
Vol too low for nebulizer	<i>Low priority.</i> The nebulizer was turned on, but it cannot operate because the ventilator settings would require > 50% of the tidal volume to be delivered by the nebulizer.	Check and adjust ventilator settings to increase inspiratory peak flow.
Wrong Flow Sensor type	<i>High priority.</i> The type of Flow Sensor installed (pediatric/ adult or infant) does not match the patient age group setting. This is detected during calibration.	Make sure the Flow Sensor is for the appropriate patient age group.

8.6 Troubleshooting the battery backup system

The backup batteries have their own alarm system, complete with a separate continuous-tone buzzer and their own indicators on the battery panel. Refer to Table 8-3 to troubleshoot the battery system.

Table 8-3. Battery system troubleshooting

Symptoms	Meaning	Corrective action
Neither ac nor battery power indicator is lit, but ventilator is plugged in	Technical failure	Provide alternative ventilation. Check integrity of electrical outlet. Have the ventilator serviced.
Battery test shows that batteries are not fully charged after 8 hours	There is a battery system fault	Have the ventilator serviced.
Battery power indicator lit. Buzzer on.	The ventilator has switched over to battery power	Press the battery system alarm silence button. This will silence this particular alarm indefinitely. Prepare for power loss. Prepare alternative ventilation. Check ac power source.
Battery power and battery low indicators lit. Buzzer on.	The battery charge is low. This alarm cannot be silenced.	Provide alternative ventilation. Recharge the batteries by leaving the ventilator connected to ac power for a minimum of 8 hours.
Battery ERROR indicator lit	Battery system failure	Provide alternative ventilation. Have the ventilator serviced.

9 Special functions

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9.1 Nebulization

WARNING

Do not use an expiratory filter or HME in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.

NOTE:

- To determine whether your ventilator has the nebulization option, view the setup screen. Verify that nebulization is installed and enabled. If it is not enabled, enable it in the configuration mode (Appendix H).
 - Nebulization is inactive when the nebulizer volume is greater than 50% of the total delivered volume.
 - Delivered ventilation is compensated for the contribution of the nebulizer, so that the expected volume and pressure are delivered.
-

The GALILEO's optional pneumatic nebulization function provides nebulization during the breath phases and for the duration defined during configuration. To start nebulization, press the nebulizer key (Figure 9-1). This function can be activated in all modes of ventilation. To terminate nebulization before the set time, press the key again.



Figure 9-1. Special function keys

For effective nebulization, use a pneumatic nebulizer jar tested by HAMILTON MEDICAL (see Table 1-1). Section 2.8 describes how to install the nebulizer.

9.2 Standby

WARNING

- **To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the standby mode.**
 - **To prevent possible patient injury or damage to breathing circuit from overheated gas after reconnection from standby, turn off the humidifier when entering the standby mode.**
-

NOTE:

- To keep the batteries fully charged, make sure the ventilator is connected to ac power while in standby mode.
 - When in standby, the GALILEO does not automatically resume ventilation when the patient is reconnected. Instead you must *manually* deactivate standby.
 - All alarms except supply alarms and technical faults are suppressed during standby, but events continue to be recorded into the event log.
-

Standby is a waiting mode that lets you maintain ventilator settings while the GALILEO is not performing any ventilatory functions. For very short interruptions in ventilation, you may use ventilation suppression (Section 9.3).

To start standby, open the **Mode** window, then the **Standby** window (Figure 9-2). Select and activate **Activate Standby**.

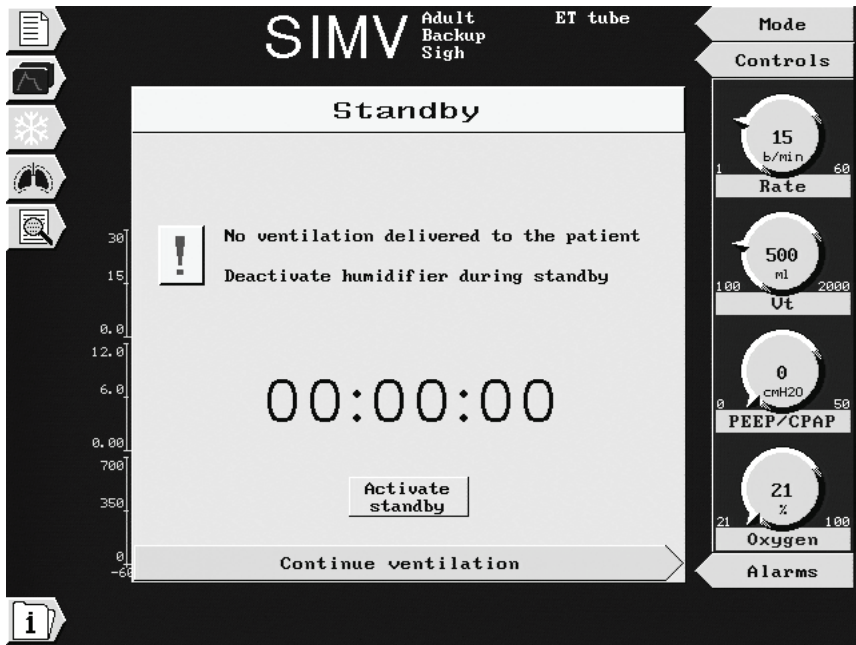


Figure 9-2. Standby window

The **Standby activated** window (Figure 9-3) automatically opens. During standby, the window shows the elapsed time since standby was started.

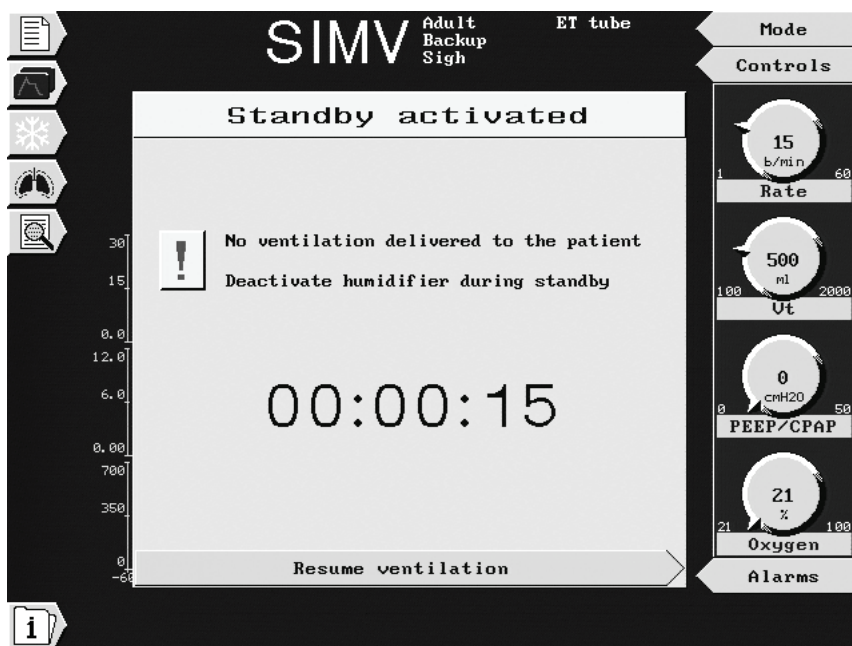


Figure 9-3. Standby activated window

To end standby and resume ventilation, press the C-knob. Ventilation resumes with the previous settings.

9.3 Ventilation suppression

WARNING

To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before suppressing ventilation. You must confirm that no patient is attached before suppressing ventilation.

NOTE:

After 2 min of ventilation suppression, the audible alarm resumes to alert you, but suppression may continue.

Ventilation suppression is a waiting mode that lets you maintain ventilator settings for a very short time while the GALILEO is not performing any ventilatory functions. This mode is useful during tracheal suctioning or for other clinical applications. To interrupt ventilation for a longer time, use the standby function.

To start ventilation suppression, do the following:

1. Press the alarm silence key and the 100% O₂ key in a sequence (not simultaneously) These keys are indicated by the words "For suctioning" beneath.
2. Disconnect the circuit now at the patient side of the Flow Sensor.

The ventilator delivers 3 to 5 additional breaths before it stops. The messages **Ventilation suppressed** and **Press MANUAL to resume** alternate in the message bar. During suppression, 100% O₂ is delivered through the inspiratory limb at 18 l/min (adult patients) or 6 l/min (pediatric or infant patients).

3. Resume ventilation by first reconnecting the patient, then pressing MANUAL.

9.4 100% O₂

The 100% O₂ function delivers 100% oxygen for 2 min. This is useful for preoxygenation before tracheal suctioning or for other clinical applications.

To start oxygen enrichment, press the 100% O₂ key (Figure 9-1). After a short time, which is required for the oxygen concentration to rise, the GALILEO starts delivering 100% oxygen. Afterwards the GALILEO resets the concentration to the previous operator-set value.

To terminate delivery of 100% O₂ before the 2-min period, press the key again. The GALILEO resumes ventilation at the set oxygen concentration.

NOTE:

Oxygen concentration alarms are disabled while the 100% O₂ function is active.

9.5 Manual breath

The MANUAL key (Figure 9-1) lets you deliver a manually triggered breath. The manual breath uses the settings of a mandatory breath (standard or operator-set). You can activate this function in all modes of ventilation.

To deliver a manual breath, press and release the key. Do not press the key quickly and repeatedly.

If you try to initiate a manual breath during the applicable minimum expiratory or inspiratory time, the breath will not be delivered.

10 Maintenance

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10.1 Introduction

Follow these maintenance procedures to ensure the safety and reliability of the GALILEO. All the procedures in this manual are intended to be performed by the operator. For further maintenance procedures, refer to the service manual.

10.2 Cleaning, disinfection, and sterilization

WARNING

- To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.
 - To prevent patient exposure to sterilizing agents and to prevent premature deterioration of parts, sterilize parts using the techniques recommended in this section only.
-

CAUTION

- Do not reuse single-patient use bacteria filters, Flow Sensors, and other accessories. They must be discarded after single use.
 - Do not attempt to sterilize the interior of the ventilator. Do not attempt to sterilize the whole ventilator with ETO gas.
 - Exposure to sterilizing agents may reduce the useful life of certain parts. Using more than one sterilization technique on a single part may damage a part.
-

NOTE:

Because sanitation practices vary among institutions, HAMILTON MEDICAL cannot specify specific practices that will meet all needs or be responsible for the effectiveness of these practices. This manual only gives general guidelines for cleaning, disinfecting, and sterilizing. It is the user's responsibility to ensure the validity and effectiveness of the actual methods used.

The following subsections provide general guidelines for cleaning and decontaminating parts. Table 10-1 tells you the specific methods that are applicable to each GALILEO part. For parts not supplied by HAMILTON MEDICAL, follow the manufacturers' guidelines. Do not attempt cleaning procedures unless specified by HAMILTON MEDICAL or the original manufacturer.

After cleaning and decontaminating parts, perform any required tests and calibrations described in Section 3.

Table 10-1. Decontamination methods for GALILEO parts

Part (material)	How to decontaminate	Remarks
Ventilator exterior, including housing, basket, tray, gas supply hoses, and power cord	Wipe with an appropriate bactericidal agent after each patient use	Do not use alcohol as a disinfectant. It does not harm the ventilator but it has not been proven to be an effective bactericidal or bacteriostatic. Do not clean the ventilator interior. This can damage internal parts.
Breathing tubes (silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Roll tubes into large coils. Do not twist, kink, or cross tubes when sterilizing them. The tubing lumen should not have vapor or moisture before wrapping for autoclaving. Avoid exposing silicone rubber breathing tubes to grease, oil, silicone-based lubricants, organic solvents (benzene, ether, ketone, and chlorinated hydrocarbons), acids, concentrated alkaline cleaning products, and phenols and derivatives.
Mask (silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Avoid exposing silicone rubber masks to grease, oil, silicone-based lubricants, organic solvents (benzene, ether, ketone, and chlorinated hydrocarbons), acids, concentrated alkaline cleaning products, and phenols and derivatives. Deflate air cushion before steam autoclaving to prevent possibility of explosion.

Table 10-1. Decontamination methods for GALILEO parts (continued)

Part (material)	How to decontaminate	Remarks
Flow Sensor, single-patient use	Chemically disinfect (only if this single-patient use Sensor requires decontamination before use)	The Flow Sensor is designed for single-patient use. It is delivered clean and ready for patient use. If the Sensor must be decontaminated, do not use hard brushes, pointed instruments, or rough materials. These can damage the Flow Sensor's membrane.
Flow Sensor, reusable	Chemically disinfect or ETO sterilize	Do not use hard brushes, pointed instruments, or rough materials. These can damage the Flow Sensor's membrane.
Inspiratory filter, reusable autoclavable	Steam autoclave	Inspect the filter media for cracks or foreign matter; replace if necessary. Replace after 20 autoclave cycles. Do not chemically disinfect or expose to ETO gas.
Expiratory valve membrane (silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Inspect the membrane for damage; replace if necessary. Replace after 30 autoclave cycles.
Nebulizer jar, reusable (polysulfone)	Steam autoclave or chemically disinfect	
Expiratory valve cover (polysulfone) Y-piece, water traps, adapters, connectors (polysulfone) Temperature probe housing (polysulfone and silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Solutions such as Medizyme, Pyroneg, Control 3, Solution 2, and Cidex have been tested according to the manufacturers' guidelines. Other brand names with similar active ingredients may also be suitable. Do not autoclave if medications containing chlorinated or aromatic hydrocarbons are used.

Table 10-1. Decontamination methods for GALILEO parts (continued)

Part (material)	How to decontaminate	Remarks
Humidifier and chamber, temperature probe, and other accessories	Follow the manufacturer's guidelines	
Small-bore tubing for Paux measurement		Discard every 48 hours or when changing breathing circuit.

10.2.1 General guidelines for cleaning

CAUTION

- To prevent damage to breathing circuit parts, do not clean with hard brushes, pointed instruments, or rough materials.
 - To prevent damage to breathing circuit parts, follow the soap manufacturer's guidelines. Exposure to soap solution that is stronger than recommended can shorten the useful life of some products. Soap residue can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during sterilization.
-

Clean the GALILEO parts as follows:

1. Disassemble parts. Breathing circuits must be disassembled completely.
2. Wash parts in warm water and soap or mild detergent solution.
3. Rinse parts thoroughly with clean, warm water.
4. Air dry.
5. Inspect all parts, and replace if damaged.
6. If you will sterilize or disinfect the part, continue with the appropriate sterilization/disinfection procedure (Section 10.2.2 or Section 10.2.3). If you will not sterilize or disinfect the part, reassemble and reinstall parts, and perform any required tests.

10.2.2 General guidelines for chemical disinfection

CAUTION

Table 10-1 lists materials of construction for the GALILEO parts. To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material.

Disinfect the GALILEO parts as follows:

1. Disassemble.
2. Clean (Section 10.2.1).
3. Disinfect with a mild bactericidal chemical solution.
Acceptable chemicals include: Schülke & Mayr Lysetol® AF and Gigasept® FF, Henkel-Ecolab Incidur®, Sekusept® PLUS, and CIDEX®. Solutions such as these have been tested according to the manufacturers' guidelines. Other brand names with similar active ingredients may also be suitable.
4. Reassemble and reinstall parts, and perform any required tests.

10.2.3 General guidelines for autoclave sterilization

Autoclave the GALILEO parts as follows:

5. Clean (Section 10.2.1).
6. Reassemble.
7. Inspect.
8. Autoclave.
9. Perform any required tests.

10.3 Preventive maintenance

Perform preventive maintenance on your GALILEO according to the schedule in Table 10-2. You can view the hours of ventilator operation on the setup screen or in the numeric data monitoring window.

The following subsections provide details for some of these preventive maintenance procedures.

NOTE:

- HAMILTON MEDICAL recommends that you document all maintenance procedures.
- Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).

Table 10-2. Preventive maintenance schedule

Interval	Part/accessory	Procedure
Between patients and according to hospital policy	Breathing circuit (including mask, inspiratory filter, Flow Sensor, nebulizer jar, exhalation valve cover and membrane)	Replace with sterilized or new single-patient use parts. Run the tightness test and the Flow Sensor calibration (Section 3.2).
	Entire ventilator	Run the preoperational check (Section 3.4).
Every day or as required	Gas inlet water trap	Empty any water by pressing on drain valve.
Every 2 days or according to hospital policy	Breathing circuit	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.

* Must be done by a qualified service technician according to instructions in the service manual.

Table 10-2. Preventive maintenance schedule (continued)

Interval	Part/accessory	Procedure
Every month (or more often, if required)	Fan filter (rear panel)	Check for dust and lint. If needed, clean or replace (Section 10.3.1).
	WARNING To reduce the risk of patient cross-contamination through the fan filter, always perform maintenance at the prescribed interval.	
Every 3 months (1250 hours)	Gas supply filter assemblies	Inspect filter. Replace if dirty or discolored. Clean filter housing if desired (Section 10.3.2).
Yearly or every 5000 hours, whichever comes first, or as necessary	Oxygen cell	Replace if depleted (Section 10.3.3).
	NOTE: Oxygen cell life specifications are approximate. The actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.	
	Ventilator	Perform service-related preventive maintenance.*
Every 2 years or as necessary	Backup batteries	Replace.*
	NOTE: Battery life specifications are approximate. The actual battery life depends on ventilator settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.	
	Clock battery	Replace.*
Every 5 years	Backlight LCD display	Replace.*

* Must be done by a qualified service technician according to instructions in the service manual.

10.3.1 Cleaning or replacing the fan filter

Pull off the filter cover (Figure 10-1). Either install a new filter; or wash the existing filter in a mild soap solution, rinse, and dry.



Figure 10-1. Removing the fan filter

10.3.2 Replacing gas supply filters

Disconnect the ventilator from the gas supply. Unscrew the filter housing, then the filter (Figure 10-2). Install a new filter; never attempt to clean the filter. Clean the housing if desired (Section 10.2.1) and replace it.



Figure 10-2. Replacing a gas supply filter

10.3.3 Replacing the oxygen cell

Unscrew the oxygen cell carrier, then disconnect the cell connector (Figure 10-3). Install the new cell, then replace the oxygen cell carrier. Run the oxygen cell calibration.

WARNING

To reduce the risk of explosion, do not burn the oxygen cell or force the cell open.

NOTE:

Observe the orientation of the connector when installing the oxygen cell.

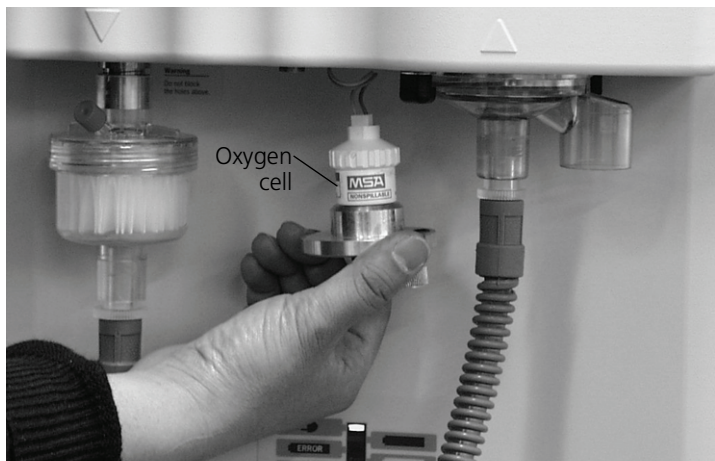


Figure 10-3. Replacing the oxygen cell

10.3.4 Replacing a fuse

WARNING

- **To reduce the risk of electrical shock, disconnect electrical power from the ventilator before removing a fuse.**
 - **For continued protection against a fire hazard, replace fuses only with those of the same type and rating.**
-



Disconnect the power cord from the GALILEO. Remove the fuse holder by pressing down on the tab and pulling the holder out. Replace the fuse with a T4.0 A H 250 V fuse, and push the holder back in.

10.4 Storage

To maintain the battery charge and to prolong the life of the batteries, keep the ventilator connected to ac power if possible. If this is not possible and you intend to store the ventilator for an indefinite period of time, have the batteries disconnected and recharged every 3 to 6 months, depending on storage conditions (see specifications in Appendix A).

NOTE:

The batteries must be disconnected by a HAMILTON MEDICAL authorized service technician according to instructions in the service manual.

10.5 Repacking and shipping

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your HAMILTON MEDICAL representative for replacement materials.

A Specifications

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A.1 Physical characteristics

Table A-1. Physical characteristics

Weight	48 kg (105 lb) with standard trolley 35 kg (77 lb) with shelf mount
Dimensions (W x D x H)	440 x 620 x 1540 mm (17.3 x 24.4 x 60.6 in.) (ventilator with standard trolley) 440 x 620 x 1415 mm (17.3 x 24.4 x 55.7 in.) (ventilator with short trolley) 382 x 433 x 719 mm (15.0 x 17.0 x 28.3 in.) (ventilator with shelf mount)

A.2 Environmental requirements

Table A-2. Environmental requirements

Temperature	Operating: 10 to 40 °C (50 to 104 °F), 30 to 75% relative humidity, noncondensing, out of direct sunlight Storage: -10 to 60 °C (14 to 140 °F), 5 to 85% relative humidity, noncondensing
Altitude	Up to 3000 m (9843 ft) above sea level

A.3 Pneumatic specifications

Table A-3. Pneumatic specifications

Oxygen and air inlet supplies	Pressure: 200 to 600 kPa / 2 to 6 bar / 29 to 86 psi Flow: Maximum of 120 l/min STPD, minimum of 40 l/min STPD The supplied air or oxygen need be dry and clean for medical use. The O ₂ concentration in the O ₂ supply must be minimally 95%.
Gas mixing system	Delivered flow: 120 l/min typical, 4 to 30 l/min continuous base flow Delivered pressure: 0 to 120 cmH ₂ O Operating pressure range: 200 to 600 kPa (29 to 86 psi)
Connectors	Inspiratory limb connector: ISO 22 mm male/15 mm female conical Expiratory limb connector (on exhalation valve): ISO 15 mm female/22 mm conical male Air and oxygen inlets: DISS male or NIST

A.4 Electrical specifications

Table A-4. Electrical specifications

Input power	100 to 240 V ac $\pm 10\%$; 50/60 Hz; 2.1 A (at 100 V), 0.9 A (at 240 V) Power consumption: 210 VA
Mains fuses (2)	T 4.0 AH 250 V

Table A-4. Electrical specifications (continued)

Leakage current	According to IEC 60601-1								
Batteries	2 x 12 V dc, 5 Ah Type: Sealed lead-acid, supplied by HAMILTON MEDICAL only. Operating time (at standard settings and with nebulizer and communications interface option enabled): At least 1 hour typical; 20 min minimum. These operating times apply to new, fully charged batteries not exposed to extreme temperatures. The actual operating time depends on battery age and on how the batteries are used and recharged. Recharge time: 8 hours minimum while ventilator is connected to ac power Storage: Remove batteries from ventilator for long-term storage. Store at -20 to 40 °C (-4 to 104 °F), but preferably below 30 °C (86 °F), with relative humidity of 25 to 85%. Storage place must be free from vibration, dust, direct sunlight, and moisture. Avoid storing the batteries for more than 12 months. To maintain battery integrity, recharge the batteries at these intervals: <table> <tr> <th>Storage temperature</th><th>Recharge interval</th></tr> <tr> <td>< 20 °C (68 °F)</td><td>6 months</td></tr> <tr> <td>20 to 30 °C (68 to 86 °F)</td><td>3 months</td></tr> <tr> <td>> 30 °C (86 °F)</td><td>Avoid storage</td></tr> </table> NOTE: Battery life specifications are approximate. The actual battery life depends on ventilator settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.	Storage temperature	Recharge interval	< 20 °C (68 °F)	6 months	20 to 30 °C (68 to 86 °F)	3 months	> 30 °C (86 °F)	Avoid storage
Storage temperature	Recharge interval								
< 20 °C (68 °F)	6 months								
20 to 30 °C (68 to 86 °F)	3 months								
> 30 °C (86 °F)	Avoid storage								

A.5 Control settings

Table A-5 lists the GALILEO's modes, patient age group, and mode additions, including standard settings. Table A-6 is an alphabetical list of the GALILEO's control settings, their ranges, and their resolutions. Table A-7 lists the control settings that apply to the various ventilation modes. Table A-8 lists the P/V Tool 2 setting ranges, standard settings, and resolutions.

Table A-5. Modes, patient age groups, and mode additions

Parameter	Range	Standard setting
Mode		
Adult/pediatric	(S)CMV (A/C), P-CMV (P-A/C), SIMV, P-SIMV, SPONT, APVcmv, APVsimv, ASV, DuoPAP, APRV, NIV	(S)CMV (A/C)
Infant	P-CMV (P-A/C), P-SIMV, SPONT, APVcmv, APVsimv, ASV, DuoPAP, APRV	P-CMV (P-A/C)
Patient age group	Infant, pediatric, or adult	Setting in effect when ventilator was last powered down
Mode additions	Sigh, apnea backup, TRC (tube resistance compensation, GALILEO Gold only)	Apnea backup on; sigh and TRC off

Table A-6. Control setting ranges and resolutions

Setting	Range	Standard setting	Resolution
%MinVol (% minute volume)			
Adult/ pediatric	10 to 350%	100%	5%
Infant	--	--	--
%TI (% inspiratory time)*			
Adult	10 to 80% (of cycle time)	33%	1%
Pediatric/ infant	--	--	--
Body Wt (ASV only)			
Adult	10 to 200 kg	70 kg	1 kg
Pediatric	3 to 30 kg	10 kg	1 kg
Infant	--	--	--

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
ETS (expiratory trigger sensitivity)			
Adult	5 to 70% (of inspiratory peak flow)	25%	5%
Pediatric/ infant	5 to 70% (of inspiratory peak flow)	15%	5%
FlowPattern			
Adult/ pediatric	Sine, square, 100% decelerating, 50% decelerating	50% decelerating	--
Infant	--	--	--
Flowtrigger			
Adult	0.5 to 15 l/min	5 l/min	0.5 l/min
Pediatric	0.5 to 15 l/min	3 l/min	0.5 l/min
Infant	0.5 to 5 l/min	1.5 l/min	0.1 l/min for ≤ 1.9 l/min 0.5 l/min for > 1.9 l/min
I:E*			
Adult	1:9.0 to 4.0:1	1:2.0	1 for 1:9 to 1:4 0.1 for 1:4 to 4:1
Pediatric/ infant	--	--	--

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
Oxygen	21 to 100%	50%	1%
Pause*			
Adult/ pediatric	0 to 70% (of cycle time)	0%	5%
Infant	--	--	--
Pcontrol (pressure control, added to PEEP/ CPAP)			
Adult/ pediatric	5 to 100 cmH ₂ O	15 cmH ₂ O	1 cmH ₂ O
Infant	5 to 50 cmH ₂ O	15 cmH ₂ O	1 cmH ₂ O
Peak Flow*			
Adult	1 to 180 l/min	54 l/min	1 l/min
Pediatric/ infant	--	--	--
PEEP/CPAP			
Adult/ pediatric	0 to 50 cmH ₂ O	5 cmH ₂ O	1 cmH ₂ O
Infant	0 to 25 cmH ₂ O	5 cmH ₂ O	0.5 cmH ₂ O
P high	0 to 50 cmH ₂ O	15 cmH ₂ O	1 cmH ₂ O
P low			
Adult/ pediatric	0 to 50 cmH ₂ O	5 cmH ₂ O	1 cmH ₂ O
Infant	0 to 25 cmH ₂ O	5 cmH ₂ O	0.5 cmH ₂ O

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
P-ramp (pressure ramp)			
Adult: P-CMV (P-A/ C) and APVcmv	50 to 200 ms	50 ms	25 ms
Other modes	25 to 200 ms	50 ms	
Pediatric/ infant: P-CMV (P-A/ C) and APVcmv (as applicable)	50 to 200 ms	100 ms	25 ms
Other modes	25 to 200 ms	100 ms	
Psupport (pressure support, added to PEEP/CPAP or P low)			
Adult/ pediatric	0 to 100 cmH ₂ O	15 cmH ₂ O	1 cmH ₂ O
Infant	0 to 50 cmH ₂ O	15 cmH ₂ O	1 cmH ₂ O
P-trigger (pressure trigger)			
Adult/ pediatric	0.5 to 10 cmH ₂ O (below PEEP/ CPAP)	2 cmH ₂ O	0.5 cmH ₂ O
Infant	0.5 to 5 cmH ₂ O (below PEEP/ CPAP)	1 cmH ₂ O	0.5 cmH ₂ O

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
Rate			
Adult: (S)CMV (A/C), P-A/C (P-CMV)	5 to 120 b/min	15 b/min	1 b/min
SIMV, P-SIMV, DuoPAP	1 to 60 b/min	15 b/min	
Pediatric: (S)CMV (A/C), P-A/C (P-CMV)	5 to 120 b/min	25 b/min	1 b/min
SIMV, P-SIMV, DuoPAP	1 to 60 b/min	25 b/min	
Infant: P-A/C (P-CMV)	10 to 120 b/min	30 b/min	1 b/min
P-SIMV, DuoPAP	1 to 60 b/min	30 b/min	
T high			
Adult	0.1 to 30 s	1.3 s	0.1 s
Pediatric	0.1 to 30 s	0.8 s	0.1 s
Infant	0.1 to 30 s	0.7 s	0.1 s
TI (inspiratory time)*			
Adult	0.1 to 10.0 s	1.3 s	0.1 s
Pediatric	0.1 to 3.0 s	0.8 s	0.1 s
Infant	0.1 to 3.0 s	0.6 s	0.05 s

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
Ti max (maximum inspiratory time, spontaneous breaths)			
Adult	1.0 to 3.0 s	2.0 s	0.1 s
Pediatric	0.5 to 3.0 s	1.0 s	0.1 s
Infant	0.3 to 3.0 s	1.0 s	0.05 s
Tip (inspiratory time)*			
Adult	0 to 8 s	0.0 s	0.1 s
Pediatric/ infant	--	--	--

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-6. Control setting ranges and resolutions (continued)

Setting	Range	Standard setting	Resolution
T low			
Adult	0.2 to 30 s	2.7 s	0.1 s
Pediatric	0.2 to 30 s	1.6 s	0.1 s
Infant	0.2 to 30 s	1.3 s	0.1 s
Trigger	P-trigger, Flowtrigger, Trigger off	Flowtrigger	--
Vt (tidal volume)			
Adult	100 to 2000 ml	500 ml	10 ml for < 1000 ml 50 ml for ≥ 1000 ml
Pediatric	20 to 300 ml	100 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml
Infant	--	--	--
Vtarget (target tidal volume)			
Adult	100 to 2000 ml	500 ml	10 ml for < 1000 ml 50 ml for ≥ 1000 ml
Pediatric	20 to 300 ml	100 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml
Infant	10 to 150 ml	20 ml	1 ml

* Depending on how the ventilator was configured, you may see different time-related control settings. See Appendix H for details.

Table A-7. Control settings applicable to GALILEO's ventilation modes

Mode	Control settings		
	Adult	Pediatric	Infant
(S)CMV (A/C)	FlowPattern I:E and Pause, Peak Flow and Tip, or %TI and Pause Rate Vt P-trigger, Flowtrigger, or Trigger off PEEP/CPAP Oxygen	FlowPattern TI and Pause Rate Vt P-trigger, Flowtrigger, or Trigger off PEEP/CPAP Oxygen	--
P-CMV (P-A/C)	I:E or %TI Rate P-ramp P-trigger, Flowtrigger, or Trigger off Pcontrol PEEP/CPAP Oxygen	TI Rate P-ramp P-trigger, Flowtrigger, or Trigger off Pcontrol PEEP/CPAP Oxygen	TI Rate P-ramp P-trigger, Flowtrigger, or Trigger off Pcontrol PEEP/CPAP Oxygen
APVcmv	I:E or %TI Rate P-ramp Vtarget P-trigger, Flowtrigger, or Trigger off PEEP/CPAP Oxygen	TI Rate P-ramp Vtarget P-trigger, Flowtrigger, or Trigger off PEEP/CPAP Oxygen	TI Rate P-ramp Vtarget P-trigger, Flowtrigger, or Trigger off PEEP/CPAP Oxygen

Table A-7. Control settings applicable to GALILEO's ventilation modes (continued)

Mode	Control settings		
	Adult	Pediatric	Infant
SIMV	FlowPattern TI and Pause, Tip and Peak Flow, or %TI and Pause Rate P-ramp Vt ETS P-trigger or Flowtrigger Psupport PEEP/CPAP Oxygen	FlowPattern TI and Pause Rate P-ramp Vt ETS Ti max P-trigger or Flowtrigger Psupport PEEP/CPAP Oxygen	--
P-SIMV	TI or %TI Rate P-ramp ETS P-trigger or Flowtrigger Pcontrol Psupport PEEP/CPAP Oxygen	TI Rate P-ramp ETS Ti max P-trigger or Flowtrigger Pcontrol Psupport PEEP/CPAP Oxygen	TI Rate P-ramp ETS Ti max P-trigger or Flowtrigger Pcontrol Psupport PEEP/CPAP Oxygen

Table A-7. Control settings applicable to GALILEO's ventilation modes (continued)

Mode	Control settings		
	Adult	Pediatric	Infant
APVsimv	TI or %TI Rate P-ramp Vtarget ETS P-trigger or Flowtrigger Psupport PEEP/CPAP Oxygen	TI Rate P-ramp Vtarget ETS Ti max P-trigger or Flowtrigger Psupport PEEP/CPAP Oxygen	TI Rate P-ramp Vtarget ETS Ti max P-trigger or Flowtrigger Psupport PEEP/CPAP Oxygen
SPONT	P-ramp Psupport ETS P-trigger or Flowtrigger PEEP/CPAP Oxygen	P-ramp Psupport ETS Ti max P-trigger or Flowtrigger PEEP/CPAP Oxygen	P-ramp Psupport ETS Ti max P-trigger or Flowtrigger PEEP/CPAP Oxygen
ASV	Body Wt %MinVol P-ramp ETS P-trigger or Flowtrigger PEEP/CPAP Oxygen	Body Wt %MinVol P-ramp ETS P-trigger or Flowtrigger PEEP/CPAP Oxygen	--

Table A-7. Control settings applicable to GALILEO's ventilation modes (continued)

Mode	Control settings		
	Adult	Pediatric	Infant
DuoPAP	T high Rate P-ramp P high ETS P-trigger or Flowtrigger PEEP/CPAP Psupport Oxygen	T high Rate P-ramp P high ETS P-trigger or Flowtrigger PEEP/CPAP Psupport Oxygen	T high Rate P-ramp P high ETS P-trigger or Flowtrigger PEEP/CPAP Psupport Oxygen
APRV	T high T low P-ramp P high ETS P-trigger or Flowtrigger P low Psupport Oxygen	T high T low P-ramp P high ETS P-trigger or Flowtrigger P low Psupport Oxygen	T high T low P-ramp P high ETS P-trigger or Flowtrigger P low Psupport Oxygen
NIV	P-ramp Psupport ETS Ti max P-trigger or Flowtrigger PEEP/CPAP Oxygen	P-ramp Psupport ETS Ti max P-trigger or Flowtrigger PEEP/CPAP Oxygen	--

Table A-8. P/V Tool 2 setting ranges and resolutions

Setting	Range	Standard setting	Resolution
Pstart	0 to 20 cmH ₂ O	Current PEEP/ CPAP setting	1 cmH ₂ O
Ptop	25 to 60 cmH ₂ O	35 cmH ₂ O	1 cmH ₂ O
End PEEP	0 to 20 cmH ₂ O	Current PEEP/ CPAP setting	1 cmH ₂ O
Tpause	0 to 30 s	0 s	1 s
Ramp speed	2 to 5 cmH ₂ O/s	3 cmH ₂ O/s	1 cmH ₂ O/s

A.6 Monitored parameters

Table A-9 is an alphabetical list of monitored parameter ranges and resolutions. Table A-10 lists the ranges of the real-time curves. Pressure, flow, and volume measurements are based on readings from the Flow Sensor. Optionally, you can select an auxiliary pressure sensing site via the Paux connector. Directly measured (non-calculated) parameters have the following accuracies:

- Volume-related parameters > 20 ml: $\pm 15\%$ or 20 ml, whichever is greater (ATPD)
- Pressure-related parameters: $\pm 5\%$ or 1 cmH₂O, whichever is greater
- Oxygen: $\pm 3\%$, including stability of measurement

Table A-9. Monitored parameter ranges and resolutions

Parameter	Range	Resolution
Pressure		
Ppeak	0 to 120 cmH ₂ O	0.1 cmH ₂ O for < 10 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
Pmean	0 to 99 cmH ₂ O	0.1 cmH ₂ O for < 10 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
Pminimum	-99 to 99 cmH ₂ O	1 cmH ₂ O for ≤ -10 cmH ₂ O 0.1 cmH ₂ O for -9.9 to 9.9 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
Pplateau	0 to 99 cmH ₂ O	0.1 cmH ₂ O for < 10 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
PEEP/CPAP	0 to 99 cmH ₂ O	0.1 cmH ₂ O for < 10 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
AutoPEEP	0 to 99 cmH ₂ O	0.1 cmH ₂ O for < 10 cmH ₂ O 1 cmH ₂ O for ≥ 10 cmH ₂ O
Flow		
Insp Flow	0 to 999 l/min	0.1 l/min for < 100 l/min 1 l/min for ≥ 100 l/min
Exp Flow	0 to 999 l/min	0.1 l/min for < 100 l/min 1 l/min for ≥ 100 l/min
Volume		
VTE	0 to 9999 ml	1 ml
ExpMinVol	0.0 to 99.9 l/min	0.01 l/min for < 3.0 l/min 0.1 l/min for ≥ 3.0 l/min
VLeak	0 to 9999 ml	1 ml

Table A-9. Monitored parameter ranges and resolutions (continued)

Parameter	Range	Resolution
Time		
I:E	1:9 to 9:1	1 for 1:9 to 1:4 0.1 for 1:4 to 4:1 1 for 4:1 to 9:1
fTotal	0 to 999 b/min	1 b/min
fSpont	0 to 999 b/min	1 b/min
TI	0.00 to 99.9 s	0.01 s for < 10.0 s 0.1 s for ≥ 10.0 s
TE	0.00 to 99.9 s	0.01 s for < 10.0 s 0.1 s for ≥ 10.0 s
Other calculated parameters		
Cstat	0 to 200 ml/cmH ₂ O	0.1 ml/cmH ₂ O for < 100 ml/cmH ₂ O 1 ml/cmH ₂ O for ≥ 100 ml/cmH ₂ O
P0.1	-99 to 0.0 cmH ₂ O	1 cmH ₂ O for ≤ -10 cmH ₂ O 0.1 cmH ₂ O for > -10 cmH ₂ O
PTP	0 to 99.9 cmH ₂ O*s	0.1 cmH ₂ O*s
RCexp	0.0 to 99.9 s	0.01 s for < 10.0 s 0.1 s for ≥ 10.0 s
RCinsp	0.0 to 99.9 s	0.01 s for < 10.0 s 0.1 s for ≥ 10.0 s
Rexp	0 to 999 cmH ₂ O/l/s	1 cmH ₂ O/l/s
Rinsp	0 to 999 cmH ₂ O/l/s	1 cmH ₂ O/l/s
RSB	0 to 999 1/l*min	1 1/l*min
WOBimp	0.00 to 9.99 J/l	0.01 J/l
Oxygen	18 to 100%	1%

Table A-10. Real-time curves

Parameter	Range
Volume (V)	0 to 3200 ml
Flow	-200 to 200 l/min
Airway pressure (Paw)	-10 to 120 cmH ₂ O
Auxiliary pressure (Paux)	-10 to 120 cmH ₂ O
Time	5 to 60 s

A.7 Alarms

Table A-11 is an alphabetical list of the ventilator alarm settings, their ranges, plus the automatic and standard alarm settings. Table A-12 lists the ventilator's nonadjustable alarms and their triggering conditions.

Table A-11. Adjustable alarms with automatic and standard settings

Parameter	Range	Automatic setting	Standard setting	Resolution
Air trapping				
Adult	Off, 1 to 10 l/min (end expiratory flow)	4 l/min	Off	0.5 l/min
Pediatric	Off, 1 to 10 l/min (end expiratory flow)	2 l/min	Off	0.5 l/min
Infant	Off, 1 to 10 l/min (end expiratory flow)	2 l/min	Off	0.5 l/min

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
Apnea time				
Adult:	15 to 60 s	20 s	20 s (all but NIV) 30 s (NIV)	5 s
Pediatric	15 to 60 s	20 s	20 s	5 s
Infant	10 to 60 s	15 s	15 s	5 s
ExpMinVol (low)				
Adult:				
All modes except NIV	1 to 49 l/min	ExpMinVol - 40%	4 l/min	0.01 l/min for < 1 l/min 1 l/min for ≥ 1 l/min
NIV	0.01 to 49 l/min	2 l/min	2 l/min	
Pediatric:				
All modes except NIV	0.1 to 9.8 l/min	ExpMinVol - 40%	1.5 l/min	0.01 l/min for < 1.0 l/min 0.1 l/min for ≥ 1.0 l/min
NIV	0.1 to 9.8 l/min	ExpMinVol - 40%	1 l/min	
Infant	Off, 0.01 to 9.8 l/min	ExpMinVol - 40%	0.5 l/min	0.01 l/min for < 1.0 l/min 0.1 l/min for ≥ 1.0 l/min

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
ExpMinVol (high)				
Adult	Off, 2 to 50 l/min	ExpMinVol + 40%	10 l/min	1 l/min
Pediatric	Off, 0.3 to 10.0 l/min	ExpMinVol + 40%	3.5 l/min	0.1 l/min
Infant	Off, 0.03 to 10.0 l/min	ExpMinVol + 40%	2 l/min	0.01 l/min for < 1.0 l/min 0.1 l/min for ≥ 1.0 l/min
Pressure (low)	2 to 119 cmH ₂ O	PEEP/CPAP + 5 cmH ₂ O	5 cmH ₂ O	1 cmH ₂ O

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
Pressure (high)				
Adult/ pediatric:	10 to 120 cmH ₂ O	P _{peak} + 10 cmH ₂ O, or minimum of 40 cmH ₂ O	40 cmH ₂ O	1 cmH ₂ O
Volume modes, ASV				
APV modes		Peak Pressure + 10 cmH ₂ O		
SPONT		PEEP/CPAP + P _{support} + 10 cmH ₂ O		
Pressure modes		PEEP/CPAP + P _{control} + 10 cmH ₂ O		
DuoPAP, APRV		P high + 10 cmH ₂ O		
Infant	10 to 120 cmH ₂ O	P _{peak} + 10 cmH ₂ O, or minimum of 40 cmH ₂ O	40 cmH ₂ O	1 cmH ₂ O

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
Rate (low)				
Adult: Volume modes, ASV Other modes	0 to 128 b/min	Rate/ fControl - 40% fTotal - 40%	8 b/min	1 b/min
Pediatric: Volume modes, ASV Other modes	0 to 128 b/min	Rate/ fControl - 40% fTotal - 40%	12 b/min	1 b/min
Infant	0 to 128 b/min	fTotal - 40%	12 b/min	1 b/min
Rate (high)				
Adult: Volume modes, ASV Other modes	2 to 130 b/min	Rate/ fControl + 40% fTotal + 40%	23 b/min	1 b/min
Pediatric: Volume modes, ASV Other modes	2 to 130 b/min	Rate/ fControl + 40% fTotal + 40%	38 b/min	1 b/min
Infant	2 to 130 b/min	fTotal + 40%	45 b/min	1 b/min

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
Vt (low)				
Adult:				
Volume modes, ASV	Off, 50 to 2950 ml	Vt - 50%	250 ml	10 ml for < 1000 ml 50 ml for ≥ 1000 ml
NIV	0.1 ml	Off		
Other modes	Off, 50 to 2950 ml	VTE - 50%		
Pediatric:				
Volume modes, ASV	Off, 0 to 300 ml	Vt - 50%	50 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml
NIV		Off		
Other modes		VTE - 50%		
Infant	Off, 0 to 249 ml	VTE - 50%	3 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml

Table A-11. Adjustable alarms with automatic and standard settings (continued)

Parameter	Range	Automatic setting	Standard setting	Resolution
Vt (high)				
Adult: Volume modes, ASV Other modes	Off, 100 to 3000 ml	Vt + 50% VTE + 50%	750 ml	10 ml for < 1000 ml 50 ml for ≥ 1000 ml
Pediatric: Volume modes, ASV Other modes	Off, 10 to 500 ml	Vt + 50% VTE + 50%	150 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml
Infant	Off, 1 to 250 ml	VTE + 50%	40 ml	1 ml for < 100 ml 10 ml for ≥ 100 ml

Table A-12. Nonadjustable alarm triggering conditions

Alarm	Triggering conditions
Apnea	No patient trigger after the operator-set Apnea time in SPONT, SIMV, P-SIMV, APVsimv, DuoPAP, APRV, or NIV mode. The Apnea alarm is not activated if ExpMinVol is ≤ 0.01 l/min.
Check Flow Sensor tubing	Sensing lines disconnected or occluded
Disconnection pat. side	VTE < than 1/8 delivered tidal volume for 2 consecutive breaths. Disabled in the NIV mode.

Table A-12. Nonadjustable alarm triggering conditions (continued)

Alarm	Triggering conditions
Disconnection vent. side	Inspiratory tidal volume < 1/2 VTE for 2 consecutive breaths.
Exhalation obstructed	Proximal airway pressure does not drop during exhalation
High oxygen	Monitored Oxygen > (Oxygen setting + 5%), maximum 103%, display corrected to 100%
High pressure during sigh	Ppeak during a sigh > high Pressure limit setting
Loss of PEEP	Monitored PEEP/CPAP < (PEEP/CPAP setting - 3 cmH ₂ O) for > 10 s
Low internal pressure	Internal reservoir pressure < 150 cmH ₂ O for 3 s and exactly one gas is missing
Low oxygen	Monitored Oxygen < (Oxygen setting - 5%), minimum 18%
O2 cell defective	Monitored Oxygen < approximately 10%, or calibration is not possible
Oxygen supply failed/Air supply failed	Input pressure of either air or oxygen < 190 kPa (28 psi) or input flow < 40 l/min
Oxygen + air supply failed	Input pressures of both air and oxygen < 190 kPa (28 psi) or input flow < 40 l/min
Technical Fault	Hardware or software error
Others	ASV/APV initialization failed, ASV unable to meet target, ASV/APV check high pressure limit, settings incompatibility, expiratory valve calibration needed, Flow Sensor calibration needed, oxygen cell calibration needed, Flow Sensor mismatch during calibration and ventilation, mains power failure (switching to batteries), nebulizer inactive, oxygen cell not in use or defective

A.8 Breathing circuit specifications

Table A-13 lists specifications for HAMILTON MEDICAL breathing circuits.

Table A-13. Breathing circuit specifications

Parameter	Specification
Resistance*	Adult circuit (22 mm ID, flow of 60 l/min): Inspiratory limb: 6.0 cmH ₂ O/60 l/min Expiratory limb: 4.2 cmH ₂ O/60 l/min Pediatric circuit (15 mm ID, flow of 30 l/min): Inspiratory limb: 4.0 cmH ₂ O/30 l/min Expiratory limb: 4.8 cmH ₂ O/30 l/min Infant circuit (10 mm ID, flow of 5 l/min): Inspiratory limb: 3.0 cmH ₂ O/5 l/min Expiratory limb: 3.3 cmH ₂ O/5 l/min
Compliance*	Adult circuit (22 mm ID): 2.1 ml/cmH ₂ O Pediatric circuit (15 mm ID): 1.9 ml/cmH ₂ O Infant circuit (10 mm ID): 1 ml/cmH ₂ O
Volume*	Adult circuit (22 mm ID): 2.4 l Pediatric circuit (15 mm ID): 1.8 l Infant circuit (10 mm ID): 0.9 l
Bacteria filter	Particle size: Captures particles of 0.3 µm (micron) with > 99.99% efficiency Resistance: < 2 cmH ₂ O at 60 l/min

* The inspiratory limb includes ambient valve, Flow Sensor, inspiratory filter, inspiratory tubes, and humidifier. It does not include the heating wire. The expiratory limb includes expiratory tubes, water trap, expiratory valve, and Flow Sensor.

A.9 Other technical data

Table A-14 lists other ventilator technical data.

Table A-14. Other technical data

Parameter	Specification
Inspiratory time (SPONT breaths)	0.2 to 3 s 0.2 to 10 s (ASV)
Minimum expiratory time	20% of cycle time
Automatic expiratory base flow (flow-triggered breaths)	4 to 30 l/min For Flowtrigger ≤ 2 l/min: 4 l/min For Flowtrigger > 2 l/min: 2 x Flowtrigger
Leak compensation flow (pressure-triggered breaths)	1 l/min
Maximum limited pressure	120 cmH ₂ O, ensured by overpressure valve
Maximum working pressure	120 cmH ₂ O, ensured by high Pressure limit
Measuring and display devices	Pressure and volume measurements: Type: Differential pressure transducer, variable orifice Sensing position: Patient Y-piece Measurements: See Table A-9
	Time measurements: Type: Microprocessor Sensing position: Inside ventilator Measurements: See Table A-9

Table A-14. Other technical data (continued)

Parameter	Specification
Measuring and display devices (continued)	Oxygen measurement: Type: Galvanic cell Sensing position: Inspiratory pneumatics Measurement: Delivered oxygen concentration, range: 18 to 105% Response time: 20 s, according to ISO 7767 Time from switching on until operating performance: < 40 s
	Display of settings, alarms, and monitored data: Type: LCD (liquid crystal display) Size: 480 x 640 pixels / 216,2 mm x 163.4 mm / 8.5 in. x 6.4 in. (W x H) 271 mm / 10.7 in. (diagonal)
Minute volume capability	Up to 60 l/min
Inspiratory valve response time	< 13 ms
Oxygen cell life	1 year or 5000 hours nominal. Actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.
Alarm loudness	≈50 dB(A) (loudness setting 1) ≈85 dB(A) (loudness setting 10) at 1 m
Tests and special functions	Tightness test, oxygen cell calibration, Flow Sensor calibration, 100% oxygen flush, manual breath, inspiratory/ expiratory hold maneuver, P/V Tool and P/V Tool 2 maneuvers, Paux measurement, nebulization (optional, 30 min, 6 l/min at 100 kPa), communications interface (optional), battery backup

A.10 Standards and approvals

The GALILEO was developed in accordance with pertinent international standards and FDA guidelines.

The ventilator is manufactured within an EN ISO 9001, certified quality assurance system.

The ventilator meets relevant parts of the following standards:

- EN 60601-1 / IEC 60601-1 and Amendments A1 and A2, class I, Type B, ordinary enclosed equipment without protection against ingress of liquids, continuous operation
- EN 60601-1-2 / IEC 60601-1-2
- EN 60601-1-4 / IEC 60601-1-4
- IEC 60601-2-12 / EN 60601-2-12
- EN 794-1
- C22.2 No. 601.1
- UL 60601-1
- EN 60601-1-6 / IEC 60601-1-6
- EN 60601-1-8 / IEC 60601-1-8
- EN ISO 21647

A.11 EMC declarations (IEC/EN 60601-1-2)

The GALILEO ventilator is intended for use in the electromagnetic environment specified in Table A-15, Table A-16, and Table A-17. The customer or the user of the GALILEO ventilator should ensure that it is used in such an environment.

The GALILEO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GALILEO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GALILEO as recommended in Table A-17, according to the maximum output power of the communications equipment.

**Table A-15. Guidance and manufacturer's declaration –
electromagnetic emissions**

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GALILEO ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table A-16. Guidance and manufacturer's declaration – electromagnetic immunity¹

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 25% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. Due to its internal battery the GALILEO ventilator is immune against mains power interruptions up to 30 min.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Table A-16. Guidance and manufacturer's declaration –
electromagnetic immunity¹ (continued)**

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61 000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ² 10 Vrms 150 kHz to 80 MHz in ISM bands ⁴	10 Vrms 10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the GALILEO ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0,35 \sqrt{P}$ $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) ³ . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ⁴ , should be less than the compliance level in each frequency range ⁵ . Interference may occur in the vicinity of equipment marked with the symbol 

1. U_T is the ac mains voltage prior to application of the test level.

2. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
3. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.3 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
4. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GALILEO ventilator is used exceeds the applicable RF compliance level above, the GALILEO ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GALILEO ventilator.
5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table A-17. Recommended separation distances between portable and mobile RF communications equipment and the GALILEO ventilator¹

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m) ^{2,3,4,5}			
	150 kHz to 80 MHz outside ISM bands $d = 0,35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
2. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
3. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
4. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
5. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

A.12 Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

Whereas HAMILTON MEDICAL guarantees its products to be shipped free from defects in material and workmanship.

Whereas the warranty doesn't include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the operator's manual.

Whereas HAMILTON MEDICAL shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/ or liabilities for alleged negligence, or for strict liability. In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply:

- A. If the product has not been installed and connected by an authorized local representative of HAMILTON MEDICAL in accordance with the instructions furnished by HAMILTON MEDICAL and by a HAMILTON MEDICAL representative;
- B. If no evidence is present that the occurrence of damage/ repair happened within the certified warranty period;
- C. If the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product's purchase date;

-
- D. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification or replacement made outside HAMILTON MEDICAL's factories or other than an authorized service center or authorized service representative;
 - E. If the product has been mechanically or electronically altered without specific written authorization from HAMILTON MEDICAL.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty.

To obtain service under this Limited Warranty, claimant must promptly notify the country's sales partner of HAMILTON MEDICAL regarding the nature of the problem, serial number and the date of purchase of the Product.

Except as stated above, HAMILTON MEDICAL shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages.

B Modes of ventilation

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B.1 Introduction

The GALILEO offers the following types of ventilation mode:

- Mandatory modes
 - (S)CMV (synchronized controlled mandatory ventilation)/A/C (assist/control)
 - P-CMV (pressure-controlled CMV)/P-A/C (pressure-controlled A/C)
- Synchronized intermittent mandatory ventilation (SIMV) modes
 - SIMV
 - P-SIMV (pressure-controlled SIMV)
- SPONT (pressure support ventilation) mode
- Advanced modes
 - ASV (adaptive support ventilation)
 - APVcmv (pressure-controlled mandatory ventilation with adaptive pressure ventilation)
 - APVsimv (pressure-controlled SIMV with adaptive pressure ventilation)
 - DuoPAP (duo airway positive airway pressure)
 - APRV (airway pressure release ventilation)
 - NIV (noninvasive ventilation)

Table B-1 summarizes the characteristics of these modes.

The following subsections provide details specific to the modes. In general, PEEP/CPAP, oxygen, and patient trigger sensitivity (flow or pressure) are set in all modes, although you can lock out trigger sensitivity in the mandatory modes.

There are no negative pressures generated during exhalation.

Table B-1. Ventilation mode summary

Mode	Pressure controlled	Volume controlled	Time-cycled	Flow-cycled	Pressure-triggered	Flow-triggered
(S)CMV (A/C)		X	X		X	X
P-CMV (P-A/C)	X		X		X	X
SIMV	X	X	X	X	X	X
P-SIMV	X		X	X	X	X
SPONT	X			X	X	X
APVcmv	X	X	X		X	X
APVsimv	X	X	X		X	X
ASV	X		X	X	X	X
DuoPAP	X		X	X	X	X
APRV	X		X	X	X	X
NIV	X		X	X	X	X

B.2 Mandatory modes

The mandatory modes of ventilation (A/C or (S)CMV, P-A/C or P-CMV) deliver time-cycled mandatory breaths, either volume-controlled or pressure-controlled, respectively.

When the patient triggers or the user initiates a breath, the respiratory rate increases, while both the inspiratory time and the tidal volume (for A/C or (S)CMV) or the inspiratory pressure (for P-A/C or P-CMV) remains constant. The minute volume increases as a result.

B.2.1 Assist control (A/C) / synchronized controlled mandatory ventilation ((S)CMV) mode

The (S)CMV (A/C) mode provides volume-controlled mandatory breaths only. The tidal volume (V_t) setting defines the delivered volume (Figure B-1). The Rate and breath timing settings (see Section H.5) define the breath cycle timing. Breaths can be triggered by the ventilator, patient, or user.

In this mode, the user sets the V_t , the Rate and other breath timing controls, and the FlowPattern. As in all other modes, the user also sets the PEEP/CPAP and Oxygen, and the pressure or flow trigger if desired.

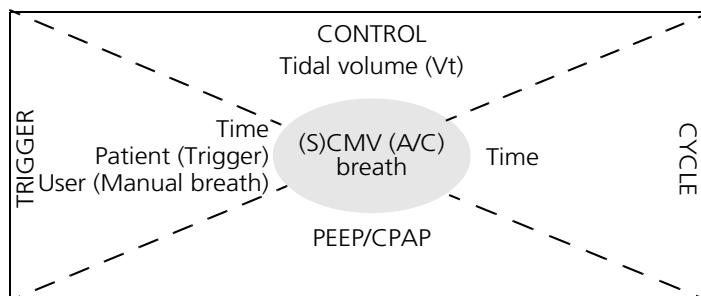


Figure B-1. (S)CMV (A/C) mode characteristics

B.2.2 Pressure-controlled A/C (P-A/C) / pressure-controlled CMV (P-CMV) mode

The P-CMV (P-A/C) mode provides pressure-controlled mandatory breaths only. The pressure control (Pcontrol) setting defines the applied pressure (Figure B-2). The Rate and breath timing settings (see Section H.5) define the breath cycle timing. Breaths can be triggered by the ventilator, patient, or user.

In this mode, the user sets the Pcontrol and the Rate and other breath timing controls, and the pressure rise time (P-ramp). As in all other modes, the user also sets the PEEP/CPAP and Oxygen controls, and the pressure or flow trigger if desired.

The P-CMV (P-A/C) mode, while delivering a preset pressure, does not guarantee delivery of a fixed tidal volume, especially during changes in respiratory system compliance, airway resistance, AutoPEEP, or the patient's respiratory activity.

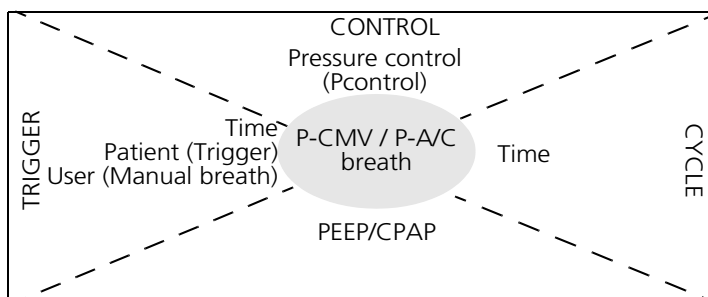


Figure B-2. P-CMV (P-A/C) mode characteristics

B.3 SIMV (synchronized intermittent mandatory ventilation) modes

SIMV is a popular conventional mode which may be used for the ventilated patients who are passive, partially active and active in terms of spontaneous breathing activity.

SIMV is a mixed mode of mandatory breaths and spontaneous breaths. If the mandatory breath is volume-based, it is a volume SIMV mode or simply SIMV. If the mandatory breath is pressure-based, it is a pressure-SIMV or simply P-SIMV mode.

An operator needs to set (SIMV) rate to define the SIMV breath interval between two consecutive breaths. The length of the interval is defined by set rate (i.e., $60 / \text{set rate}$). SIMV breath interval is divided into three parts: Tmand, Tspont and trigger window.

- Tmand (mandatory breath time) of which the length is set $T_i + 0.2$ second. Only mandatory breath is allowed.
- Trigger window of which the length is 20% of SIMV breath interval. If patient trigger is sensed, a mandatory breath is delivered slightly earlier than that defined with the set rate.
- Tspont (spontaneous interval) of which the length is difference between SIMV breath interval and Tmand + Trigger window. During Tspont, spontaneous breath with or without pressure support is allowed.

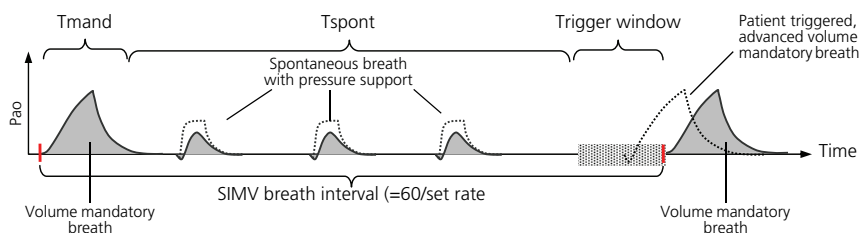


Figure B-3. Breath delivery in SIMV modes

If the ventilated patient is passive...

The set rate should be relatively high, e.g. above 10 b/min. The resultant SIMV breath interval is so short that there is no room for Tspont. SIMV in this case behaves similar to an (S)CMV or P-CMV mode. The total actual rate may be equal to the set rate.

If the ventilated patient is partially active...

The rate may be reduced with caution for a longer SIMV breath interval. The Tspont gains the room for one or two patient triggered breaths between two consecutive mandatory breaths. As the patient's breath is weak and unstable, mandatory breaths safeguard the minimal minute ventilation. You may want to apply pressure support to patient's spontaneous breaths. The trigger window assures synchronization. The actual total rate may be slightly higher than the set rate.

If the ventilated patient is active...

The rate may be further reduced. Tspont becomes so long that a serial of spontaneous breaths may occur between two consecutive mandatory breaths. Pressure support to spontaneous breath may also be decreased. SIMV in this case behaves similar to SPONT or PSV mode. The actual total rate may be much higher than the set rate. With minimal rate and minimal or no pressure support, SIMV has been used for weaning trial.

It is recommended to activate apnea backup when using SIMV modes, especially when the set rate is low.

B.4 Pressure support mode (SPONT)

In the pressure support (SPONT) mode, spontaneous and user-initiated manual (mandatory) breaths are delivered. In this mode, the GALILEO functions as a demand flow system while supporting the patient's spontaneous breathing efforts with a set pressure support. It is recommended that apnea backup ventilation be enabled in the SPONT mode.

The pressure support (Psupport) setting defines the applied pressure (Figure B-4). The patient determines the breath timing. Breaths can be triggered by the patient or user.

In this mode, the user sets the Psupport, the pressure rise time (P-ramp), and the expiratory trigger sensitivity (ETS) in percentage of peak flow. As in all other modes, the user also sets the PEEP/CPAP, Oxygen, and the pressure or flow trigger.

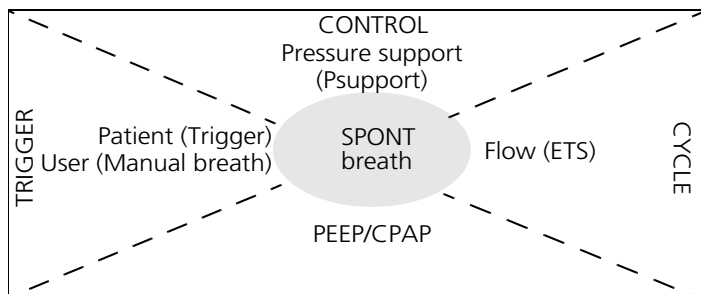


Figure B-4. Spontaneous breath characteristics

B.5 Advanced ventilation modes

B.5.1 Adaptive pressure ventilation (APV) modes

The APV modes, APVcmv and APVsimv, function much like the conventional pressure-controlled modes of ventilation (P-CMV (P-A/C) and P-SIMV) except that these conventional modes do not ensure a tidal volume. The APV modes ensure that the set target volume will be delivered.

In the APV versions of these pressure-controlled modes, the user sets the target tidal volume (V_{target}) instead of P_{control} . Otherwise, the settings are the same as for the pressure-controlled mode.

B.5.1.1 Advantages

The APV modes offer these benefits:

- Through the automatic regulation of the inspiratory pressure and flow, the set target volume is achieved with the lowest pressure possible depending on the lung characteristics.
- During short-term post-operative ventilation, the delivered volume remains constant despite rapid changes in breathing activity.

B.5.1.2 Principles of operation

The APV modes follow this sequence:

1. **Assessing the breathing pattern.** The APV modes start by determining the patient's volume/pressure response (V/P). This is achieved based on the previous ventilation or on a sequence of three test breaths. V/P is defined as:

$$V_t / (P_{\text{peak}} - \text{PEEP/CPAP})$$

2. **Achieving the target volume.** The GALILEO uses the V/P to calculate the lowest inspiratory pressure to be applied in order to achieve the VTarget. The minimal pressure delivered is 5 cmH₂O above PEEP.

The user sets the VTarget, rate, PEEP, and the high Pressure alarm limit. The adaptive controller compares the monitored Vt to the VTarget. If the patient's actual tidal volume is equal to the VTarget, APV maintains the inspiratory pressure. If the monitored tidal volume is higher or lower than the target volume, the inspiratory pressure is gradually adjusted by up to 2 cmH₂O per breath to attain the target level.

The inspiratory pressure is adjusted within this range:

$$(\text{PEEP} + 5 \text{ cmH}_2\text{O}) \text{ to } (\text{high Pressure alarm limit} - 10 \text{ cmH}_2\text{O})$$

HAMILTON MEDICAL recommends a high Pressure alarm limit setting at least 10 cmH₂O above peak pressure. On its pressure curve display, the GALILEO displays a blue band 10 cmH₂O below the set high Pressure alarm limit.

3. **Maintaining the target volume with the lowest inspiratory pressure.** The parameters needed for APV are measured breath by breath. If necessary, the GALILEO recalculates the minimal inspiratory pressure to achieve the target volume based on the current lung characteristics.

The continuous reassessment of the patient's dynamic lung status is designed to guarantee the required ventilation while preventing hypoventilation or barotrauma.

B.5.2 Adaptive support ventilation (ASV)

See Appendix D for detailed information on this mode.

B.5.3 DuoPAP (duo positive airway pressure) and APRV (airway pressure release ventilation)

B.5.3.1 Introduction

DuoPAP and APRV are two related forms of pressure ventilation designed to support spontaneous breathing on two alternating levels of CPAP. In these modes, the ventilator switches automatically and regularly between two operator-selected levels of positive airway pressure or CPAP (P high and low). Both modes permit a combination of mandatory and spontaneous breaths. The patient may breathe freely at either level; pressure support can be added to these spontaneous breaths. Cycling between the levels is triggered by DuoPAP/APRV timing settings or by patient effort. Pressure/time curves for these modes are shown in Figure B-5 and Figure B-6.

In DuoPAP (Figure B-5), the switchover between the two levels is defined by pressure settings P high and PEEP/CPAP and time settings T high and Rate. Like PEEP/CPAP, P high is relative to *atmospheric pressure*. In APRV (Figure B-6), the switchover is defined by pressure settings P high and P low and time settings T high and T low. In DuoPAP, PEEP/CPAP is the baseline for P_{support}, while in APRV, P low is the baseline for P_{support} -- P_{support} is relative to *PEEP/CPAP* or *P low*.

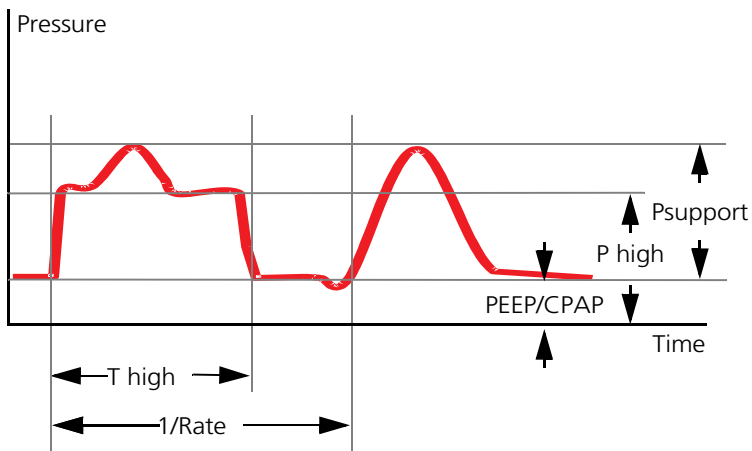


Figure B-5. DuoPAP pressure curve

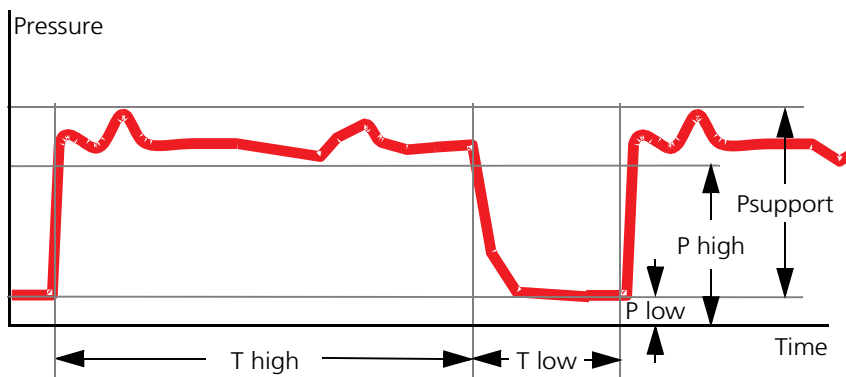


Figure B-6. APRV pressure curve

B.5.3.2 Differences between DuoPAP and APRV

As the figures show, the two modes differ in the operator settings required to determine the breath pattern. In DuoPAP, you set Rate and T high to establish the breath timing. In APRV, you set T high and T low to establish the time at each level. In DuoPAP you set P high and PEEP/CPAP to establish the two pressure levels, while in APRV you set P high and P low.

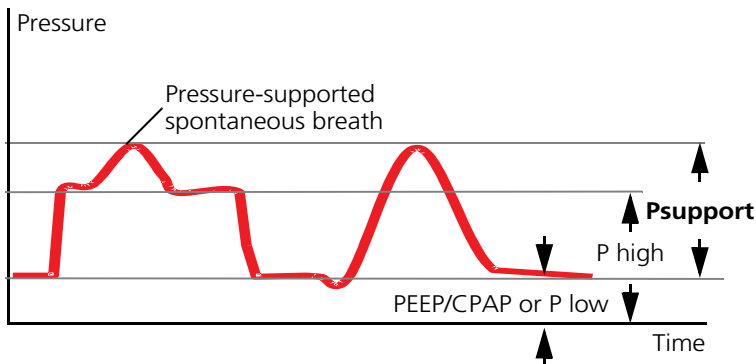
In clinical use, these two ventilation modes typically differ in the time allowed at the lower pressure level. When using DuoPAP, operators tend to prefer relatively long times at both the high and low pressure levels to allow spontaneous breathing at both. When using APRV, operators tend to prefer relatively long T high and shorter T low settings, so that the spontaneous breathing is mostly done at the upper pressure level. The pressure is then “released” to the lower pressure level just long enough for the lung volume to decrease, then is immediately returned to the upper pressure level.

B.5.3.3 The many faces of DuoPAP and APRV

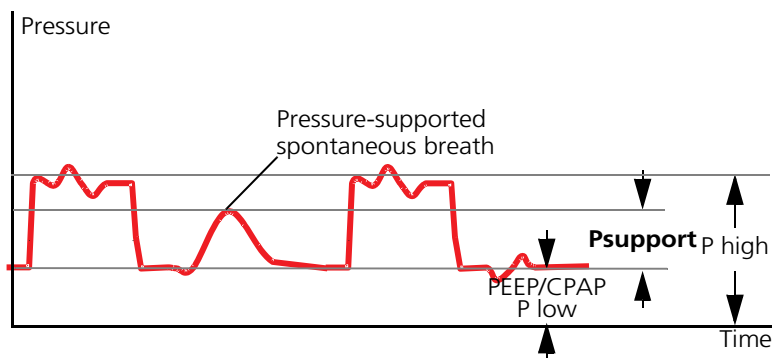
With different patients and with different combinations of control settings, DuoPAP and APRV can be made to resemble a variety of conventional ventilation modes. At conventional settings and in the absence of spontaneous breathing, DuoPAP and APRV resemble P-CMV (P-A/C). As you decrease the rate, keeping T high short relative to the time at the lower pressure level, the modes look more like P-SIMV, with spontaneous breaths following mandatory breaths. If you set the breath cycle time to a total of 7.5 to 15 s with just enough time at the low level to allow full or near-full exhalation, these modes look like classical APRV. By setting PEEP/CPAP / P low and P high equal to one another and adjusting other parameters, the modes can be made to resemble SPONT.

B.5.3.4 Pressure support in DuoPAP/APRV breaths

Pressure support can be set to assist spontaneous breaths in DuoPAP/APRV, whether they occur at the PEEP/CPAP / P low or P high level. P_{support} is set relative to PEEP/CPAP / P low -- the target pressure becomes PEEP/CPAP / P low + P_{support}. *That means that spontaneous breaths at the P high level are supported only when this target pressure is greater than P high.* Figure B-7 (a) shows the situation where breaths at both the P low and P high level are pressure-supported. Figure B-7 (b) shows the situation where only breaths at the PEEP/CPAP / P low level are pressure-supported.



a. All spontaneous breaths pressure-supported



b. Only spontaneous breaths at PEEP/CPAP / P low pressure-supported

Figure B-7. Pressure support in DuoPAP/APRV

B.5.3.5 Synchronization

To adapt easily to the patient's spontaneous breathing pattern, the change-overs from low to high pressure level and vice versa are synchronized with the patient's spontaneous breathing.

The frequency of the change-over is kept constant, even with patient synchronization, by defining a trigger time window with a fixed time constant.

B.5.3.6 References

- **Rasanen J et al.** Airway pressure release ventilation during acute lung injury: a prospective multicenter trial. *Crit Care Med* 1991 Oct;19(10):1234-41.
- **Stock MC, Downs JB et al.** Airway pressure release ventilation. *Crit Care Med* 1987 May;15(5):462-6.
- **Antonsen K et al.** Invasive ventilation. Classification, technique and clinical experiences with BIPAP/APRV (Biphasic Positive Airway Pressure/Airway Pressure Release Ventilation. *Ugeskr Laeger* 1996 Jan 22;158(4):413-9.
- **Rathgeber J.** Ventilation modes and strategies in intensive care medicine. *Anaesthesiol Reanim* 1997;22(1):4-14.
- **De Carvalho WB et al.** Airway Pressure release in postoperative cardiac surgery in pediatric patients. *Rev Assoc Med Bras* 2000 Apr-Jun;46(2):166-73.

B.5.4 Noninvasive ventilation (NIV)

See Appendix E for detailed information on this mode.

B.6 Leak compensation

For an invasive ventilator to function properly, there must be no significant leak throughout the entire system, including ventilator, breathing circuit, and patient respiratory system. For optimal ventilator performance, leakage should be stopped or minimized rather than compensated. Early and sensitive

recognition is the key to stopping leakage. Thanks to a proximal flow sensor, HAMILTON MEDICAL ventilators can distinguish leakage at the breathing circuit from that at the patient side. This is not possible with ventilators that monitor flow in the expiratory limb.

In fact, when it comes to handling leakage the GALILEO is superior in these ways:

- Detection and notification of the presence of leakage plus its location (i.e., tubing or patient side)
- Display of the actual exhaled tidal volume (VTE) so that the clinician can easily note any discrepancy between set and exhaled tidal volumes
- Display of the leak volume (VLeak) breath by breath, a far more sensitive indicator than the leak minute volume displayed by other devices. VLeak is determined as the difference between delivered (inspiratory) tidal volume and exhaled tidal volume. VLeak indicates the leak at the patient side only.

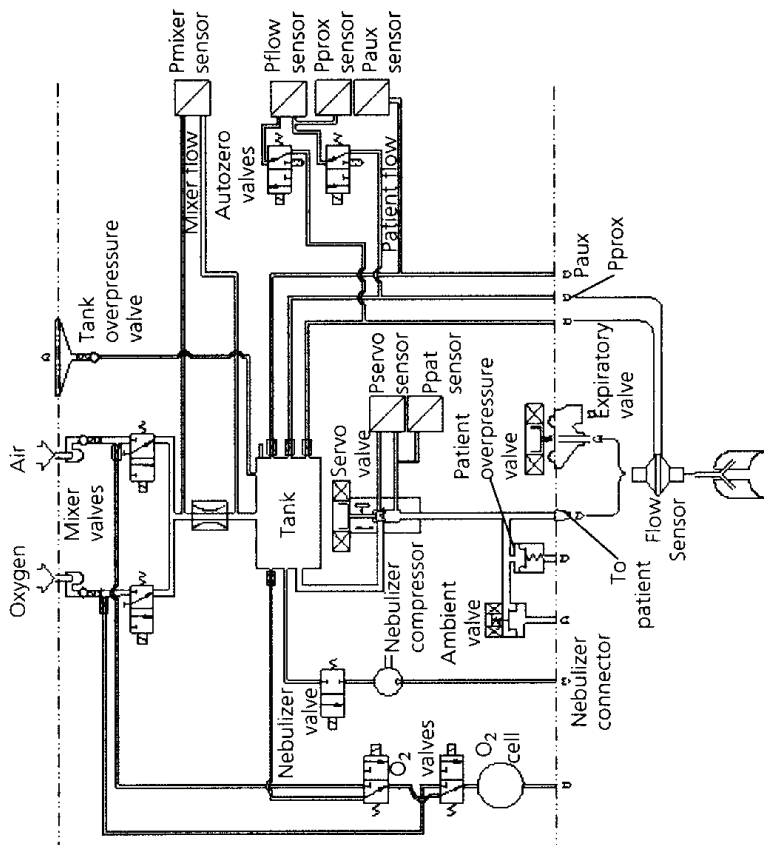
With its constant base flow during the later part of exhalation, the GALILEO automatically compensates for leakage at the breathing circuit up to 1 l/min with pressure triggering and up to 30 l/min (minimally 4 l/min) with flow triggering.

In all pressure modes, the GALILEO automatically compensates for leakage by adjusting gas delivery to achieve and maintain the set pressure profile.

In all modes that permit spontaneous breathing, there are two mechanisms to cycle to exhalation: flow (ETS) and time (Ti max), used as a backup. This backup mechanism can prevent the possibility of endless inspiration resulting from a large leak, and is critically important in the NIV mode.

An automatic adjustment mechanism maintains PEEP stability even with a moderate breathing circuit leak.

Pneumatic diagram



ASV (adaptive support ventilation)

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D.1 Introduction

In 1977, Hewlett et al. introduced mandatory minute volume (MMV). "The basic concept is that the system is supplied with a metered, preselected minute volume of fresh gas, from which the patient breathes as much as he is able, the remainder being delivered to him via a ventilator. Thus the patient is obliged to breathe, one way or the other, a Mandatory Minute Volume MMV" (Hewlett 1977).

Since then, many ventilators have included versions of MMV under different names. However, all commercially available MMV algorithms have clear limitations, which lead to certain risks for the patient (Quan 1990). These include rapid shallow breathing, inadvertent PEEP creation, excessive dead space ventilation, and inadvertent wrong user settings due to very complicated use.

Adaptive Support Ventilation (ASV) was designed to minimize those risks and limitations. ASV maintains an operator-preset, minimum minute ventilation independent of the patient's activity. The target breathing pattern (tidal volume and rate) is calculated using Otis' equation, based on the assumption that if the optimal breath pattern results in the least work of breathing, it also results in the least amount of ventilator-applied inspiratory pressure when the patient is passive. Inspiratory pressure and machine rate are then adjusted to meet the targets. A lung protection strategy ensures ASV's safety. In contrast to MMV, ASV attempts to guide the patient using a favorable breathing pattern and avoids potentially detrimental patterns like rapid shallow breathing, excessive dead space ventilation, breath stacking (inadvertent PEEP), and excessively large breaths.

Contrary to what may be believed, ASV does not eliminate the need for a physician or clinician. However, ASV alleviates the need for tedious tasks and laborious readjustments of the ventilator; thus, it is a modern tool for the clinician. As such, ASV does not make clinical decisions. ASV executes a general command from the clinician and the clinician can modify it. This command can be summarized as follows, where the modifiable parts are in bold:

Maintain a preset minimum minute ventilation , take spontaneous breathing into account, prevent tachypnea, prevent AutoPEEP, prevent excessive dead space ventilation, fully ventilate in apnea or low respiratory drive, give control to the patient if breathing activity is okay, and do all this without exceeding a plateau pressure of 10 cmH ₂ O below the upper pressure limit .

This appendix explains in practical terms how to use ASV at the patient's bedside and provides a detailed functional description. Since Otis' equation (Otis 1950) is the cornerstone of the optimal-breath pattern calculation, this equation is included and described. A table of detailed technical specifications and pertinent references is also given.

WARNING

This appendix describes ASV as it is implemented in the HAMILTON MEDICAL GALILEO ventilator. It does not replace the clinical judgment of a physician and should not be used for clinical decision making.

D.2 ASV use in clinical practice

ASV does not require a special sequence of actions. It is used in much the same way as are older modes of ventilation.

Figure D-1 summarizes how to use ASV, while the subsequent subsections explain it in detail.

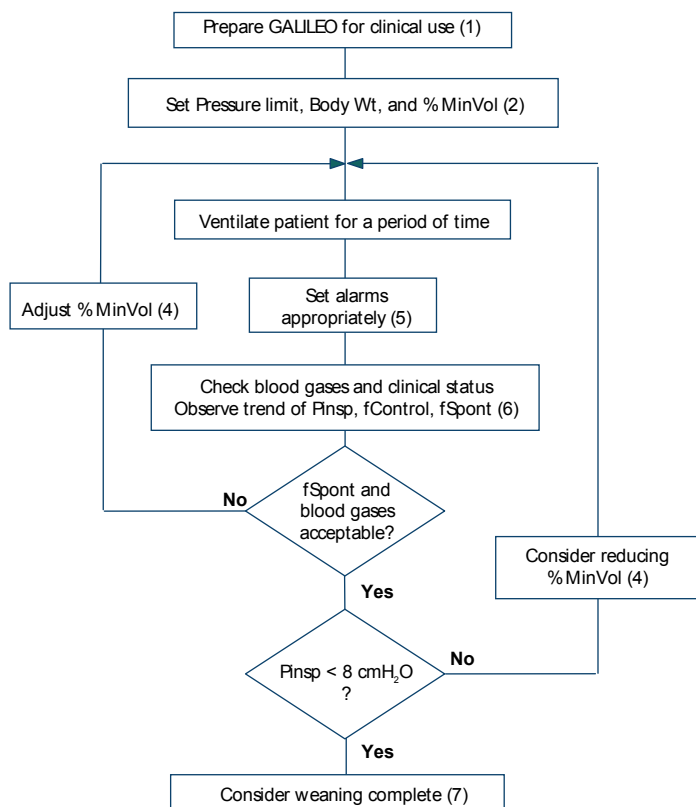


Figure D-1. Clinical use of ASV. The numbers in parentheses are step numbers, which are explained in the next subsections.

Step 1: Before connecting the patient to the GALILEO

It is important to prepare GALILEO for clinical use according to Section 2. This includes, but is not limited to, performing the preoperational procedures and testing indicated.

Step 2: Preparing GALILEO for ASV before connecting the patient to the ventilator

ASV requires that you set the following three basic parameters:

Pressure	High Pressure alarm limit, in cmH ₂ O (in the Alarms window)
Body Wt	Patient's ideal body weight, in kg
%MinVol	Desired minute ventilation, in % of normal values

It is suggested you do the following before connecting the patient to the ventilator:

1. Remove the test bag, when a test bag is used, and silence the alarm.
2. Open the **Alarms** window and set the upper Pressure limit to an appropriate value (e.g., 45 cmH₂O). The maximum inspiratory pressure delivered in ASV will be **10 cmH₂O below the preset upper Pressure limit**, indicated by a blue bar on the pressure curve display.

NOTE:

The upper limit must be at least 25 cmH₂O above PEEP/CPAP.

3. Set PEEP/CPAP and Oxygen values according to clinical requirements.
4. Activate ASV in the **Ventilation mode** window and then **Close** the window. The **Controls** window automatically opens and permits access to the Body Wt and %MinVol controls.

5. Enter the appropriate ideal body weight for the patient as Body Wt. If in doubt, consult Table D-6 or Table D-7.
6. Enter the appropriate %MinVol. A safe starting value is 100%. If appropriate, add 10% per °C (5% per °F) above normal body temperature and 5% per 500 m (1500 ft) above sea level.
7. Enter the desired trigger method (pressure or flow) and sensitivity.
You can leave the P-ramp and ETS settings at their standard values unless clinical judgment calls for adjustments. To set them, see Section 4.
8. **Confirm** the settings.
9. Connect the patient to the ventilator. This will initiate three test breaths.

Alternative Step 2: Preparing GALILEO for ASV while the patient is ventilated in another mode

ASV requires that you set the following three basic parameters:

Pressure	High Pressure alarm limit, in cmH ₂ O (in the Alarms window)
Body Wt	Patient's ideal body weight, in kg
%MinVol	Desired minute ventilation, in % of normal values

It is suggested you do the following when switching from another mode to ASV:

1. Open the **Alarms** window and make sure the upper Pressure limit is a safe value (e.g., 45 cmH₂O). The maximum available inspiratory pressure is **10 cmH₂O below the preset upper Pressure limit**, indicated by a blue bar on the pressure curve display after ASV is activated.

NOTE:

The upper limit must be at least 25 cmH₂O above PEEP/CPAP.

2. Activate ASV in the **Ventilation mode** window and then Close the window. The **Controls** window automatically opens and permits access to the Body Wt and %MinVol controls.
3. Enter the appropriate ideal body weight for the patient as Body Wt. If in doubt, consult Table D-6 or Table D-7.
4. Enter the appropriate %MinVol. Check that the target MinVol is in accordance with your expectations.

A logical starting point is a %MinVol setting that will result in the same minute volume as the previous mode. A safe start is 100%. If appropriate, add 10% per °C (5% per °F) above normal body temperature and 5% per 500 m above sea level.

You can leave the previous patient trigger method (pressure or flow) and sensitivity level as well as the P-ramp and ETS unchanged unless clinical judgment calls for adjustments.

5. **Confirm** the settings. This will initiate three test breaths.

Step 3: Compensation for changes in apparatus dead space

The GALILEO calculates the (anatomical or “series”) dead space based on the ideal body weight entered and calculated as 2.2 ml per kg (1 ml per lb). This dead space is a nominal value that is valid, on average, for intubated patients whose endotracheal tube is connected to the Y-piece of the ventilator by means of a standard catheter mount. If this dead space is altered by an artificial airway configuration such as the use of a heat and moisture exchange filter (HME) or nonstandard tubing, modify the Body Wt setting accordingly to take into account the added or removed dead space.

It is suggested that you consider the following points:

- A shorter than standard endotracheal or tracheostomy tube has a minor effect and probably does not require compensation.
- The use of different sizes of endotracheal tube has a minor effect, and probably does not require compensation.
- A much longer-than-normal catheter mount may be important, and may require compensation.
- A bacterial filter or an HME may have an important effect. The volume of these devices, for an adult, is on average 50 to 60 ml, but may be as high as 95 ml (Mallinckrodt Hygroster).
- A simple rule of thumb is to add 10% Body Wt if using an HME.

NOTE:

Changes in alveolar dead space due to ventilation/perfusion mismatch must be compensated via the %MinVol control.

Step 4: Adjusting ventilation: maintaining adequate ventilation

Once ASV is started, GALILEO calculates an optimal breath pattern and associated target values for tidal volume and rate according to the rules in Section D.4. ASV then adjusts the inspiratory pressure (P_{insp}) and machine rate (f_{Control}) to achieve the targets.

Once the calculated targets are reached, the result of the ventilation needs to be assessed. All GALILEO monitored parameters can be used for this purpose. However, to assess respiratory acid-base status, it is recommended that arterial blood gases be measured and minute ventilation be adjusted accordingly. Table D-1 provides examples of how to adjust the %MinVol setting.

WARNING

It is inappropriate to use the Body Wt control to adjust minute volume. Always use the %MinVol control to adjust ventilation.

Table D-1. Blood gas results and possible adjustments for ASV

Blood gas result	%MinVol change	Remarks
Normal arterial blood gases	None	--
High PaCO ₂	Increase %MinVol	Pay attention to inspiratory pressures
Low PaCO ₂	Decrease %MinVol	Pay attention to mean pressures and oxygenation status

Table D-1. Blood gas results and possible adjustments for ASV (continued)

Blood gas result	%MinVol change	Remarks
High respiratory drive	Consider increase in %MinVol	Consider sedation, analgesia, or other treatments
Low O ₂ saturation	None	Consider increase in PEEP/CPAP and/or Oxygen

Step 5: Alarm settings review and special ASV alarms

To monitor the breathing pattern, you must review the alarm settings periodically and set them according to clinically acceptable values. As described below, ASV changes the breathing pattern according to the respiratory system mechanics and within the boundaries resulting from the operator's settings for ASV. However, you can closely monitor ASV's actions through the alarm system, since the alarm settings work totally independently of ASV.

It is possible to select a %MinVol that is incompatible with the lung-protective rules that govern ASV (for a detailed description, see Section D.3.3). For example, the operator might want a high ventilation for a COPD patient in spite of severe pulmonary obstruction. In such a case, ASV tries to achieve the maximum possible ventilation and alarms that **ASV: Cannot meet target**. Such a case is shown in Figure D-2, where a high ventilation (300% at 70 kg) was set by the operator for a patient with severely obstructed lungs ($R_{aw} = 40 \text{ cmH}_2\text{O}/(\text{l/s})$). The high ventilation moves the minimum minute volume curve to the right while the obstructive disease causes the safety limit of rate to shift to the left. These two effects cause the minute volume curve to lie outside the safety limits as determined by the lung-protective rules strategy (see functional description below). ASV thus chooses the safest point closest to the user-set minute volume.

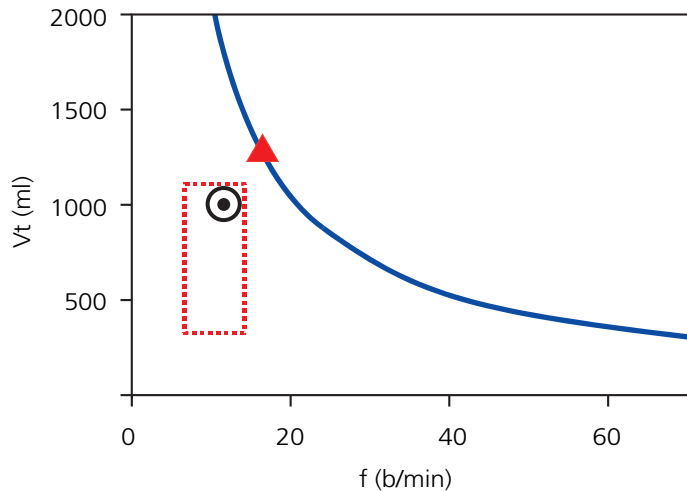
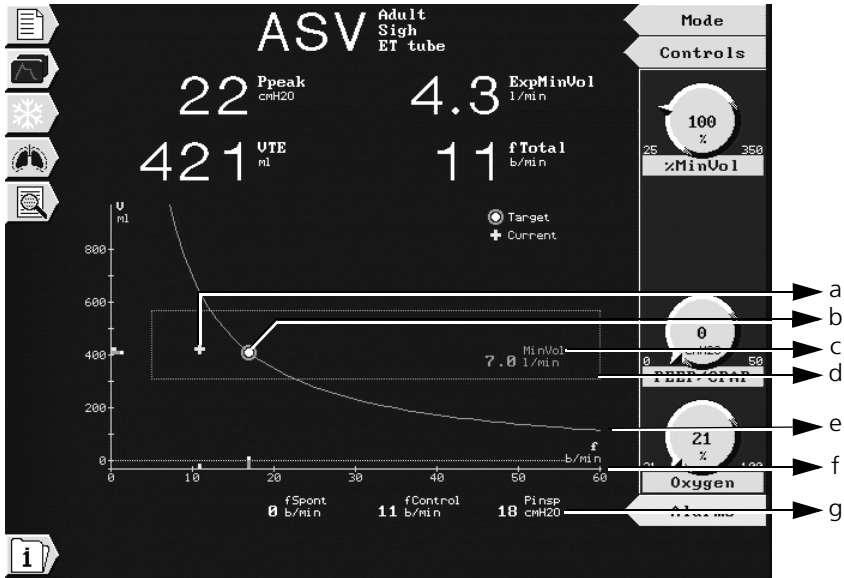


Figure D-2. Hypothetical example of high %MinVol setting incompatible with the lung-protective rules strategy. The open circle denotes the actual target, the closed triangle (never shown on the ventilator) denotes the (energetically) optimal target according to Otis' equation. The GALILEO will alarm and inform the user that the ASV target cannot be achieved.

Step 6: Monitoring ASV

ASV interacts with the patient continuously. Whenever the patient's respiratory mechanics change, ASV adapts to this change. Whenever the patient's breathing activity changes, ASV adapts. To let you view the current status, the GALILEO provides the ASV target graphics screen (Figure D-3) and the ASV monitored data window (Figure D-4).

To monitor progress over time, it is recommended that the trends for P_{insp} , f_{Total} , and f_{Spont} be plotted. These trends, together with the %MinVol setting, must be interpreted. Table D-2 through Table D-4 give an overview of typical ventilatory patterns and their possible interpretation from a technical point of view.



- Current measured point, formed by intersection of measured tidal volume and rate.
- Target point, formed by intersection of target tidal volume and target rate.
- Numerical value of target minute volume.
- Safety frame in which target point may move.
- Minute volume curve.
- Horizontal axis for rate (f). Vertical axis for tidal volume (Vt).
- fSpont = spontaneous breath rate, fControl = machine rate, Pinsp = inspiratory pressure set by ventilator.

Figure D-3. ASV target graphics screen

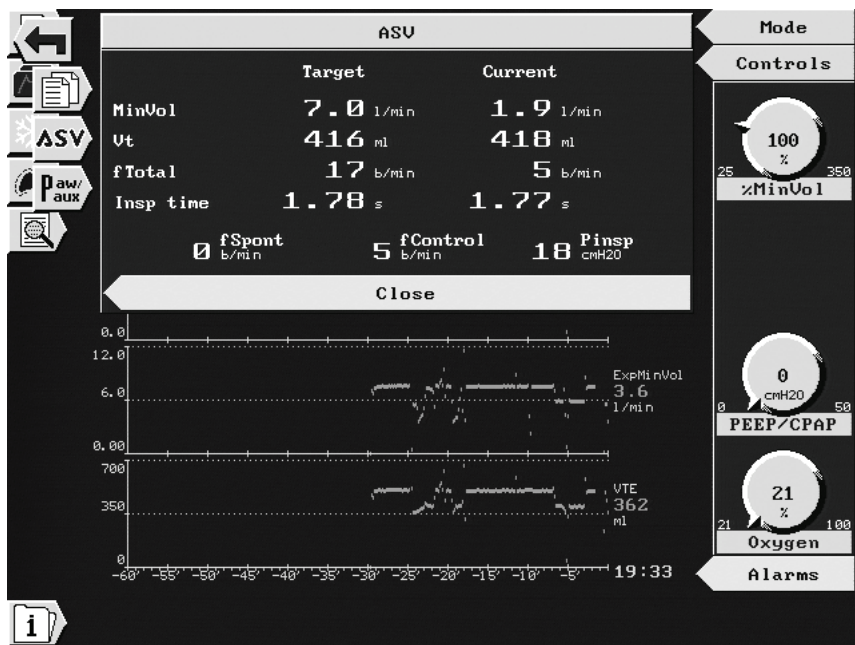


Figure D-4. ASV monitored parameter window

Table D-2. Interpretation of breathing pattern at 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled, mechanical ventilation. To start weaning, consider reducing %MinVol.
> 10	0	Acceptable	Supported spontaneous breathing. Consider reducing %MinVol.
< 8	0	Acceptable	Unsupported breathing. Consider extubation.
> 10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Table D-3. Interpretation of breathing pattern at much higher than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled mechanical ventilation. Check arterial blood gases. To start weaning, consider reducing %MinVol.
> 10	0	Acceptable	Supported spontaneous breathing. Check reason for increased ventilation requirement. Consider reducing %MinVol.
< 8	0	Acceptable	Unsupported breathing. Check reason for increased ventilation requirement. Consider reducing %MinVol and extubation.
> 10	0	High	Dyspnea. Check reason for increased ventilation requirement. Consider other mode of ventilation and clinical treatment. Check for autotriggering.

Table D-4. Interpretation of breathing pattern at much lower than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
>10	> 10	0	Danger of hypoventilation. Check arterial blood gases and consider increasing %MinVol.
>10	0	Acceptable	Enforced weaning pattern. Monitor arterial blood gases and patient respiratory effort. Consider decreasing or increasing %MinVol accordingly.
<8	0	Acceptable	Unsupported breathing. Consider extubation.
>10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Step 7: Weaning

Weaning patients from the ventilator is a clinical task that requires tremendous experience and involves more than just ventilation issues. This appendix does not intend to provide clinical information other than that needed to operate the ventilator with ASV.

ASV always allows patients to take spontaneous breaths. Episodes of spontaneous breathing can occur and are supported by ASV even within a period of fully controlled ventilation. In other words, weaning can start with ASV so early that it may go unrecognized clinically. It is therefore important to monitor the spontaneous efforts of the patient over time.

The weaning progress can be monitored in the trends display when inspiratory pressure (P_{insp}), total rate (f_{Total}), and spontaneous rate (f_{Spont}) are plotted. If the patient tolerates minimum respiratory support after a period of time with

$$P_{\text{insp}} < 8 \text{ cmH}_2\text{O}$$

$$f_{\text{Control}} = 0$$

weaning can be considered achieved, if minimum

f_{Spont} is acceptable

ExpMinVol is acceptable

What is “acceptable” must be defined by the clinician.

It may be necessary to reduce the %MinVol setting to 70% or even lower to “motivate” the patient to resume spontaneous breathing. If a patient can sustain minutes or even hours with a low %MinVol setting, it does not mean that weaning is complete. In fact, the %MinVol setting must always be interpreted in conjunction with the level of P_{insp} needed to achieve the set minute ventilation. Only if P_{insp} and f_{Control} are at their minimal values can weaning be assumed to be complete.

D.3 Detailed functional description of ASV

D.3.1 Definition of normal minute ventilation

ASV defines normal minute ventilation according to the graph in Figure D-5.

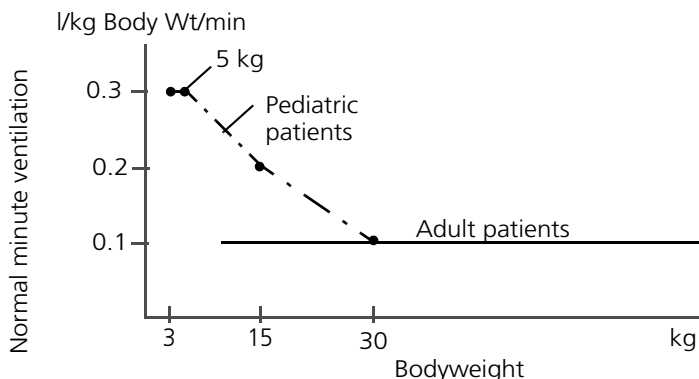


Figure D-5. Normal minute ventilation as a function of body weight. For adult patients, minute ventilation is calculated as 100 ml/kg x ideal body weight (solid line). For pediatric patients, the value indicated by the dotted line is used. Minute ventilation for a 15 kg patient thus is calculated as 200 ml/kg * 15 kg = 3 l/min.

For example, for a Body Wt setting of 70 kg, normal minute ventilation corresponds to 7 l/min.

D.3.2 Targeted minute ventilation

When selecting ASV, it is necessary to select an appropriate minute ventilation for the patient. Minute ventilation is set with the %MinVol control, which, together with the Body Wt control, determines the total minute ventilation in liters per minute.

A %MinVol setting of 100% corresponds to a normal minute ventilation, as defined above. A setting less than 100% or higher than 100% corresponds to a minute ventilation lower or higher than normal.

From the %MinVol, the target minute ventilation (in l/min) is calculated as:

$$\text{Bodyweight (in kg)} \times \text{NormMinVent (in l/kg/min)} \times (\% \text{MinVol}/100)$$

where NormMinVent is the normal minute ventilation from Figure D-5.

For example, with a %MinVol = 100 and a Body Wt = 70 kg, a target MinVol of 7 l/min is calculated. This target can be achieved with a number of combinations of tidal volume (V_t) and respiratory rate (f). This is shown in Figure D-6, where all possible combinations of V_t and f lie on the bold line, the target minute volume curve.

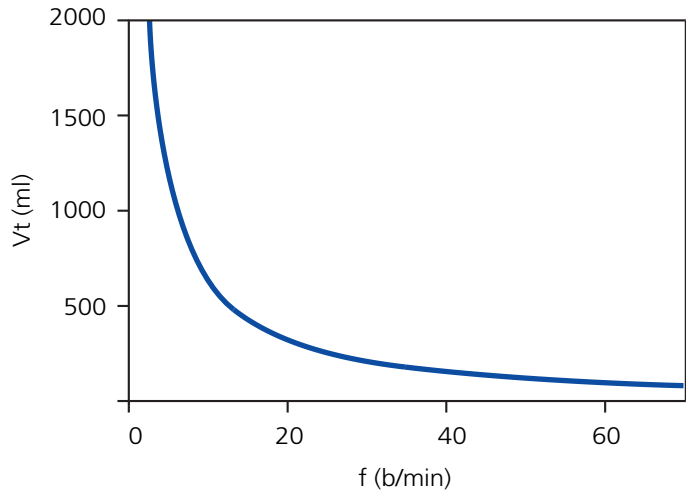


Figure D-6. MinVol = 7 l/min. All possible combinations of V_t and f which result in a minute ventilation of 7 l/min lie on the bold line.

D.3.3 Lung-protective rules strategy

Not all combinations of V_t and f shown in Figure D-6 are safe for the patient. The high tidal volumes would overdistend the lungs and the small tidal volumes may not produce alveolar ventilation at all. Another risk lies in inadequate respiratory rates. High rates could lead to dynamic hyperinflation or breath stacking and thus inadvertent PEEP. Low rates may lead to hypoventilation and apnea. It is therefore necessary to limit the number of possible combinations of V_t and f . In limiting the possible combinations of V_t and f , ASV uses a double strategy:

- The operator input for ASV determines the absolute boundaries.
- Internal calculations based on patient measurements further narrow the limits to counteract possible operator errors and to follow changes of respiratory system mechanics.

The effect of the strategy is shown in Figure D-7 and explained in the subsequent subsections.

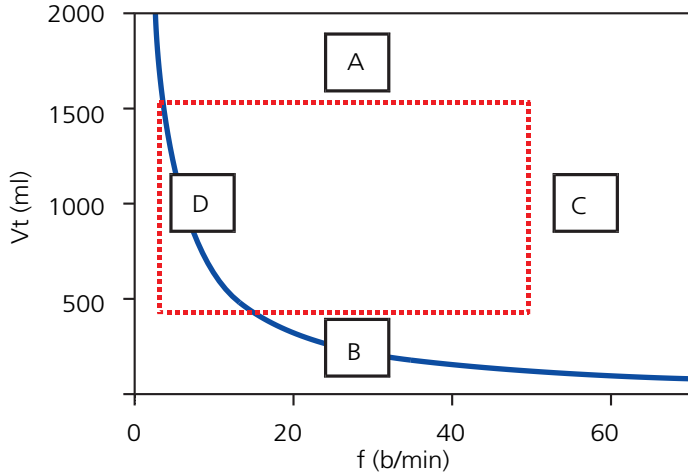


Figure D-7. Lung-protective rules strategy to avoid high tidal volumes and pressures (A), low alveolar ventilation (B), dynamic hyperinflation or breath stacking (C), and apnea (D)

A: High tidal volume limit

The tidal volume applied by ASV is limited (see A in Figure D-7) by two operator settings: high Pressure alarm limit and Body Wt.

The operator is required to set the high Pressure limit before connecting a patient to the GALILEO. It was recommended by a group of physicians (Slutsky 1994) that the plateau pressure not exceed 35 cmH₂O. To achieve this with ASV, the high Pressure limit must be set to 45 cmH₂O. The maximum pressure to be applied in the ASV mode is 10 cmH₂O below the high Pressure limit.

For example, a normal 70 kg normal (post-operative) patient would have a compliance of about 50 ml/cmH₂O. A high Pressure limit of 45 cmH₂O would result in a maximum applied pressure of 35 cmH₂O. With a PEEP level of 5 cmH₂O, the effective pressure swing would be 30 cmH₂O. This in turn would lead to an effective Vt of equal to or less than 1500 ml. If the patient's lungs stiffen, say to a compliance of 30 ml/cmH₂O, the maximum tidal volume becomes 900 ml.

If the operator sets the Pressure limit to a very high pressure, say 60 cmH₂O, the target volume is limited by the second criterion: 22 x Body Wt. For the 70 kg sample patient, a maximum target volume of 1540 ml results.

B: Low tidal volume limit

The minimum target Vt in ASV (see B in Figure D-7) is determined by the Body Wt setting and corresponds to 4.4 ml/kg. Thus, in a 70 kg patient, the minimum target Vt is 308 ml.

The danger with low tidal volumes is insufficient alveolar ventilation. The determining parameter for alveolar ventilation is dead space (VD). Tidal volume must always be larger than VD. It is widely accepted that a first approximation of dead space can be obtained by the following simple equation (Radford 1954):

$$VD = 2.2 * \text{Body Wt} \quad (1)$$

The lower limit for tidal volume is based on this equation and calculated to be at least twice the dead space. In other words, the minimum V_t is $4.4 \times \text{Body Wt}$.

C: High rate limit

The maximum rate (see C in Figure D-7) is derived from the operator settings, %MinVol and Body Wt. The equation used to calculate the maximum rate is as follows:

$$f_{\max} = \text{target MinVol} / \text{minimum } V_t \quad (2)$$

For example, the 70 kg patient described above would have a maximum rate of 22 b/min, when %MinVol is set to 100%.

However, if the operator chooses an excessively high %MinVol of, say, 350%, the maximum rate becomes 77 b/min. To protect the patient against such high rates, ASV employs a further safety mechanism, which takes into account the patient's ability to exhale.

A measure of the ability to exhale is the expiratory time constant (RCexp) (Marini 1989, Brunner 1995). In order to achieve a nearly complete exhalation to the equilibrium point of the respiratory system (90% of the maximum potential volume change), an expiratory time of at least $2 \times \text{RCexp}$ is theoretically required. For this reason, ASV calculates the maximum rate based on the principle of giving a minimum inspiratory time equal to $1 \times \text{RCexp}$ and a minimum expiratory time equal to $2 \times \text{RCexp}$, which results in the following equations:

$$\begin{aligned} f_{\max} &= 60 / (3 \times \text{RCexp}) = 20 / \text{RCexp} \\ f_{\max} &\leq 60 \text{ b/min} \end{aligned} \quad (3)$$

For example, the 70 kg patient with a respiratory system compliance of 50 ml/cmH₂O (equal to 0.05 l/cmH₂O), an airway resistance including endotracheal tube of 5 cmH₂O/l/s, and a resistance of the expiratory hose and valve of another 5 cmH₂O/l/s, would have an RCexp of

$$0.05 \text{ l/cmH}_2\text{O} \times (5+5) \text{ cmH}_2\text{O/l/s} = 0.5 \text{ s}$$

and thus a maximum rate of 40 b/min. Since this value is higher than the one calculated above, the lower of the two values is in effect, i.e., 22 b/min.

This limit applies to the respiratory rate of the ventilator only, *not* to the respiratory rate of the patient.

D. Low rate limit

The lowest target rate (see D in Figure D-7) is fixed at 5 b/min. This low rate in turn limits the maximum tidal volume to 1400 ml in the example of the 70 kg patient above, when %MinVol is set to 100%.

D.3.4 Optimal breath pattern

Although the lung-protective rules strategy limits possible combinations of V_t and f , ASV prescribes an explicit target combination. In fact, Figure D-7 shows considerable room for selection within the dotted rectangle. The selection process is an exclusive feature of ASV. The basic assumption is that the optimal breath pattern is identical to the one a totally unsupported patient would choose naturally, provided that patient is capable of maintaining the pattern.

According to textbooks of physiology, the choice of breathing pattern is governed by either work of breathing or the force needed to maintain a pattern. ASV uses the original equation by Otis (Otis 1950) and calculates the optimal rate based on operator entries of %MinVol and Body Wt as well as on the measurement of RC_{exp} (see Section D.4).

For example, with the 70 kg patient, a setting of 100 %MinVol, and a measured RC_{exp} of 0.5 s, the optimal rate is 15 b/min according to Otis' equation.

Once the optimal rate is determined, the target V_t is calculated as:

$$V_t = \text{target MinVol} / \text{optimal rate} \quad (4)$$

In the example of the 70 kg patient, the target V_t becomes 467 ml (see Section D.4 for details).

Figure D-8 summarizes the calculations done in the previous subsections and shows the position of the target breathing pattern as well as the safety limits imposed by the lung-protective rules strategy.

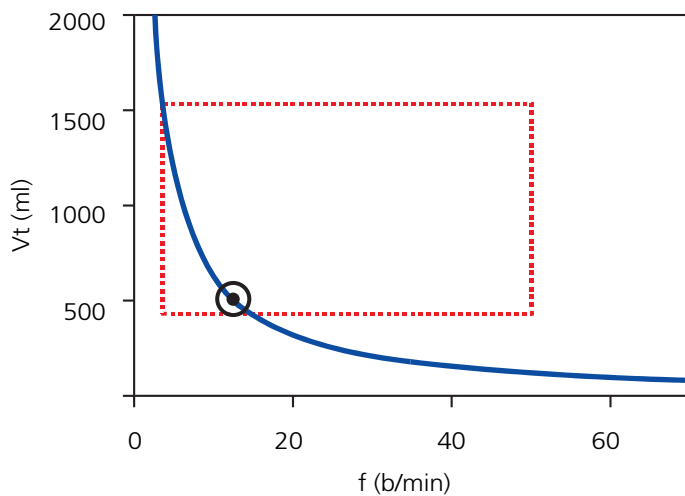


Figure D-8. ASV target screen. The rectangle shows the safety limits; the circle shows the target breath pattern.

D.3.4.1 Initial breaths: How ASV starts

The question is, how to achieve the target values in a given patient if it is not known whether or not the patient can breathe spontaneously. For this purpose, ASV employs a synchronized intermittent mandatory pressure ventilation mode.

Every breath triggered by the patient is pressure-supported and flow-cycled, i.e., the transition to exhalation is made based on flow. In contrast, if the patient does not trigger the breath, the delivery of the breath is pressure-preset and time-cycled.

The following controls can be set by the operator:

- PEEP/CPAP
- Oxygen
- P-ramp
- ETS
- Trigger type and sensitivity

The following controls are adjusted automatically by ASV and thus cannot be adjusted by the operator:

- SIMV rate: to change total respiratory rate
- Inspiratory pressure level: to change inspiratory volume
- Inspiratory time: to allow gas flow into the lungs
- Startup breath pattern

To safely start ASV, the operator inputs initial parameters through the Body Wt control, according to Table D-8 or Table D-9.

Three initial test breaths are delivered. The resulting rate and tidal volume are measured and compared with the target values. ASV then responds according to the differences between the actual and target V_t as well as the actual and target rates.

D.3.4.2 Approaching the target

Figure D-9 shows a possible scenario after the three initial test breaths. The actual breath pattern, which is plotted as a cross, shows clear deviation from the target. The task of ASV is now to move the cross as close to the circle as possible.

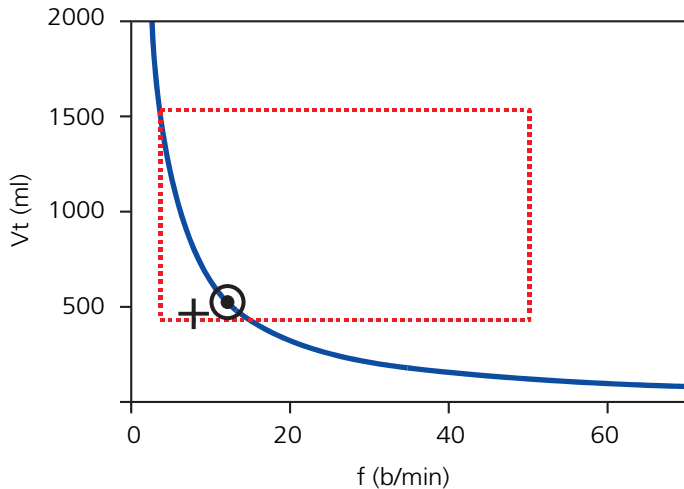


Figure D-9. Example of a situation after the three initial breaths. The cross marks the actual measured values for V_t and rate.

To achieve the target, the following strategy is used:

- If actual $V_t <$ target V_t , the inspiratory pressure is increased.
- If actual $V_t >$ target V_t , the inspiratory pressure is decreased.
- If actual $V_t =$ target V_t , the inspiratory pressure is left unchanged.
- If actual rate $<$ target rate, the SIMV rate is increased.
- If actual rate $>$ target rate, the SIMV rate is decreased.
- If actual rate $=$ target rate, the SIMV rate is left unchanged.

As a result, the cross in Figure D-9 moves toward the circle. The actual V_t is calculated as the average of inspiratory and expiratory volumes of the last 8 breaths. This definition compensates in parts for leaks in the breathing circuit, including the endotracheal tube.

D.3.5 Dynamic adjustment of lung protection

The operator preset values are not changed by ASV, and the corresponding safety limits remain as defined above. However, if the respiratory system mechanics change, the safety limits change accordingly and as defined in Section D.3.3. The safety limits are updated on a breath-by-breath basis.

For example, if the lungs stiffen, the high V_t limit is lowered proportionally, and the high Rate limit is increased according to Equation 5.

This dynamic adjustment ensures that ASV applies a safe breathing pattern at all times. In graphical terms, the dotted rectangle changes as shown in Figure D-10.

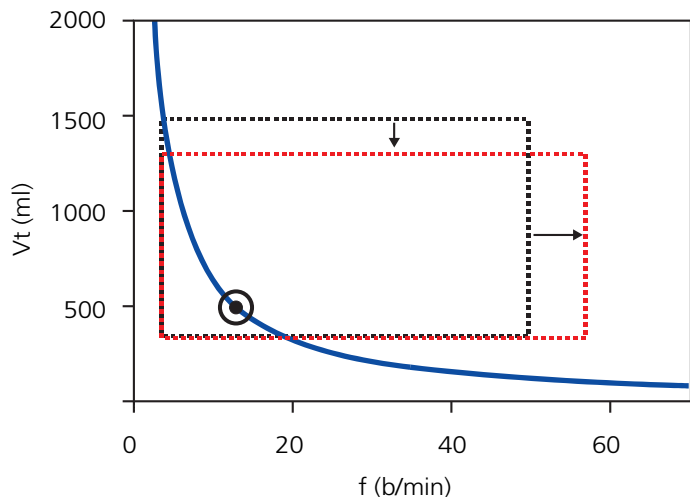


Figure D-10. Lung-protective limits are changed dynamically and according to the respiratory system mechanics. However, the limits derived from the operator input are never violated.

D.3.6 Dynamic adjustment of optimal breath pattern

Once calculated, the optimal breath pattern is revised with each breath according to the measurements of RC_{exp} . Otis' equation is applied and a new target breathing pattern is calculated. Under steady-state conditions, the targets do not change. However, if the patient's respiratory system mechanics change, the target values also change.

For example, if the bronchi of our normal 70 kg sample patient (being ventilated at 15 b/min and with a V_t of 467 ml) constrict due to asthma, the expiratory resistance increases to values higher than 5 cmH₂O/l/s. For this reason, more time is needed during exhalation for the lungs to reach the end-expiratory equilibrium position. Technically speaking, RC_{exp} has increased and this increase requires a longer expiratory time. For a given minute ventilation, this calls for an increase in V_t and a decrease in rate (longer expiratory time). Otis' equation yields the following new targets: $f = 11$ b/min and $V_t = 636$ ml. Figure D-11 shows the change. Note also that the increase in resistance results in a decrease in the volume/pressure ratio (V/P). The changes in RC_{exp} and dynamic compliance affect the safety limits accordingly and with each breath (see previous subsection).

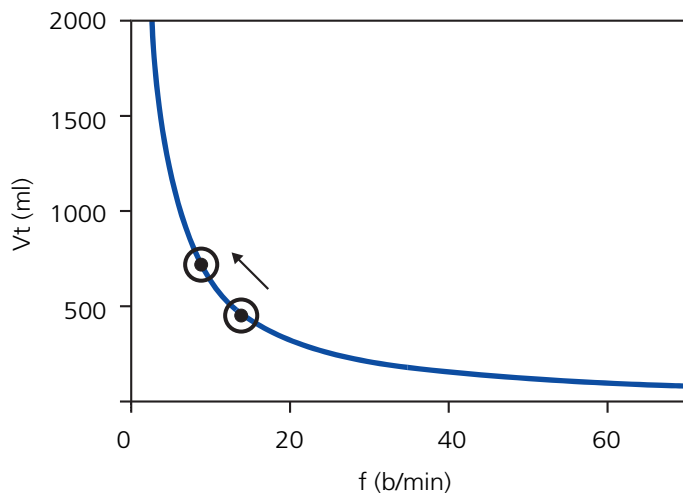


Figure D-11. Changes of target values in bronchoconstriction. For clarity, the safety limits are omitted. For clinical examples, see Belliato 2000.

D.4 Minimum work of breathing (Otis' equation)

Otis' basic question was: how do mammals choose their breathing pattern and on what parameters does it depend (Otis 1950)? The same question was investigated years before by Rohrer and a very similar result was obtained (Rohrer 1925). The hypothesis was that the breath pattern with the least work of breathing (WOB) is chosen by mammals. Figure D-12 below shows the relationship between rate and WOB graphically, for resistive load, elastic load, and total load to breathing.

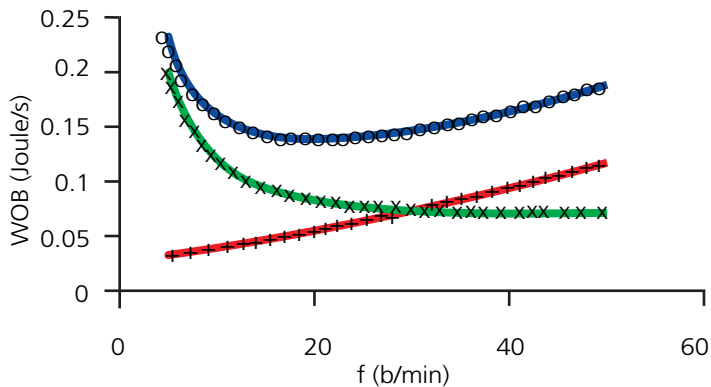


Figure D-12. Three different relationships between rate and WOB are plotted for a hypothetical lung: (+) purely resistive load causes WOB to rise with rate, (x) purely elastic load creates highest load at low rates, (o) the total lung shows a clear minimum which can be calculated according to the equation below.

The following equation was found to represent the rate where WOB is minimum:

$$f = \frac{\sqrt{1 + 2a \cdot R_{Ce} \cdot (\text{MinVol} - f^* V_d) / V_d} - 1}{a \cdot R_{Ce}}$$

where a is a factor that depends on the flow waveform. For sinusoidal flows, a is $2\pi^2/60$.

The corresponding tidal volume is calculated as:

$$V_t = \text{MinVol}/f$$

Example: A 70 kg male patient with normal lungs ($R_{\text{total}} = 5 \text{ cmH}_2\text{O/l/s}$, expiratory resistance hose and valve = $5 \text{ cmH}_2\text{O/l/s}$, $C_{rs} = 50 \text{ ml/cmH}_2\text{O}$) may have a measured RC_{exp} of 0.5 s, an estimated VD of 154 ml, and an operator-set %MinVol of 100%. With these values, the target MinVol becomes

$$\text{MinVol} = 100\% \times 70 \text{ kg} \times 0.1 \text{ l/min/kg} = 7 \text{ l/min}$$

Next, Otis' equation is applied with the following parameters:

$$\text{MinVol} = 7 \text{ l/min}$$

$$VD = 154 \text{ ml}$$

$$RC_{\text{exp}} = 0.5 \text{ s}$$

$$a = 2\pi^2/60$$

$$f = 10 \text{ b/min (determined using Table D-8 or Table D-9)}$$

The result is a new rate $f(1)$

$$f(1) = 15 \text{ b/min}$$

This rate is again inserted into Otis' equation, the calculation is performed again, and the next estimate for rate $f(2)$ is obtained. This procedure is repeated until the difference between subsequent results for rate (f) becomes lower than 0.5 b/min. In the present example, one iteration step is sufficient, i.e.,

$$f_{\text{target}} = 15 \text{ b/min}$$

Finally, the target tidal volume is obtained by dividing MinVol by f :

$$V_{\text{target}} = 7000 \text{ ml/min} / 15 \text{ b/min} = 467 \text{ ml}$$

D.5 ASV technical data

Table D-5 lists technical data related to ASV. Underlined parameters are operator-set in the ASV mode.

Table D-5. ASV technical data

ASV-related operator settings	
<u>%MinVol</u>	10 to 350%
<u>Body Wt</u> (ideal body weight, IBW)	10 to 200 kg (adults) 3 to 30 kg (pediatrics)
Internal calculations	
MinVol (target)	In l/min, target minute volume is calculated as: $\frac{\text{Body Wt (in kg)} \times \text{NormMinVent (in l/kg/min)} \times \% \text{MinVol}}{100}$ where NormMinVent is the normal minute ventilation from Figure D-5.
fTotal	In b/min, calculated on the basis of Otis' equation
VD	2.2 ml/kg <u>Body Wt</u>
Vt (target)	MinVol/ f(target)
ASV monitor	
Target values (numerical)	MinVol, Vt, fTotal
Current achieved values (numerical)	MinVol, Vt, fTotal
Status of patient (numerical)	fSpont, fControl, P _{insp}
Graphics display (curve)	f versus Vt, target value, actual value, safety boundaries

Table D-5. ASV technical data (continued)

Alarms	
All GALILEO alarms are functional except apnea alarms	See Section 8
Special	ASV: Check hi press limit, Initialization failed, ASV: Cannot meet target
Performance specifications	
Response time (90% of steady state)	< 1 min (typical)
Overshoot/undershoot	< 20%
Maximum pressure change per breath	2 cmH ₂ O
Lung-protective rules	
Maximum Vt	Depends on high <u>Pressure</u> alarm limit setting and volume/pressure ratio (V/P) However, normally MinVol/5, but always < 22 x <u>Body Wt</u>
Minimum Vt	4.4 x <u>Body Wt</u>
Maximum machine rate	22 b/min x <u>%MinVol</u> /100 (adults) 45 b/min x <u>%MinVol</u> /100 (pediatrics) but always < 60 b/min
Minimum target rate	5 b/min
Maximum Pinsp	High <u>Pressure</u> limit - 10 cmH ₂ O
Minimum Pinsp	5 cmH ₂ O above <u>PEEP/CPAP</u>
Minimum inspiratory time (TI)	0.5 s or RCexp, whichever is longer
Maximum inspiratory time (TI)	2 s

Table D-5. ASV technical data (continued)

Minimum expiratory time (Te)	2 x RCexp
Maximum expiratory time (Te)	12 s
I:E range	1:4 to 1:1

Table D-6. Determining adult IBW from height*

Height		IBW (kg)	
ft	m	Male	Female
5'0"	1.52	50	46
5'1"	1.55	52	48
5'2"	1.57	55	50
5'3"	1.60	57	52
5'4"	1.62	59	55
5'5"	1.65	62	57
5'6"	1.67	64	59
5'7"	1.70	66	62
5'8"	1.72	68	64
5'9"	1.75	71	66

Height		IBW (kg)	
ft	m	Male	Female
5'10"	1.77	73	69
5'11"	1.80	75	71
6'0"	1.82	78	73
6'1"	1.85	80	75
6'2"	1.88	82	78
6'3"	1.90	85	80
6'4"	1.93	87	82
6'5"	1.95	89	85
6'6"	1.98	91	87
6'7"	2.00	94	89

* Source: Pennsylvania Medical Center. HAMILTON MEDICAL assumes no responsibility for the accuracy of this data. Use of this information is the responsibility of the clinician.

Table D-7. Determining pediatric IBW from height*

Height		IBW (kg)
in.	cm	
19	50	6
21	55	6
23	60	7
25	65	8
27	70	8
29	75	9
31	80	10
33	85	11
35	90	12
37	95	14
39	100	15

Height		IBW (kg)
in.	cm	
41	105	17
43	110	19
45	115	20
47	120	23
49	125	25
51	130	28
53	135	31
55	140	34
57	145	37
59	150	41

* Adopted from Traub SL; Johnson CE. Comparison of methods of estimating creatine clearance in children. Am J Hosp Pharm 1980;37:195-201.
HAMILTON MEDICAL assumes no responsibility for the accuracy of this data. Use of this information is the responsibility of the clinician.

D.6 Initialization of ventilation

When ASV is started, GALILEO delivers three test breaths in the synchronized intermittent mandatory pressure ventilation mode. GALILEO automatically selects the values for SIMV rate, inspiratory time (TI), and inspiratory pressure (P_{insp}) based on the operator-selected Body Wt and Adult or Pediatric settings, and according to Table D-8 and Table D-9.

Table D-8. Initial breath pattern for Adult settings

Body Wt (kg)	P_{insp} (cmH₂O)	TI (s)	SIMV rate (b/min)
30 to 39	15	1	14
40 to 59	15	1	12
60 to 89	15	1	10
90 to 100	18	1.5	10
> 100	20	1.5	10

Table D-9. Initial breath pattern for Pediatric settings

Body Wt (kg)	P_{insp} (cmH₂O)	TI (s)	SIMV rate (b/min)
3 to 5	15	0.6	35
6 to 8	15	0.6	25
9 to 11	15	0.6	20
12 to 20	15	1	20
22 to 26	15	1	15
27 to 29	15	1	15

D.7 References

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- **.....more** and updated references on www.hamilton-medical.com

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E.1 Introduction

NOTE:

- Noninvasive ventilation (NIV) in critically ill patients should only be used by properly trained and experienced personnel.
 - As a precaution, you must be prepared to intubate the patient and start invasive ventilation at any time while NIV is in use.
 - The use of a mask may increase dead space. Always heed the mask manufacturer's instructions when using NIV.
-

The noninvasive ventilation (NIV) mode is the GALILEO's implementation of noninvasive positive pressure ventilation (NPPV). NPPV may use as its patient interface a mask, mouthpiece, or helmet-type interface, rather than an invasive conduit such as an endotracheal tube.

Used for years in homecare and subacute care settings, NPPV can also benefit intensive care ventilation patients by decreasing the need for intubation and promoting early extubation. Benefits such as reduced mortality (COPD patients), reduced ventilation time (COPD and ARF patients), and reduced complication rates (of ventilator-associated pneumonias) have been clearly demonstrated^{1,2}.

Intended for actively breathing patients, NIV is an adaptation of the GALILEO's SPONT mode. In NIV, pressure support ventilation (PSV) is provided through a non-vented or non-ported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ventilator achieves and maintains the prescribed PSV pressure

1. Mehta S et al. Noninvasive ventilation. *Am J Respir Crit Care Med* 2001 Feb;163(2):540-77.

2. Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. *Respiratory Care* 2004 Jul;49(7):810-25.

by adjusting the inspiratory flow. If the leak is large, the ventilator's inspiratory flow can be large -- up to 180 l/min -- thus compensating at least in part for most leaks. The NIV mode was also designed to minimize nuisance leak-related alarms.

E.2 Benefits of NIV^{1,2}

NIV offers these short-term benefits:

- Relieves respiratory symptoms
- Optimizes patient comfort
- Reduces work of breathing
- Improves or stabilizes gas exchange
- Improves patient-ventilator synchrony
- Minimizes risks associated with aspiration, intubation, injury to the mucus membranes and teeth, and circulatory reactions

NIV offers these long-term benefits:

- Improves sleep duration and quality
- Maximizes quality of life
- Enhances functional status
- Prolongs survival

-
1. Mehta S et al. Noninvasive ventilation. *Am J Respir Crit Care Med* 2001 Feb;163(2):540-77.
 2. Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. *Respiratory Care* 2004 Jul;49(7):810-25.

E.3 Required conditions for use

WARNING

- **To prevent possible patient injury, do not use NIV on patients with no or irregular spontaneous breaths. NIV was intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.**
 - **To prevent possible patient injury, do not attempt to use NIV on intubated patients.**
-

Be sure that the following requirements are met when using NIV:

- The patient must not be intubated.
- The patient must be able to trigger the ventilator and must have regular spontaneous breaths.
- The patient must be conscious.
- The patient must be able to maintain an adequate airway.
- The clinician's instructions must be strictly followed.
- The patient must be monitored by external monitors.
- Intubation must be possible at any time.
- The mask should fit face structures well.

E.4 Contraindications

- Intolerance of interface
- Inability to trigger breath
- Facial or brain injury
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Inability to protect airway

E.5 Potential adverse reactions

- Skin breakdown from interface (pressures sores)
- Aspiration
- Conjunctivitis
- Gastric insufflation
- Claustrophobic reaction
- Potential hemodynamic instability

E.6 Selecting a patient interface

The quality and performance of the patient interface largely determine the effectiveness of NIV. Either a face (oronasal) mask that covers the mouth and nose, a nasal mask that covers the nose only, a mouthpiece, or a helmet-type interface may be used with NIV. In general, a face mask is more efficient than a nasal mask, but a nasal mask is better tolerated. Consider the following additional advantages and disadvantages when selecting a patient interface:

Type	Advantage	Disadvantage
Face mask	• Little patient cooperation required • Little leakage • Ability to sleep	• Verbal communication not possible • Gastric distension • Greater dead space
Nasal mask	• Comfort • Verbal communication possible • Little dead space	• Patient cooperation required • Oral leakage
Mouthpiece	• Simple to use • Inexpensive	• Nasal air leakage • Greater dead space

In general a mask used with the NIV mode should meet these requirements:

- It must be of the non-vented/non-ported design
- Gas leakage should be controllable at low mask application pressures
- The material in contact with the face should be soft, biocompatible, and nonallergenic
- It should be easy to install and remove
- It should remain properly positioned when the patient moves their head

If you try using a nasal mask, but there is significant gas leakage through the open mouth, switch to a face mask.

E.7 Control settings

WARNING

When ventilating with a mask, avoid high airway pressures. High pressures may cause gastric distension.

Peak pressures exceeding 33 cmH₂O may increase the risk of aspiration due to gastric insufflation¹.

When ventilating with such pressures, consider using an invasive mode.

In case of a significant leak, the inspiratory flow may never fall below ETS, thus not allowing the ventilator to cycle into exhalation and resulting in endless inspiration. For this reason, the Ti max setting was added, providing an alternative way to cycle into exhalation. When inspiration lasts longer than Ti max, the GALILEO cycles into exhalation.

1. Bach JR, Alba AS, Saporito LR. Intermittent positive pressure ventilation via the mouth as an alternative to tracheostomy for 257 ventilator users. Chest 1993;103:174-182.

It is the most comfortable for the patient when the ventilator cycles based on the ETS setting rather than Ti max, however. Make sure the Ti max setting is sufficiently long to give ETS the chance to cycle the ventilator. Adjusting the Ti max setting increases or decreases the allowable inspiratory time. Increasing ETS above the default 25% allows the ventilator to cycle to terminate inspiration at a higher flow, in order to accommodate larger leaks.

Other controls require special attention. Carefully observe the patient/ventilator interaction. The Flowtrigger control may require adjustment in NIV. The leakage in this mode may reduce the actual applied PEEP/CPAP and give rise to auto-triggering. Adjust Psupport to obtain appropriate tidal volumes (e.g., 6 ml/kg). Adjust PEEP/CPAP further, considering oxygenation and AutoPEEP.

E.8 Alarms

Volume alarms are less meaningful in NIV than in other modes, because of the unpredictable gas leakage in this mode. These alarms are based on the returned expiratory gas volume measured at the Flow Sensor; this value may be significantly lower than the delivered tidal volume, because the delivered tidal volume is the sum of the displayed VTE and the leakage volume. To avoid nuisance volume alarms, set the low Vt and ExpMinVol alarms to a low level.

Because NIV is a pressure mode, however, do pay attention to the pressure-related alarms. If the defined PEEP and inspiratory pressure can be maintained, the device is compensating the gas leak sufficiently.

NOTE:

Due to leakage around the mask during NIV, the **Disconnection pat. side** alarm, which is based on volume criteria, is disabled. This helps prevent nuisance alarms. The **Low Tidal Volume**, **Low minute volume**, and **Disconnection vent. side** alarms remain enabled.

E.9 Monitored parameters

NOTE:

Due to the changing and unpredictable amount of leakage, these numeric monitoring parameters cannot be used for reliable analysis of patient conditions: ExpMinVol, RCexp, Rinsp, Insp Flow, MV Spont, AutoPEEP, and Cstat. Close monitoring of the clinical parameters and patient comfort is therefore of critical importance.

Due to the leakage at the patient interface, displayed exhaled volumes in NIV may be substantially smaller than the delivered volumes. The Flow Sensor, a bidirectional device proximal to the patient, measures both the delivered volume and the exhaled tidal volume, then displays the difference as VLeak (leakage volume). Use VLeak to assess the fit of the mask or other noninvasive patient interface.

While a leak at the patient interface influences the tidal volume measurement, leaks in the breathing circuit itself do not influence the tidal volume measurement.

Besides all the other clinical parameters, TI, Ppeak, PEEP/CPAP, I:E, fTotal, Pmean, and fSpont can be used to assess the patient's ventilatory status.

E.10 Additional notes about using NIV

Due to some unique characteristics of NIV, consider the following points when using it. As with any mode of ventilatory support, monitor the patient closely to evaluate the adequacy of the prescribed therapy.

Maintaining PEEP and preventing autotriggering.

Significant leakage may be present in NIV, which may serve to reduce the actual applied PEEP/CPAP and give rise to autotriggering. Adjust the Flowtrigger control as needed to maintain PEEP and to prevent autotriggering in the presence of leakage in NIV. If the monitored PEEP/CPAP is too low, increase

the Flowtrigger setting. If you cannot achieve the set PEEP, check the mask fit. If the mask fit cannot be improved, select an alternative treatment method.

The GALILEO maintains PEEP with the exhalation valve in combination with a compensating base flow delivered by the inspiratory valve through the breathing circuit. During exhalation, the base flow is at least 10 l/min (adults) or 4 l/min (pediatric patients), or 2 times the set Flowtrigger setting, whichever is greater.

The Loss of PEEP alarm alerts you to uncompensated leaks (that is, when the measured PEEP/CPAP is 3 cmH₂O lower than the set PEEP/CPAP).

Checking mask fit and position. For NIV to function as intended, the mask must fit well and remain in place. It is desirable to maintain a good seal and minimize leakage.

Check the mask position regularly and adjust as necessary. If the mask slides away from the mouth and nose (patient disconnection), reinstall and secure it. React promptly and appropriately to any alarms.

The ventilator's VLeak parameter provides one indicator of mask fit. You can also check the proper fit of the mask by verifying that the patient can trigger and flow-cycle inspiration and by verifying that P_{peak} is:

$$(P_{\text{support}} + \text{PEEP/CPAP}) \pm 3 \text{ cmH}_2\text{O}$$

CO₂ rebreathing in NIV. CO₂ rebreathing per breath may increase in NIV. This is not typically critical, because significant there is also generally significant leakage in NIV. CO₂ rebreathing may occur, because there is not the usual dead space reduction from an endotracheal tube or tracheostomy, and because the mask or other noninvasive interface creates additional dead space. Consider this additional dead space when prescribing a specific type of noninvasive patient interface. Despite the use of a noninvasive interface, the dead space ventilation per minute may decrease if the therapy results in an increase in tidal volume and decrease in respiratory rate.

E.11 References

- **Hess DR.** The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. *Respir Care* 2004 Jul;49(7):810-25.
- **Mehta S et al.** Noninvasive ventilation. *Am J Respir Crit Care Med* 2001 Feb;163(2):540-77.
- **Arroliga AC.** Noninvasive positive pressure ventilation in acute respiratory failure: does it improve outcome? *Cleveland Clin J Med.* 2001 Aug;68(8):677-80.
- **Hill NS.** Noninvasive ventilation in chronic obstructive pulmonary disease. *Clin Chest Med.* 2000 Dec;21(4):783-97.
- **AARC.** Consensus statement: Noninvasive positive pressure ventilation. *Respir Care* 1997;42(4):365-9.
- **Evans TW et al.** Noninvasive positive pressure ventilation in acute respiratory failure: Report of an international consensus conference in intensive care medicine, Paris, France, 13 - 14 April 2000. *Reanimation* 2001;10:112-25.

F

Parts and accessories

For additional parts and accessories, refer to the HAMILTON MEDICAL *Product Catalog*.

Table F-1. Ventilator parts and accessories

Item no. (Figure F-1)	Description	Part no.
1	Tubing holder set (Includes support arm and tubing holder)	281533
2	Patient breathing set (A1), single water trap, adult, reusable (for use with inspiratory limb heater wire)	151976
	Patient breathing set (P1), single water trap, pediatric, reusable (for use with inspiratory limb heater wire)*	260035
	Patient breathing set (I1), single water trap, infant, reusable (for use with inspiratory limb heater wire)*	151969
	Patient breathing set (A2), double water trap, adult, reusable (for use without heater wires)*	151990
	Patient breathing set (P2), double water trap, pediatric, reusable (for use without heater wires)*	260038
	Patient breathing set (A0), HME, adult, reusable (for use with HME)*	260036
	Patient breathing set (P0), HME, pediatric, reusable (for use with HME)*	260037
	Patient breathing set (A1-SPU-EV), single water trap, with expiratory valve cover and membranes, adult, single-patient use (for use with inspiratory heater wire)*	151978
	Patient breathing set (A1-SPU), single water trap, without expiratory valve cover and membranes, adult, single-patient use (for use with inspiratory heater wire)*	151965

* Not shown

Table F-1. Ventilator parts and accessories (continued)

Item no. (Figure F-1)	Description	Part no.
3	Flow Sensor, pediatric/adult, reusable (package of 10)	155362
	Flow Sensor, pediatric/adult, single-patient use (package of 10)*	279331
	Flow Sensor, infant, single-patient use (package of 10)*	155500
4	Demonstration lung assembly with endotracheal tube, 2 l, with 15 mm male x 22 mm male connector (adult)	151815
	Demonstration lung assembly with endotracheal tube, 0.5 l, with 15 mm male x 22 mm male connector (pediatric)*	151816
	Test lung model, infant*	53353
5	Membrane, expiratory valve (package of 5) (Also included in all patient breathing circuits except PN 151965)	151233
6	Cover, expiratory valve (Also included in all patient breathing circuits except PN 151965)	151228
7	Oxygen cell, Catalyst	396008
8	Humidifier, Fisher & Paykel MR850 (See <i>Product Catalog</i> for ordering information)*	--
	Humidifier, Fisher & Paykel MR730 (See <i>Product Catalog</i> for ordering information)	--
	Humidifier, Fisher & Paykel MR410 (See <i>Product Catalog</i> for ordering information)*	--
9	Trolley, standard, with backup battery	155450
	Trolley, short, with backup battery*	155451
	Shelf mount, with battery backup*	155515

* Not shown

Table F-1. Ventilator parts and accessories (continued)

Item no. (Figure F-1)	Description	Part no.
10	VENTILAIR ^{II} medical air compressor, 220 to 240 V $\pm 10\%$, 50 Hz /230 V $\pm 10\%$, 60 Hz	155600
	VENTILAIR ^{II} medical air compressor, 100 to 115 V $\pm 10\%$, 50/60 Hz	155601
11	Accessory basket, GALILEO	155198
12	Nebulizer set, reusable* (See <i>Product Catalog</i> for ordering information)	151983
13	Cylinder holder, GALILEO	155394
14	Fuse, T 4.0 A H 250 V (2 required)	363071
15	Microfilter, gas inlet, 5 μm (microns)	279676
16	Filter, fan	279166
17	Oxygen supply hose, white, 4 m*	281431
18	Air supply hose, black/white, 4 m*	281432
19	Power cord, with Schuko (continental Europe) plug, 2.5 m*	355010
	Power cord, with Swiss plug, 2.5 m*	355020
	Power cord, with British plug, 2.5 m*	355021
	Power cord, with US plug, hospital-grade, 2.5 m*	355139

* Not shown

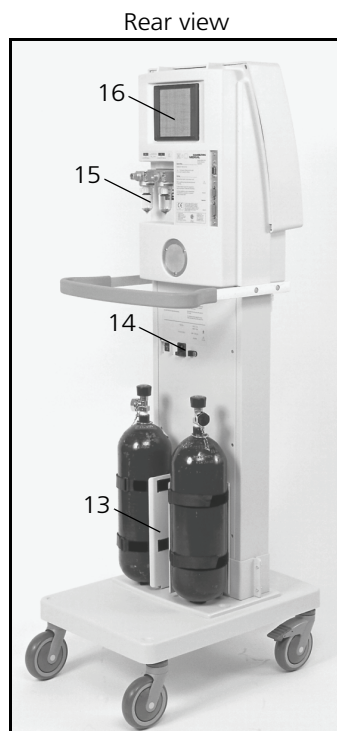
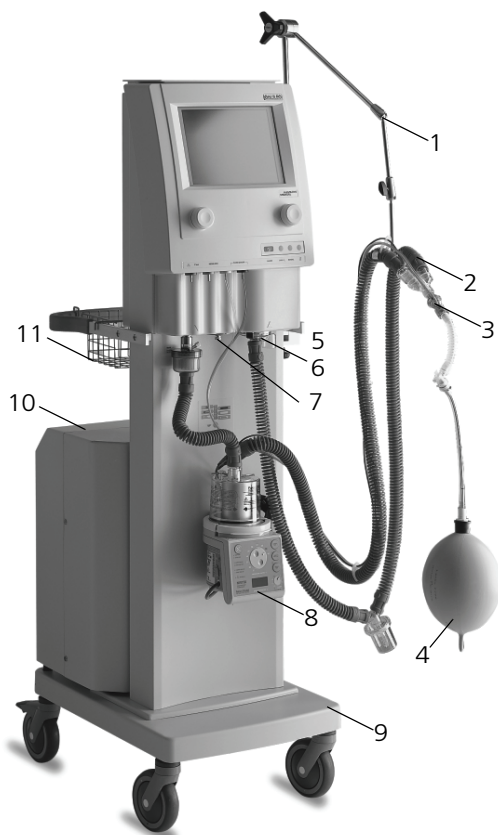


Figure F-1. Ventilator parts and accessories

Communications interface option

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G.1 Introduction

The communications interface option offers these capabilities:

- The **RS-232 interface** outputs monitored data, ventilator settings, and alarms to a patient monitor or computer.
- **The I:E timing outlet** outputs signals for time of insufflation, pause, and exhalation. These are used for special applications, such as an external nebulizer.
- The **remote alarm outlet** outputs alarm signals to a nurse's call device.

A ventilator with this option has two connectors at the back (Figure G-5). The patient monitor or computer connects to the RS232C connector. The nurse's call or other device connects to the Special connector.

WARNING

To reduce the risk of excessive leakage current due to ground loops and to prevent electromagnetic interference, make sure the connecting cable has a high-quality shield and is grounded properly *on one side only*, either at the ventilator or receiving device.

NOTE:

- All devices connected to the GALILEO must be for medical use and meet the requirements of IEC 601-1.
 - This interface includes two EMI-protective covers for the connectors. When the connectors are not in use, make sure the covers are installed.
 - The interface option can be enabled or disabled during configuration. Make sure the option is enabled before you use the interface.
 - **Check . . .** messages, which indicate a setting conflict, are not sent to the remote alarm outlet. To see all low-priority alarms, HAMILTON MEDICAL recommends you read them directly off the GALILEO screen or consult the event log.
-

G.2 RS-232 interface

The RS-232 interface lets the GALILEO send monitored data, waveforms, modes, control settings, and alarms to a patient monitor or a computer through the RS232C connector. Table G-2 lists the pin assignments for this connector.

G.2.1 Patient monitor

WARNING

To prevent possible patient injury when using a patient monitor, check the patient and the ventilator whenever the monitor reports a ventilator alarm. Not all monitors provide detailed alarm message information.

NOTE:

- Your monitor may not recognize and report all modes and parameters (for example, ASV mode, peak pressure monitoring parameter). It also may not recognize some specific alarms, but report them as general alarms. In such cases, HAMILTON MEDICAL recommends that you read the data directly from the GALILEO screen.
 - Silencing the GALILEO's audible alarm does not automatically silence the audible alarm of the remote patient monitor.
 - To connect your GALILEO to a monitor other than those described below, contact the monitor manufacturer.
-

With the RS-232 interface, the GALILEO ventilator can send data to a Philips Medical Systems, Spacelabs, GE Marquette, Schiller, Dräger, Datex-Ohmeda, or Nihon Kohden patient monitor.

Using the GALILEO with a patient monitor requires the hardware shown in Figure G-1. Interfacing hardware specific to the manufacturers' monitors is listed in Table G-1. Order this interfacing hardware directly from the monitor manufacturer.

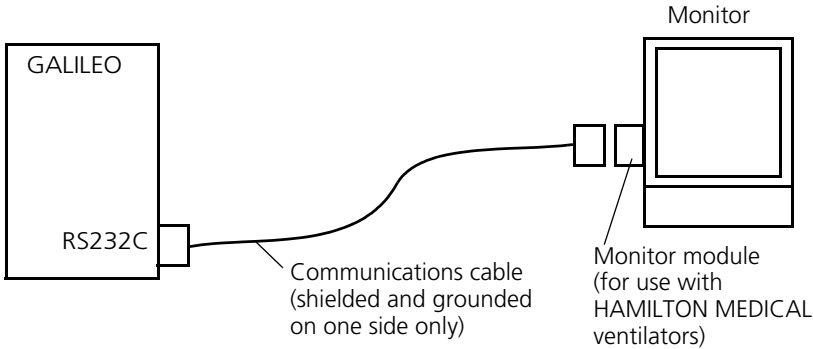


Figure G-1. GALILEO connected to a patient monitor and PDMS

Table G-1. Interfacing hardware for patient monitors

Manufacturer	Interfacing hardware required	Notes
Philips Medical Systems	VueLink Open interface cable with 25M connector, VueLink module with VueLink Open driver	Consult the accompanying document, <i>Using the GALILEO with Philips monitors and the VueLink Open Interface</i> (PN 610948)
Spacelabs Medical (GE Medical Systems)	Flexport converter and cable for HAMILTON MEDICAL ventilators	
GE Marquette Medical Systems	Octanet and cable for HAMILTON MEDICAL ventilators	Tram-net is not compatible
Schiller	Cable for HAMILTON MEDICAL ventilators	

Table G-1. Interfacing hardware for patient monitors (continued)

Manufacturer	Interfacing hardware required	Notes
Dräger Medical	MIB II Protocol Converter or MIB II Duo Protocol Converter and GALILEO MIB interface cable	For use with Infinity Modular Monitors (formerly Siemens Medical)
Datex-Ohmeda PDMS (patient data management system)	deioEthernetbox and cables	deioClinisoft version 4.0 for Microsoft® Windows® 2000/NT
Nihon Kohden BSM-4100/5100 series bedside monitor	QI-407P interface	
Capsuletech	DataCaptor terminal server, RJ45 cable, DataCaptor ID module, RJ45 to RS232 adapter	
Philips (PDMS)	Intellibridge EC5 ID module with EC40/80 Hubs and cables	
Copra	Driver V1.04 with Copra Interface V5.24@239	

Note: PDMS is the abbreviation of patient data management system.

G.2.2 Computer

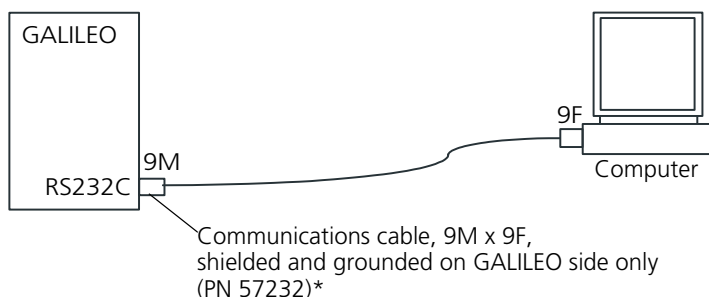
WARNING

The computer connected to the GALILEO should be for medical use and meet the requirements of IEC 60601-1. Alternatively, a battery-powered laptop computer may be used. Do not connect other types of personal computer, because such computers do not fulfill the requirements of the standard. Consult a technical specialist or safety inspector in your hospital for more information.

With the RS-232 interface, the GALILEO can transmit data from the ventilator to your computer. Data from the ventilator can ultimately be manipulated using software such as Microsoft® Excel. This is a useful tool for data management and clinical studies.

This application requires the hardware shown in Figure G-2. It also requires the Data Logger software and manual; contact your HAMILTON MEDICAL representative.

For more information about the communications protocol, contact HAMILTON MEDICAL.



*See the HAMILTON MEDICAL *Product Catalog* for pin configuration of cable

Figure G-2. GALILEO connected to a computer

G.3 Inspiratory:expiratory (I:E) timing outlet

The I:E timing outlet lets your GALILEO send I:E timing signals through the 15-pin (Special) connector. This is useful when administering nitric oxide (NO) or using an external nebulizer.

This application requires the hardware shown in Figure G-3. Table G-2 lists the pin assignments for this connector. Before using the outlet, make sure it is correctly configured (Section H.9). The I:E timing capability is based on a relay inside the ventilator.

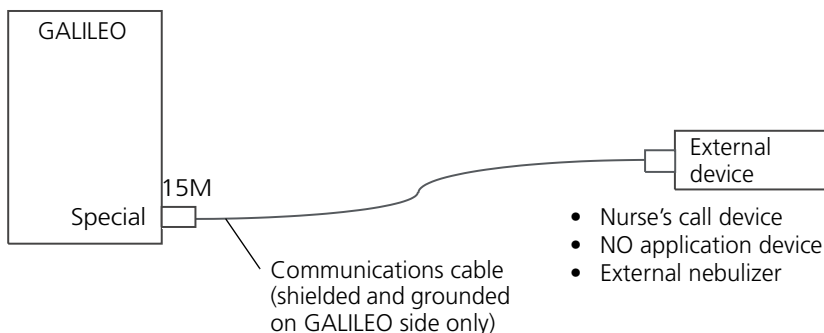


Figure G-3. GALILEO connected to an external device through the Special connector

G.4 Remote alarm outlet

NOTE:

- Before operating the remote alarm function, make sure that the remote alarm function is operational.
- If the remote alarm function is used in an isolation ward, regularly check that the remote alarm function is operational.

The remote alarm (nurse's call) capability allows alarm conditions to be annunciated at locations away from the ventilator (for example, when the ventilator is in an isolation room). This application requires the hardware shown in Figure G-3. The GALILEO sends alarm signals to a nurse's call device through the 15-pin (Special) connector. Table G-2 lists the pin assignments for this connector.

The GALILEO alarm silence key silences the audible portions of the alarms at both the ventilator and the remote alarm device.

The remote alarm capability is based on a relay inside the ventilator. Figure G-4 shows the alarm and non-alarm positions for the relay. You can use either pins 7 and 14 or pins 7 and 6, depending on the logic of your nurse's call system (normally open or normally closed).

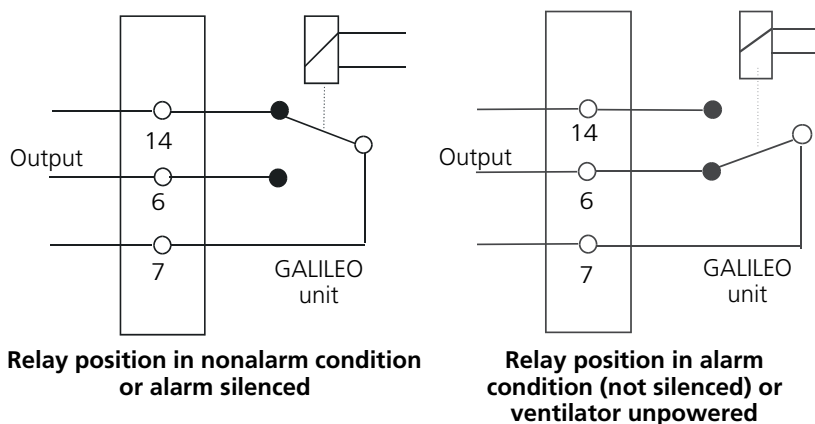


Figure G-4. Remote alarm relay positions

G.5 Connector pin assignments

Figure G-5 shows the locations of the interface connectors and pins. Table G-2 lists the pin assignments for these connectors.

The maximum allowable voltage and current between the relay contacts are 48 V, 0.5 A.

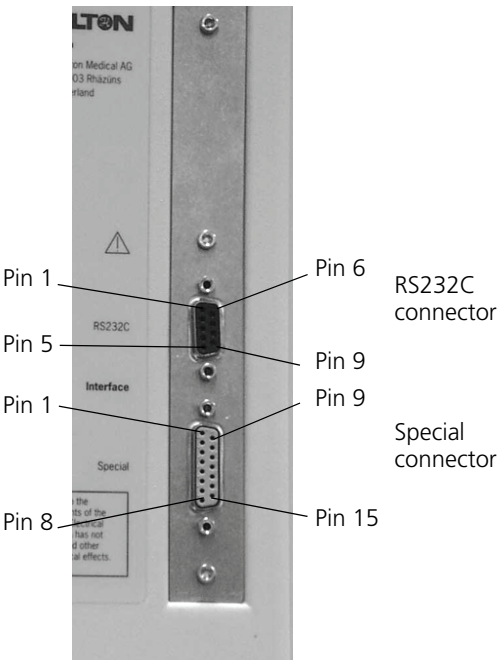


Figure G-5. Interface connectors

Table G-2. Interface connector pin assignments

RS232C connector	
Pin	Signal
1	GND
2	RXD
3	TXD
4	DTR
5	GND (signal ground)
6	DSR
7	RTS
8	CTS
9	--
Shield	Chassis ground

Special connector	
Pin	Signal
1	--
2	--
3	--
4	--
5	--
6	Remote alarm return (See Figure G-4)
7	Remote alarm
8	I:E relay
9	--
10	--
11	--
12	--
13	--
14	Remote alarm return (See Figure G-4)
15	I:E relay return

H Configuration

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H.1 Introduction

During configuration, you set up the ventilator with a default language, breath timing control philosophy, main monitoring parameter display, and nebulization parameters. Configuration also lets you enable and disable alarms and oxygen monitoring, adjust the date and time, and set up the I:E timing outlet. You typically configure the ventilator when you first acquire it, before you put it on a patient.

H.2 Accessing the configuration menu

To access the **Configuration** menu, hold down the M-knob, then power on the ventilator. Do not release the knob until the buzzer stops. You will see the **Configuration** arrow on the setup screen (Figure H-1). Select **Configuration** by turning the C-knob, and activate your selection by pressing the knob.



Figure H-1. Setup screen

The **Configuration** menu will open (Figure H-2). Select the desired configuration function, then activate it.

Follow the instructions in the next subsections to configure your ventilator. When you finish, select **Close** from the **Configuration** menu, then press the knob to confirm your selection and return to the setup screen.

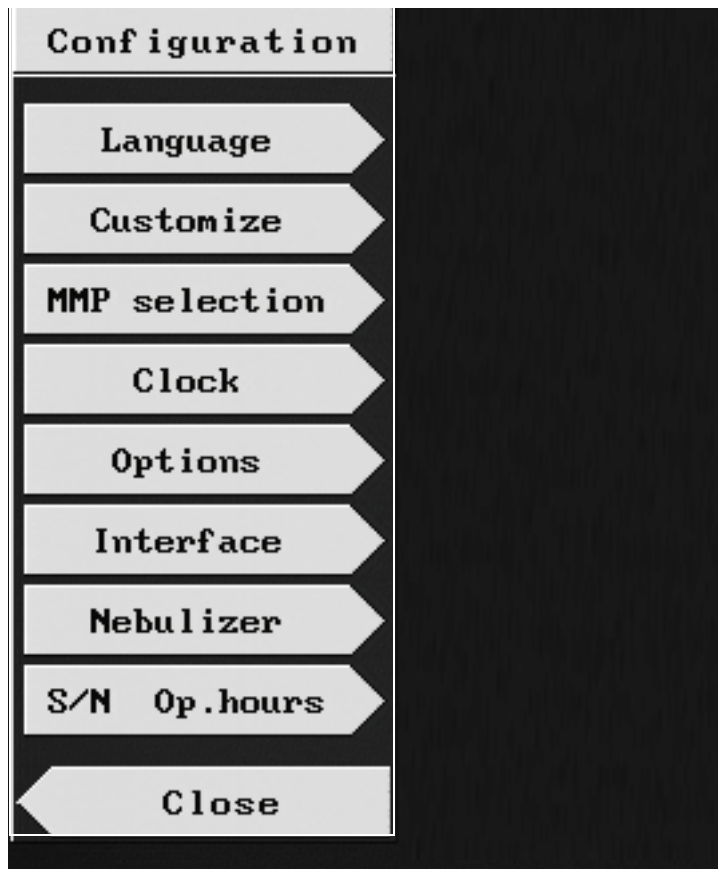


Figure H-2. Configuration menu

H.3 Language: Selecting the default language

The **Language** window lets you select the language for screen display. Turn the C-knob to select a language, then press the knob to activate. **Close** the window to confirm your selection and return to the **Configuration** menu.

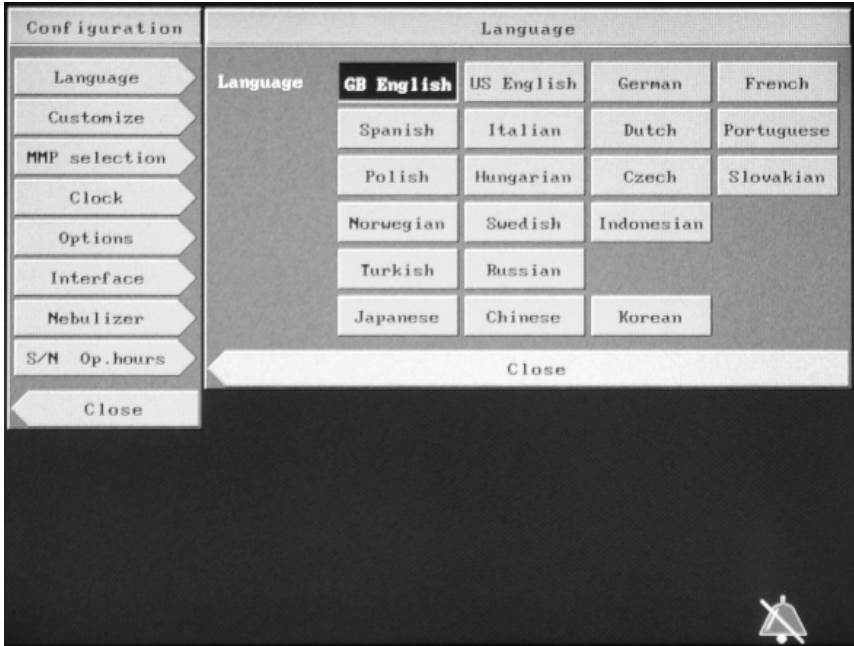


Figure H-3. Language window

H.4 Customize: Selecting the ventilation philosophy, alarms, and O₂ monitoring

The **Customize** window (Figure H-4) lets you select the breath timing philosophy to be used, enable/disable user-settable alarms, and enable/disable oxygen monitoring.

Configuration	Customize			
Language	Controls	I:E/ Pause	Peak Flow/ Tip	%Ti/ Pause
Customize	Alarms	ExpMinVol high	Pressure low	Ut high
MMP selection		Rate high	Rate low	Apnea time
Clock				Ut low
Options				Air trapping
Interface	O2 Measurement	On	Off	
Nebulizer	Close			
S/N Op.hours				
Close				



Figure H-4. Customize window

Turn the C-knob to select a parameter, then press the knob to enable or disable it, as follows:

Parameter	Notes
Controls (ventilation philosophies)	Select a preferred way to define time profiles of breath cycles (see Section H.5).
Alarms	Enable from 0 to 8 user-settable alarms. If an alarm is disabled, you will not be able to set it from the Alarms window, and the ventilator will not alarm for this condition. The high Pressure and low ExpMinVol alarms cannot be disabled. See Table 4-3 for details on the alarm settings.
O ₂ measurement	Enable or disable oxygen monitoring. NOTE: When oxygen monitoring is disabled, the GALILEO displays the message O2 Alarm off in the top left-hand corner of the Alarms window.

Close the window to confirm your selections and return to the **Configuration** menu.

H.5 GALILEO's breath timing philosophies (adult patients)

The operator defines mandatory breath timing through settings that may include:

- Breath rate, in b/min (Rate)
- Inspiratory:expiratory ratio (I:E)
- Duration of inspiration phase not including pause, in s or % of total cycle time (TI or %TI)
- Duration of inspiratory pause/plateau, in s (Pause or Tip)
- Peak flow, in l/min (Peak Flow)

The relationships between these breath timing parameters are shown in Figure H-5.

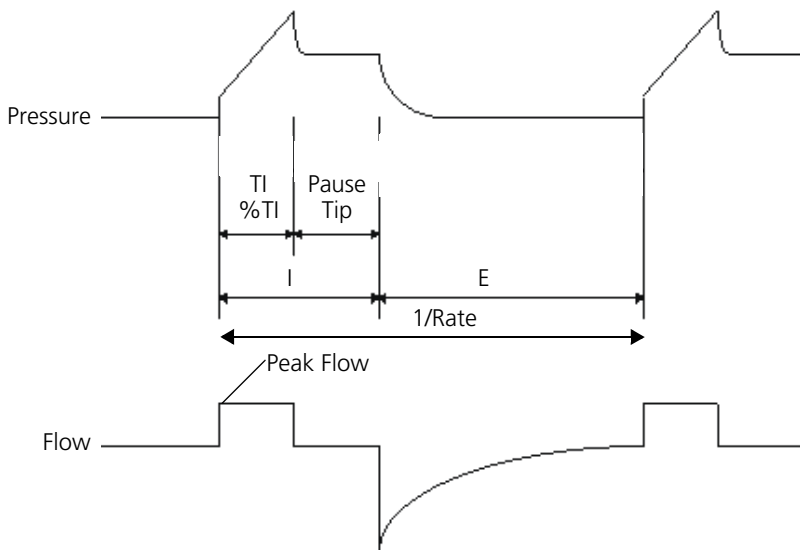


Figure H-5. Relationships between breath timing settings

Different hospitals are accustomed to specifying breath timing in different ways, however. The GALILEO ventilator provides the flexibility to configure breath timing for adult patients in whichever way is most familiar and comfortable. It offers three breath timing “philosophies” corresponding to three different ways of making these settings. You select one of these three philosophies when you configure the GALILEO. Then, when you ventilate an adult patient on the GALILEO, those settings applicable to your chosen philosophy are displayed. The three philosophies are:

- I:E/Pause
- Peak Flow/Tip
- %TI/Pause

Table H-1 shows the active timing control settings corresponding to each philosophy.

Table H-1. Timing controls applicable to breath timing control philosophies*

Philosophy	Adult				Pediatric		Infant
	(S)CMV (A/C)	P-CMV (P-A/C), APVcmv	SIMV	P-SIMV, APVsimv	(S)CMV (A/C) SIMV	P-CMV (P-A/C), P-SIMV, APVcmv, APVsimv	P-CMV (P-A/C), P-SIMV, APVcmv, APVsimv
I:E / Pause	I:E, Pause	I:E	TI, Pause	TI	TI, Pause	TI	TI
Peak Flow / Tip	Peak Flow, Tip	%TI	Peak Flow, Tip	%TI	TI, Pause	TI	TI
%TI / Pause	%TI, Pause	%TI	%TI, Pause	%TI	TI, Pause	TI	TI

* SPONT, ASV, DuoPAP, NIV, DuoPAP, and APRV modes are not shown, because breath control timing philosophies do not apply to these modes.

H.6 MMP selection: Selecting the default main monitoring parameter display

The **Main Monitoring Parameter selection** window (Figure H-6) lets you select the main monitoring parameters to be displayed on the basic screen. Select four parameters by turning the C-knob to select each parameter, then pressing the knob to activate your selection. The parameters will be displayed in the order selected (the first in the upper left-hand position, the second in the upper right-hand position, the third in the lower left-hand position, and the fourth in the lower right-hand position). **Close** the window to confirm your selections and return to the **Configuration** menu.

Configuration		Main Monitoring Parameter selection			
Language	Pressure	Ppeak cmH2O	Pmean cmH2O	PEEP/CPAP cmH2O	
Customize		Pplateau cmH2O	Pminimum cmH2O	AutoPEEP cmH2O	
MMP selection	Volume	ExpMinVol l/min	UTE ml	VLeak ml	
Clock		Peak flow	Exp Flow l/min	Insp Flow l/min	
Options	Rate	fTotal b/min	fSpont b/min		
Interface	Time	TI s	TE s	I:E	
Nebulizer	R & C	RCinsp s	RCexp s		
S/N Op.hours		Cstat ml/cmH2O	Rinsp cmH2O/l/s	Rexp cmH2O/l/s	
Close	Others	P0.1 cmH2O	WOBimp J/l	PTP cmH2O*s	RSB 1/(l*min)
		Oxygen %			
		Close			

Figure H-6. Main Monitoring Parameter selection window

H.7 Clock: Setting the date and time

The **Clock** window (Figure H-7) lets you reset the date and time of day. Turn the C-knob to select a parameter. Press the knob to activate your selection, then turn the knob to adjust the value. Press the knob again to confirm the selection. Select and activate the **Set date & time** button. **Close** the window to confirm your selections and return to the **Configuration** menu.

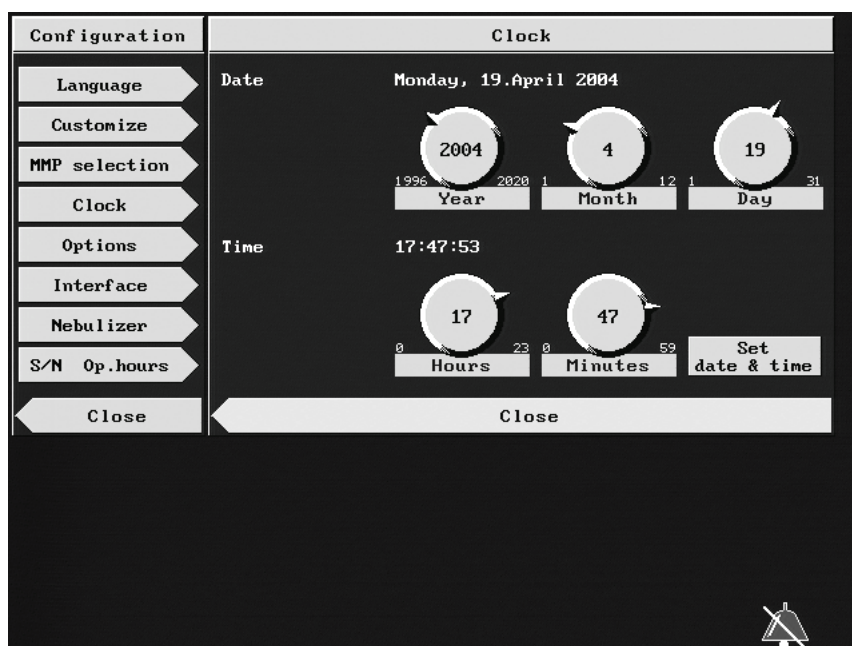


Figure H-7. Clock window

H.8 Options

This function is for use by an authorized HAMILTON MEDICAL representative only.

H.9 Interface: Configuring the I:E timing outlet

The **Interface** window (Figure H-8) lets you configure the I:E outlet, if the optional communications interface is installed.

To configure the I:E timing outlet, first determine the desired relay positions (**Open** or **Closed**) for each of the three breath cycle phases (**Insufflation**, **Pause**, and **Expiration**), referring to Figure H-9. Select a relay position, and press the C-knob to activate each selection. **Close** the window to confirm your selections and return to the **Configuration** menu.

See Appendix G for information on the communications interface option.

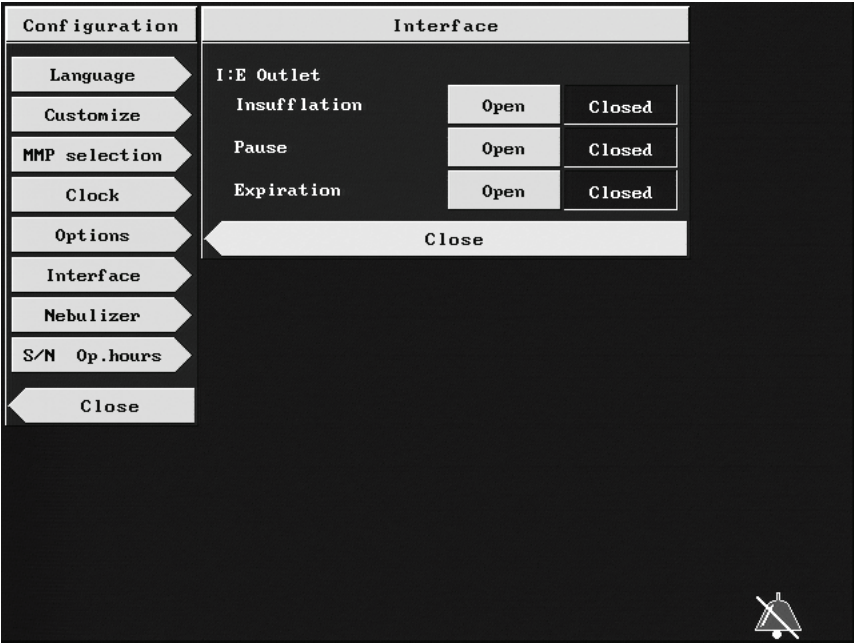


Figure H-8. Interface window

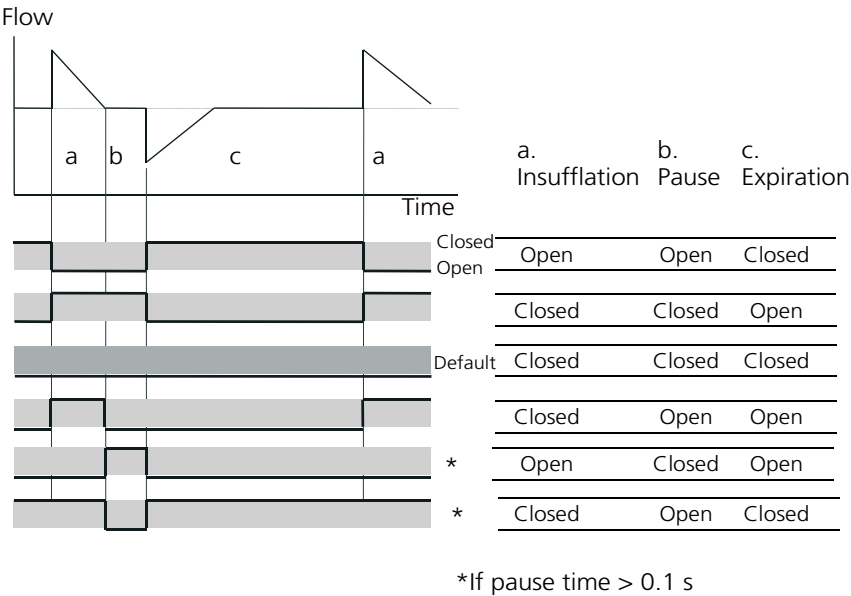


Figure H-9. I:E outlet timing

H.10 Nebulizer: Configuring nebulizer type, duration, and breath phase

NOTE:

If you are using an external pneumatic nebulizer – whether or not the internal pneumatic nebulizer option is installed and enabled – make sure to configure the nebulizer. This configuration helps prevent nuisance alarms due to inappropriate nebulizer volume compensation.

The **Nebulizer** window (Figure H-10) lets you select nebulizer type, and, if the internal nebulizer is selected, to make additional configuration settings.

If the GALILEO's nebulizer option is installed and enabled, select **Internal Nebulizer**. The internal nebulizer function adds volume to the gas delivered to the patient, but selecting **Internal Nebulizer** compensates the total volume so that the set tidal volume is delivered.

If you are using an external nebulizer, either a pneumatic (small-volume) nebulizer powered by an external gas source or a standalone ultrasonic or electronic (piezo) micropump nebulizer, select **External Nebulizer**. This deactivates volume compensation.

Configure the nebulizer as follows:

1. Turn the C-knob to select either **Internal Nebulizer** or **External Nebulizer**. Press the knob to confirm the selection.
2. If you selected **Internal Nebulizer**, do the following:
 - a. Turn the C-knob to select the breath phase when nebulization will be active (**Inspiration**, **Expiration**, or **Continuous** for continuous operation during the operator-selected **Duration**). Press the knob to confirm the selection.

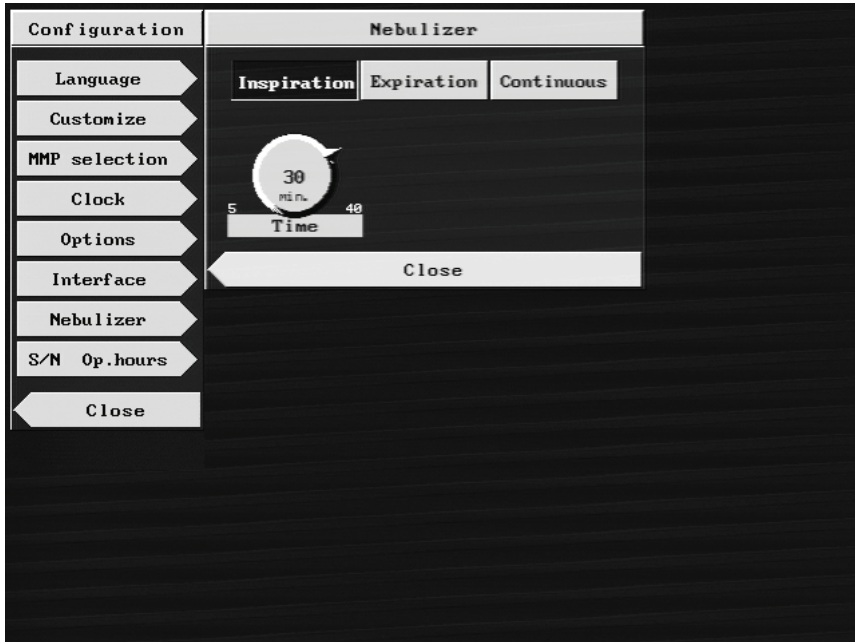


Figure H-10. Nebulizer window

- b. Turn the C-knob to select **Duration** (for limited duration during the selected phase) or **Unlimited** (for on-going operation until the NEBULIZER key is again pressed). Press the knob to confirm the selection. If you selected **Duration**, adjust the nebulization time, and press the knob again to confirm the selection.
3. **Close** the window to confirm your selection and return to the **Configuration** menu.

Figure H-11 shows the basic screen with the external nebulizer configured on.

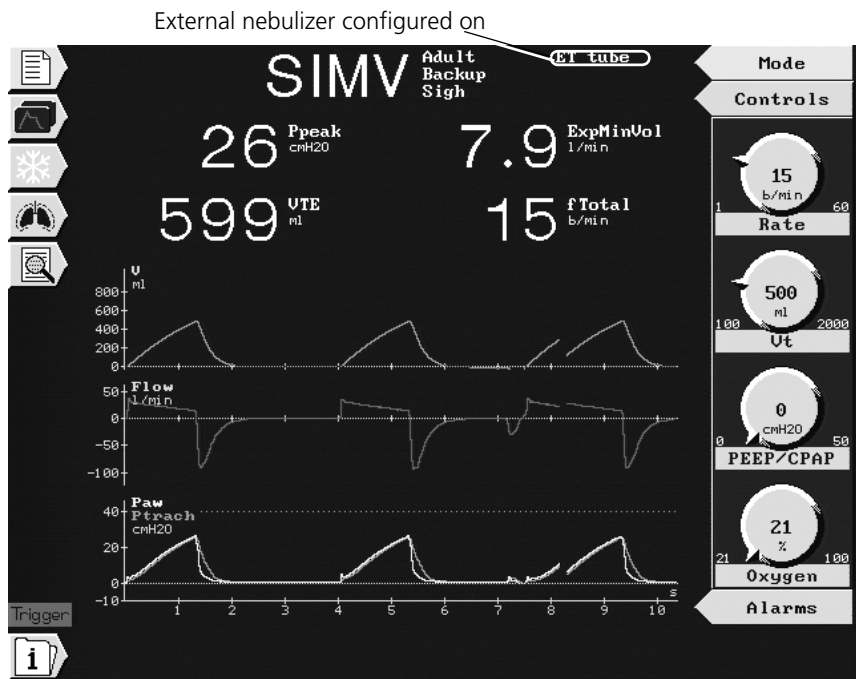


Figure H-11. Ext Neb. displayed on basic screen

H.11 S/N Op.hours (serial number and operating hours)

This function is for use by an authorized HAMILTON MEDICAL representative only.

Glossary

%MinVol	Percentage of minute ventilation, a control setting in ASV mode.
%TI	Inspiratory time, as a percentage of total cycle time, a control setting.
A/C	Assist/control ventilation mode. Also called (S)CMV.
A	Ampere, a unit of current.
Ax	Adult breathing set with x water trap(s).
A1-SPU	Adult breathing set with 1 water trap, single-patient use.
A1-SPU-EV	Adult breathing set with 1 water trap, single-patient use, with exhalation valve.
ac	Alternating current.
active alarm buffer	Contains information on up to six currently active alarms.
Air trapping	The maximum end expiratory gas flow allowed for two consecutive breaths, an alarm setting.
alarm information buffer	Contains information on the six most recent reset alarms.
alarm silence key	Silences alarm sound for 2 min.
ALI	Acute lung injury.
ambient state	An emergency state, in which the ventilator opens the ambient and exhalation valves and closes the inspiratory valves. This lets the patient breathe room air unassisted by the ventilator.
apnea	Cessation of breathing.
Apnea Time	The maximum time allowed without a breath trigger, an alarm setting.
APRV	Airway pressure release ventilation mode.
APVcmv	Adaptive pressure ventilation CMV mode.
APVsimv	Adaptive pressure ventilation SIMV mode.

ARDS	Adult respiratory distress syndrome.
ASV	Adaptive support ventilation, a positive pressure ventilation mode intended to adapt with the patient as he/she progresses from full mechanical ventilation to spontaneous breathing.
ATPD	Ambient temperature and pressure, dry.
AutoPEEP	Unintended positive end-expiratory pressure, a monitored parameter.
b/min	Breaths per minute.
backup	Apnea backup ventilation.
Body Wt	Body weight, a control setting in ASV mode. It specifies the patient's body weight assuming normal fat and fluid levels.
breathing circuit	Includes the inspiratory-expiratory tubing, humidifier, filters, and water traps.
BTPS	Body temperature, barometric pressure at sea level, saturated with water vapor.
C	Compliance.
Ccursors	Linear compliance between cursors 1 and 2, a calculated parameter displayed by the P/V Tool 2.
CE	A certification mark
cm	Centimeter, a unit of length.
cmH ₂ O	Centimeters of water, a unit of pressure. 1 cmH ₂ O is approximately equal to 1 mbar, which equals 1 hPa.
CMV	Controlled mandatory ventilation.
COPD	Chronic obstructive pulmonary disease.
CPAP	Continuous positive airway pressure.
CSA	Canadian Standards Association.
Cstat	Static compliance, a monitored parameter.

dB(A)	Decibel, a unit of acoustic power.
DIN	Deutsches Institut für Normung (German institute for standardization).
DISS	Diameter index safety standard, a standard for high-pressure gas inlet fittings.
DuoPAP	Duo positive airway pressure ventilation mode.
E	Exhalation.
EN	European Norm, a European standard.
End PEEP	PEEP to be applied after the maneuver, a control setting for the P/V Tool 2 maneuver.
ET	Endotracheal.
ETO	Ethylene oxide.
ETS	Expiratory trigger sensitivity, a control setting.
Exp Flow	Peak expiratory flow, a monitored parameter.
ExpMinVol	Expiratory minute volume, a monitored parameter and alarm setting.
fcombi	A parameter trend setting including both fControl and fSpont.
fControl	Mandatory breathing frequency, a monitored parameter in ASV mode.
FiO ₂	Fraction of inspired oxygen.
FlowPattern	Flow pattern, a control setting.
Flowtrigger	Flow trigger sensitivity, a control setting.
FRC	Functional residual capacity, the volume in the lungs at the end-expiratory position.
fSpont	Spontaneous breathing frequency, a monitored parameter.
fTotal	Total breathing frequency, a monitored parameter. The moving average of the patient's total breathing frequency over the past 8 breaths.

ft	Foot, a unit of length.
HME	Heat and moisture exchanger (artificial nose).
hPa	Hectopascal, a unit of pressure. 1 hPa is equal to 1 mbar, which is approximately equal to 1 cmH ₂ O.
Hz	Hertz, or cycles per second, a unit of frequency.
I	Inspiration.
Ix	Infant breathing set with x water trap(s).
IBW	Ideal bodyweight.
ICU	Intensive care unit.
ID	Inner diameter.
IEC	International Electrotechnical Commission.
I:E	Inspiratory:expiratory ratio, a setting, timing parameter, and monitored parameter. Ratio of inspiratory time to expiratory time.
IMV	Intermittent mandatory ventilation.
in.	Inch, a unit of length.
Insp Flow	Peak inspiratory flow, a monitored parameter.
inspiratory hold	A respiratory maneuver in which gas is retained in the patient's airways, often for X-raying purposes.
IRV	Inverse ratio ventilation.
ISO	International Standards Organization, a worldwide federation of national standards bodies.
J	Joule, a unit of work.
kg	Kilogram, a unit of mass.
kPa	Kilopascal, a unit of pressure.
l	Liter, a unit of volume.
l/min	Liters per minute, a unit of flow.

lb	Pound, a unit of weight.
limit variable	A variable (pressure, volume, or flow) that rises no higher than a preset value during inspiration, but that does not cause inspiration to be terminated just because the preset value is reached.
LSF	Least squares fitting, a mathematical procedure for finding the best fitting curve to a given set of points by minimizing the sum of the squares of the offsets of the points from the curve.
m	Meter, a unit of length.
manual breath	A user-triggered mandatory breath started by pressing the MANUAL key.
mbar	Millibar, a unit of pressure. 1 mbar equals 1 hPa, which is approximately equal to 1 cmH ₂ O.
MinVol	Minute volume, a calculated and monitored parameter used in ASV mode. Based on the operator-set %MinVol, the ventilator calculates the target MinVol in l/min, then measures and displays it in the ASV target window.
ml	Milliliter, a unit of volume.
MMP	Main monitoring parameters.
ms	Millisecond, a unit of time.
NIST	Non-interchangeable screw thread, a standard for high-pressure gas inlet fittings.
NIV	Noninvasive ventilation.
O ₂	Oxygen.
Oxygen	Oxygen concentration of the delivered gas, a setting and monitored parameter.
P0.1	Airway occlusion pressure, a monitored parameter.
Px	Pediatric breathing set with x water trap(s).
P-A/C	Pressure-controlled assist/control ventilation mode. Also called P-CMV.

Pause	Inspiratory pause, a control setting and timing parameter.
Paux	Auxiliary pressure.
Paw	Airway pressure.
P-CMV	Pressure-controlled mandatory ventilation mode. Also called P-A/C.
Pcombi	A parameter trend setting including Ppeak, Pmean, and PEEP/CPAP.
Pcontrol	Pressure control, a control setting in P-A/C (P-CMV) and P-SIMV modes. Pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
Pcursor	Monitored pressure at selected point, a displayed value when the P/V Tool's cursor measurement function is active.
Peak Flow	Maximum flow during the breath cycle, a control setting.
PEEP/CPAP	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), a control setting and monitored parameter. PEEP and CPAP are constant pressures applied during both the inspiratory and expiratory phases.
P high	High positive airway pressure level, a control setting.
Pinsp	Inspiratory pressure, the target pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase, in ASV mode.
PIP	Positive inspiratory pressure.
P low	Low positive airway pressure level, a control setting.
Pmean	Mean airway pressure, a monitored parameter.
Pminimum	Minimum airway pressure, a monitored parameter
P/N	Part number.
Ppeak	Peak airway pressure, a monitored parameter. The Pressure alarm uses Ppeak as its reference pressure.
Pplateau	Plateau airway pressure, a monitored parameter.

P-ramp	Pressure ramp, a control setting. It is the rise time for pressure in pressure-controlled and pressure-supported breaths.
Pressure	An alarm setting.
psi	Pounds per square inch, a unit of pressure.
P-SIMV	Pressure-controlled synchronized intermittent mandatory ventilation mode.
Pstart	Starting PEEP, a control setting for the P/V Tool 2 maneuver.
Psupport	Inspiratory pressure support, a control setting valid during SPONT breaths. Psupport is pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
Ptop	Pressure target, a control setting for the P/V Tool maneuvers.
PTP	Pressure time product, a monitored parameter.
P-trigger	Pressure trigger sensitivity, a control setting.
P/V Tool	Monitoring function used to record a “quasi-static” pressure-volume curve. The P/V Tool displays the inflation limb data only.
P/V Tool 2	Monitoring function used to record a “quasi-static” pressure-volume curve. The P/V Tool 2 is an advanced version of the P/V Tool, offering both inflation and deflation limb data.
Ramp speed	Rate of pressure change, a control setting for the P/V Tool maneuvers.
Rate	Number of breaths per minute, a control setting, alarm setting, and timing parameter.
RCexp	Expiratory time constant, a monitored parameter.
RCinsp	Inspiratory time constant, a monitored parameter.
RDS	Respiratory distress syndrome.
Rexp	Expiratory flow resistance, a monitored parameter.

Rinsp	Inspiratory flow resistance, a monitored parameter.
RSB	Rapid shallow breathing index, a monitored parameter.
s	Second, a unit of time.
(S)CMV	Synchronized controlled mandatory ventilation mode. Also called A/C.
sigh	Breaths delivered to deliberately increase tidal volume at a regular interval.
SIMV	Synchronized intermittent mandatory ventilation mode.
SPONT	Spontaneous pressure support mode of ventilation.
standby	The ventilator is in a waiting state, during which time there is no breath delivery.
STPD	Standard temperature and pressure, dry. Defined as gas at 0 °C (273 °K), barometric pressure at sea level, and dry.
TE	Expiratory time, a monitored parameter.
technical fault	A type of alarm, resulting because GALILEO's ability to ventilate safely is questionable.
Texp	Duration of expiratory phase, a timing parameter.
TF	Technical fault.
T high	Duration of high airway pressure level, a control setting.
TI	Inspiratory time, in s, a control setting and monitored parameter.
Ti max	Maximum inspiratory time in s, a control setting.
Tinfl	Inflation time, a calculated parameter displayed by the P/V Tool maneuver.
Tinsp	Duration of inspiratory phase, including any pause, a timing parameter.
Tip	Inspiratory pause time in s, a setting.
T low	Duration of low airway pressure level, a control setting.

Tmand	Time period for the mandatory breaths in the SIMV/P-SIMV breath interval.
Tpause	Pause to be applied at top pressure, a control setting for the P/V Tool 2 maneuver.
Trach tube	Tracheostomy tube.
TRC	Tube resistance compensation.
trend	The patient's data stored in the GALILEO for the last 1, 12, or 24 hours.
trigger	The patient's inspiratory effort, either flow or pressure, that causes the ventilator to deliver a breath.
Tspont	Time period for spontaneous breaths in the SIMV/P-SIMV breath interval.
Ttotal	Total breath cycle time, a timing parameter; or total maneuver time, a calculated parameter displayed by the P/V Tool 2 maneuver.
V	Volt, a unit of electric potential or volume.
VA	Volt-ampere, a unit of electric power.
VC	Vital capacity.
Vcursor	Delivered volume at selected point, a displayed value when the P/V Tool's cursor measurement function is active.
Vd	Dead space volume.
ventilator breathing system (VBS)	A breathing system bounded by the low-pressure gas input port(s), the gas intake port(s), and the patient connection port, together with the fresh-gas inlet and exhaust port(s), if fresh-gas inlet or exhaust ports are provided, as described in EN 794-1.
ventilation suppression	The ventilator is in a waiting state that lets you maintain ventilator settings for a very short time while the GALILEO is not performing any ventilatory functions. This mode is useful when preparing the ventilator before attaching it to a patient, during tracheal suctioning, or when changing a patient breathing circuit.

VLeak	Leakage volume, a monitored parameter.
Vpeep	PEEP volume, a calculated value displayed value by the P/V Tool maneuver or by the P/V Tool 2 maneuver when Pstart is zero.
Vt	Tidal volume, a control setting, an alarm setting, and a monitored parameter.
VTarget	Target volume, a control setting in the APV modes.
VTE	Expiratory tidal volume, a monitored parameter. It is the integral of all negative flow measurements during exhalation.
WOBimp	Work of breathing, a monitored parameter. The work performed by the patient to breathe through the ventilator's demand flow system, the breathing circuit, and the endotracheal tube.

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