



INTELLIVENT-ASV

Operator's Manual HAMILTON-C1/T1



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Operator's Manual INTELLIVENT-ASV

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Manufacturer

Hamilton Medical AG Via Crusch 8, CH-7402 Bonaduz Switzerland

Phone: (+41) 58 610 10 20 Fax: (+41) 58 610 00 20 info@hamilton-medical.com www.hamilton-medical.com

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About this guide

This guide describes the features and functions of INTELLIVENT-ASV for HAMILTON-C1/T1, and is designed for use with the following documentation:

- Your ventilator Operator's Manual
- Pulse oximetry Instructions for use for your ventilator

Conventions used in this guide

In this manual:

- Button and tab names are shown in a bold font.
- The notation **XX** > **XX** shows the sequence of buttons/tabs to touch to open the associated window.
 - For example, the text "Touch System > Settings" means touch the System button, then touch the Settings tab.
- Window names are shown using the sequence of buttons/tabs used to open them.
 - For example, "Alarms > Limits 1 window" refers to the window is accessed by touching the Alarms button, then the Limits 1 tab.
- Units of measure: Pressure is indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). The units of measure for pressure and length are configurable.
- A green check mark or button
 xxx indicates a selected item or feature.

- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
 - 1 These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts
 - These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- PI and PVI¹ are only available only with a Masimo SET[§] pulse oximeter.
- The ability to set a minimum Oxygen limit (between 21% and 30%) is not available in all markets.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

Safety messages are displayed as follows:

↑ WARNING

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

¹ Available as an option.

A 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.

NOTICE

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

⚠ WARNING!

⚠ CAUTION!

! NOTICE!

In our manuals, we refer to active and passive patients.

 An active patient is one who is making inspiratory efforts.

Active breathing is identified as the occurrence of at least five (5) consecutive spontaneous breaths. Spontaneous breaths are those for which inspiration is both patient triggered and patient cycled.

In addition to spontaneous breaths as described, an *active* patient must also meet the requirements described in Section 1.7.3.

 A passive patient is one who is not making inspiratory efforts.

Passive breathing is identified as the occurrence of at least five (5) consecutive mandatory breaths. In general, mandatory breaths are those for which inspiration is either machine triggered or machine cycled. In INTELLIVENT-ASV, mandatory inspirations are both machine triggered and machine cycled. In addition to mandatory breaths as

In addition to mandatory breaths as described, a *passive* patient must also meet the requirements described in Section 1.7.3

INTELLIVENT-ASV

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1.1 Overview

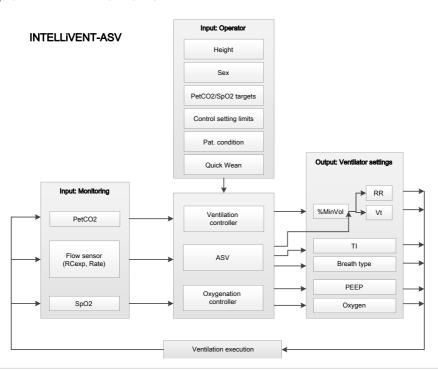
INTELLIVENT-ASV is an advanced ventilation mode, based on the proven Adaptive Support Ventilation (ASV) mode, to automatically regulate CO2 elimination and oxygenation for both *passive* and *active* patients, using both physiologic data from the patient and clinician-set targets and limits.

With this mode, the clinician sets targets for PetCO2 and SpO2, as well as limits for various controls, including PEEP and Oxygen, for the patient. INTELLIVENT-ASV then manages the controls for CO2 elimination (%MinVol), and oxygenation (PEEP and Oxygen) based on these targets, clinician-defined limits, and on the physiologic input from the patient (PetCO2 and SpO2).

INTELLIVENT-ASV continuously monitors patient conditions and automatically and safely adjusts parameters to keep the patient within target ranges, with minimal clinician interaction, from intubation until extubation.

When enabled, INTELLIVENT-ASV can also help promote early weaning with the Quick Wean feature. See Section 2.1.

Figure 1-1. INTELLiVENT-ASV workflow



For detailed information about how INTELLIVENT-ASV regulates these parameters, see:

- Section 1.7, Management of minute volume
- Section 1.8, Management of PEEP and Oxygen
- For details on the ASV mode, see your ventilator Operator's Manual

Before using INTELLIVENT-ASV, be sure to review the indications and contra-indications for use, as well as all safety-related messages.

1.2 Indications and contraindications for use

Indications for use

NOTICE

- Use INTELLIVENT-ASV for adult and pediatric patients only.
- Use INTELLIVENT-ASV for intubated patients only.
- Automated oxygenation control is only available when using HPO as the oxygen source.
- Be sure you are familiar with the use of the CO2 and SpO2 sensors. See your ventilator Operator's Manual, the Pulse Oximetry Instructions for Use, and documentation provided with the sensors.

INTELLIVENT-ASV is designed for use with all adult and pediatric patients with an ideal body weight (IBW) of 7 kg or more. It is *not* available for neonatal applications. INTELLIVENT-ASV can be used in the hospital and during intra- and interhospital transport.

Contraindications for use

M WARNING

Do not use the INTELLIVENT-ASV automatic PEEP/Oxygen adjustment if dyshemoglobin is expected or clearly evidenced, or if the difference between SaO2 and SpO2 is greater than 5%².

A CAUTION

Do NOT use SpO2 measurement and automated PEEP/Oxygen adjustments with patients being treated with intravenous dyes.

Do NOT use INTELLIVENT-ASV if:

- The patient IBW is under 7 kg
- There is high airway leakage (NIV or broncho-pleural fistula)
- Irregular drive, for example, Cheyne-Stokes respiration
- The INTELLIVENT-ASV target ranges for PetCO2 and SpO2 cannot be set according to your hospital protocol or to the patient's condition

² You can compensate for differences between SaO2/SpO2 and PaCO2/PetCO2 up to set limits. For details, see information about Target shift.

1.3 Preparing for ventilation with INTELLiVENT-ASV

↑ WARNING

- Additional ventilator-independent patient monitoring (for example, bedside vital monitoring or a blood gas analyzer) must be used during INTELLi-VENT-ASV ventilation.
 - Check PaCO2 against displayed PetCO2, and SaO2 against SpO2.
- The physician is responsible for deciding which settings are managed by INTELLIVENT-ASV, the acceptable ranges, and alarm limits.

Preparing for ventilation with INTELLIVENT-ASV comprises the following steps.

Table 1-1. Preparing for ventilation with INTELLiVENT-ASV, overview

То	See
Set up and enable the CO2 and SpO2	• Ventilator Opera- tor's Manual
sensors	 Pulse oximetry documentation
	• CO2 documentation
Prepare the ventilator for operation, includ-	• Ventilator Opera- tor's Manual
ing performing the preoperational check	• Preoperational Check Quick Ref- erence
Set up and connect the patient	Ventilator <i>Operator</i> 's <i>Manual</i>
Specify and confirm INTELLIVENT-ASV settings	Section 1.4
Start ventilation and monitor the patient	Ventilator <i>Operator</i> 's <i>Manual</i>

1.4 Specifying INTELLiVENT-ASV settings

Once the ventilator is ready for use and all preoperational tests are successfully completed, you are ready to set up INTELLIVENT-ASV for use.

The INTELLIVENT-ASV Settings window allows you to:

- Set the control management strategy (Automatic or Manual)
- If applicable, select one or more conditions that apply to the patient (for example, ARDS)
- Review SpO2 and PetCO2 target ranges, and adjust if needed
- Enable or disable Quick Wean
- Set Oxygen and PEEP limits for the Oxygenation controller (if set to Automatic)
- Fine-tune %MinVol, PEEP, and Oxygen settings

Figure 1-2. INTELLiVENT-ASV Settings window



Navigating the INTELLIVENT-ASV Settings window

Navigating the window differs depending on whether you are setting up INTELLi-VENT-ASV for the first time for the current patient or you are adjusting settings during active INTELLIVENT-ASV ventilation.

- When you first select the INTELLIVENT-ASV mode, you are guided through the setup process to enter patient information and adjust the INTELLIVENT-ASV settings as required for the patient. The setup process then prompts you to fine-tune any control settings, and review and adjust alarm limits. You are prompted to confirm the settings on each window.
- When displayed:
 - Touching **Back** returns you to the previously displayed window.
 - Touching × or Cancel, or doing nothing for 1 minute, closes the **INTELLIVENT-ASV Settings** window and returns you to the previously selected mode.
- During active ventilation, you can access the INTELLIVENT-ASV Settings window at any time to make further adjustments. All of the tabs in the window are available and function the same way as during initial setup, except that there are no navigation buttons. Changes are applied as soon as you make them. For details, see Section 1.4.10.

You can also adjust control settings and alarm limits at any time, same as with any other ventilation mode.

Specifying INTELLIVENT-ASV settings

Specifying settings comprises the following steps.

Table 1-2. Specifying INTELLIVENT-ASV settings

То	See
Specify the patient settings in the Standby window.	Section 1.4.1
Select the INTELLIVENT-ASV mode.	Section 1.4.2
Select control management options (Auto or manual).	Section 1.4.3
Select a specific condition (ARDS, Brain Injury, Chronic Hypercapnia), if applicable.	Section 1.4.4
Enable or disable Quick Wean.	Section 1.4.5
Review and adjust target ranges, if needed.	Section 1.4.6
Specify additional settings (minimum Oxygen limit, upper and lower PEEP limits).	Section 1.4.7
Review and adjust control settings.	Section 1.4.8
Review and adjust alarm limits.	Section 1.4.9
Adjust settings during active ventilation, if needed.	Section 1.4.10

1.4.1 Specifying patient data

NOTICE

When coming from Standby and Last patient is selected, the last-used settings are active, including patient height and sex, alarm limits, and control settings.

To specify patient data

In the Standby window, choose the correct patient group, sex, and height. If needed, you can adjust these settings during ventilation in the Controls > Patient window

Figure 1-3. Controls > Patient window



Be sure the patient data is accurate. It is used to calculate the patient's IBW, which is used by the INTELLIVENT-ASV controllers to regulate ventilation parameters.

You can fine-tune the settings at a later time, if needed.

For additional information, see your ventilator *Operator's Manual*.

1.4.1.1 Notes about exiting Standby

When starting ventilation from Standby with a new patient selected and activating INTELLiVENT-ASV, the controllers (%MinVol, PEEP, and Oxygen) are set to default settings.

If you select Last patient in the Standby window and start ventilating the patient, the system assumes the same settings that were in place before entering Standby.

1.4.2 Selecting the INTELLiVENT-ASV mode

INTELLIVENT-ASV is an option in the ventilator Modes window

To select the INTELLIVENT-ASV mode

- 1. Open the **Modes** window by doing any of the following:
 - Touch the mode name at the top left of the display.
 - Touch the **Modes** button at the top right of the display.
- 2. In the Modes window, touch INTELLi-VENT-ASV.
- 3. Touch Confirm.

The INTELLIVENT-ASV Settings window opens, displaying the **Auto** tab (Figure 1-4).

You can now configure INTELLIVENT-ASV options. Continue to the next section, Selecting control management options.

1.4.3 Selecting control management options (Auto/Manual)

NOTICE

- Only Manual mode is available for all controls when the patient IBW is below 7 kg. (INTELLIVENT-ASV is designed for use only with adult and pediatric patients with an IBW of 7 kg or more.)
- Only Manual mode is available for %MinVol when the CO2 sensor hardware option is deactivated in Configuration.³
- Only Manual mode is available for PEEP when:
 - Either the Chronic Hypercapnia or Brain Injury condition is selected.
 - If Chronic Hypercapnia and ARDS are both selected, PEEP management can be set to Automatic.
 - The SpO2 sensor hardware option is deactivated in Configuration.³
- Only Manual mode is available for Oxygen when the SpO2 sensor hardware option is deactivated in Configuration ³

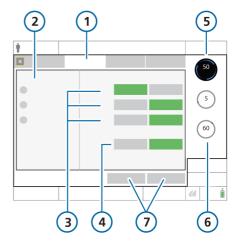
Use the INTELLIVENT-ASV Settings > Auto window to:

 Specify whether adjustments of one or more of the following controls should be performed automatically by the device or manually by the clinician: %MinVol, PEEP, and Oxygen

Sections 1.7 and 1.8 in this guide provide detailed information about how INTELLIVENT-ASV automatically regulates these controls.

- Select one or more conditions (ARDS, Brain injury, or Chronic Hypercapnia)
- Enable or disable Quick Wean

Figure 1-4. INTELLIVENT-ASV Settings window, Auto tab



- 1 Auto
- 5 Automated management indicator and parameter value
- 2 Specific conditions
- 6 Manual management indicators and parameter value
- 3 Controller settings: Automatic or Manual for %MinVol, PEEP/CPAP, Oxygen
- 7 Cancel/Continue (if displayed)

⁴ Quick Wean settings: Automatic, Disabled

³ When sensor hardware is activated in Configuration, selecting automatic management of the %MinVol, PEEP, and/or Oxygen control in INTELLIVENT-ASV automatically enables the associated CO2 and/or SpO2 sensor in the System > Sensors window. If a sensor is not connected, a medium-priority sensor-related alarm is generated.

NOTICE

- When setting PEEP and/or Oxygen to Automatic, you can specify limits that the controllers cannot exceed. These limits are set in the INTELLIVENT-ASV Settings > More window. For details, see Section 1.4.11.
- By default, all controllers are set to Manual control when first setting up INTELLIVENT-ASV.

To select management options (Auto/ Manual) for %MinVol, PEEP, and Oxygen

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- For each of the controls, %MinVol, PEEP, and Oxygen, choose whether they are managed automatically by the device or manually by the operator as follows:
 - Touch Automatic 4 to have INTELLIVENT-ASV automatically regulate the control setting to keep the patient within the target range.
 - If needed, touch Manual to manually adjust the control setting as appropriate. The ventilator does **not** make any adjustments to control settings in response to changes in the patient condition; settings are changed by the ventilator operator.
 - The selected button turns green.
- Continue to Section 1.4.4 to select a specific condition (such as ARDS), if needed.
 - Otherwise, continue to step 4.

- Continue to Section 1.4.5 to enable or disable Quick Wean, if needed.
 Otherwise, continue to step 5.
- Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen), and make adjustments, if needed.
- 6. If displayed, touch **Continue** to accept the settings and proceed to Section 1.4.6, *Reviewing SpO2 and PetCO2 target ranges*.

1.4.4 Adjusting for specific conditions

If appropriate for the patient, you can select one or more of the following conditions, ARDS, Chronic Hypercapnia, and Brain Injury in the Auto window, under Specific conditions.

Selecting a condition affects ventilation and oxygenation startup values and target ranges, as well as the upper and lower target shift limits. For details, see Section 1.4.11.1.

When selecting a condition, control settings are automatically updated in real-time. The changes are reflected in the control values shown on the right side of the display (%MinVol, PEEP/CPAP, Oxygen), as well as in the target zone of the associated CO2 elimination and Oxygenation maps shown in the Target window (Figure 1-6).

To select a specific condition

- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).

⁴ When sensor hardware is activated in Configuration, selecting automatic management of the %MinVol, PEEP, and/or Oxygen control in INTELLIVENT-ASV automatically enables the associated CO2 and/or SpO2 sensor in the System > Sensors window. If a sensor is not connected, a medium-priority sensor-related alarm is generated.

- 2. Before proceeding, be sure to read the safety information related to specific conditions, in Section 1.4.11.1.
- 3. *Only* if the patient has any specific conditions, select the appropriate entry(ies): ARDS, Brain Injury, or Chronic Hypercapnia.



If the patient does *not* have a specific condition, proceed to step 4.

Selecting a condition may change the startup settings and targets for CO2 elimination and/or oxygenation, and can affect whether regulation of PEEP can be set to Automatic. It may also affect whether Quick Wean can be enabled. See Table 1-5 for details.

The Oxygenation and CO2 elimination maps in the Target window show the associated SpO2 and PetCO2 target ranges based on the condition(s) (or no condition) selected in the Auto window

You review these ranges in the procedure that follows

4. Continue to Section 1.4.3 to select control management options, if needed

Otherwise, continue to step 5.

- 5. Continue to Section 1.4.5 to enable or disable Quick Wean, if needed. Otherwise, continue to step 6.
- 6. Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen) and, if needed, make any adjustments.
- 7. If displayed, touch **Continue** to accept the settings and proceed to Section 1.4.6, Reviewing SpO2 and PetCO2 target ranges.

1.4.5 Enabling or disabling Quick Wean

NOTICE

Ouick Wean remains disabled when either of the following occurs:

- The Brain injury condition is selected
- %MinVol is set to Manual

When Quick Wean is enabled, the target range of acceptable PetCO2 values is permanently shifted up to +5 mmHg to the right to support spontaneous breathing. The ventilator also continuously screens the readiness-to-wean criteria. These parameters are displayed in the Quick Wean panel in view 5.

When the patient becomes active, so long as they meet the required criteria as described in Section 2.2, the ventilator gradually reduces %MinVol to 70%. In addition, the target respiratory Rate range is also increased. For details, see Section 172

By default, Quick Wean is disabled when first setting up INTELLIVENT-ASV.

Figure 1-5. Quick Wean options in the INTELLi-VENT-ASV Settings > Auto window



To enable or disable Quick Wean

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- 2. To enable or disable Quick Wean, select one of the following options:

To enable Quick Wean, touch Automatic.

A low-priority alarm, PetCO2 target range changed, is generated, indicating that Quick Wean is enabled and the target range is moved +5 mmHg (+0.67 kPa) to the right.

If needed, disable Quick Wean by

touching Disabled.

The selected button turns green.

 Continue to Section 1.4.3 to select control management options, if needed.

Otherwise, continue to step 4.

- Continue to Section 1.4.4 to select a condition (ARDS, Brain Injury, and/or Chronic Hypercapnia), if appropriate. Otherwise, continue to step 5.
- Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen), and make adjustments, if needed.
- 6. If displayed, touch **Continue** to accept the settings and proceed to Section 1.4.6, *Reviewing SpO2 and PetCO2 target ranges*.

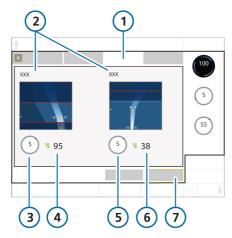
1.4.6 Reviewing SpO2 and PetCO2 target ranges

INTELLIVENT-ASV uses SpO2 and PetCO2 target ranges as inputs (upper and lower limits), among others, for dynamic management of controls.

Use the Target window to review the configured SpO2 and PetCO2 target ranges, and adjust them, if needed.

Use the **Target Shift** controls to change either range, if needed. For additional details about target shift, see Section 1.4.11.2.

Figure 1-6. INTELLIVENT-ASV Settings window, Target tab



1 Target

ranges

- 5 Target Shift control (PetCO2)
- 2 Oxygenation map (left), CO2 elimination map (right)
- 6 Current PetCO2 value and quality index
- 3 Target Shift control (SpO2)
- 7 Back/Continue (if displayed)
- 4 Current SpO2 value and quality index
- To review the SpO2 and PetCO2 target
- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 3.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- 2. To display the SpO2 and PetCO2 target ranges, touch the Target tab (Figure 1-6).

- 3. Carefully review the target ranges. Selecting a condition in the Auto window affects the default SpO2 and PetCO2 target ranges, as well as the upper and lower target shift limits. The Oxygenation map shows the SpO2 target range; the CO2 elimination map shows the PetCO2 target range.
- 4. If needed, make adjustments using the appropriate **Target Shift** control, as described in the procedures that follow
- 5. When finished, if displayed, touch **Continue** to accept the settings. Proceed to the next section, as follows.
 - If PEEP and/or Oxygen are set to Automatic, touching Continue displays the More window. Proceed to Section 1.4.7, Specifying additional settings.
 - If both PEEP and Oxygen are set to Manual, touching Continue displays the Controls window. Proceed to Section 1.4.8, Adjusting control settings.

To adjust the SpO2 target range

For details on target shift limits associated with specific conditions, see Tables 1-6 and 1-7

1. Under the Oxygenation map, touch Target Shift next to the SpO2 value.

The button turns orange, and the limits appear on either side of the control

Oxygenation



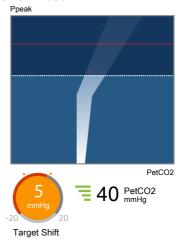


- 2. Turn the P&T knob clockwise or counterclockwise to move the target range as described below, then press the P&T knob to accept the setting. The control turns gray again.
 - Setting the value to a positive number moves the target range to the right, targeting a higher SpO2.
 - Setting the value to a negative number moves the target range to the left, targeting a lower SpO2.

To adjust the PetCO2 target range

 Under the CO2 elimination map, touch Target Shift next to the PetCO2 value. The button turns orange, and the limits appear on either side of the control.

CO₂ elimination



- Turn the P&T knob clockwise or counterclockwise to move the target range as described below, then press the P&T knob to accept the setting. The control turns gray again.
 - Setting the value to a positive number moves the target range to the right, targeting a higher PetCO2.
 - Setting the value to a negative number moves the target range to the left, targeting a lower PetCO2.
- 3. To shift the PetCO2 target range to a value beyond ±5 mmHg:
 - a. Set the value now to +5 or -5, as needed, and press the P&T knob to accept the value.
 - b. Touch the **Target Shift** control again and set the value beyond ±5, as needed, and press the P&T knob to accept the value.

22

1.4.7 Specifying additional settings

If you set the PEEP and/or Oxygen controls to Automatic in the Auto window, the **More** tab becomes available, providing access to additional options:

- When PEEP is set to Automatic, you can set an upper and/or lower PEEP limit for the PEEP controller
- When Oxygen is set to Automatic, you can set the minimum Oxygen level for the Oxygen controller

The Oxygenation map is displayed when you open the More window.

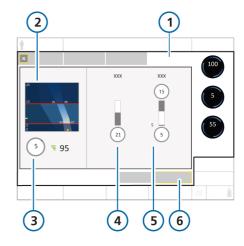
If both controls are set to Manual, the More tab is disabled. In this case, clicking Continue in the Target window opens the Controls window.

Table 1-3. More tab settings

Setting	Description
Oxygen limit (%)	When the Oxygen control is set to Automatic, you can set an absolute lower limit that the Oxygen controller cannot fall below.
	The limit can be set between 21% (the default) and 30%. For details, see Section 1.4.11.3.

Setting	Description
PEEP limit (cmH2O)	When the PEEP control is set to Automatic, you can set an absolute upper limit that the PEEP controller cannot exceed, as well as an absolute lower limit that it cannot fall below. The minimum difference allowed between the low and high limit is 2 cmH2O.
	You can set a range of values between 5 and 24 cmH2O. By default, the lower limit is set to 5, and the upper limit is set to 15. For details, see Section 1.4.11.4.

Figure 1-7. INTELLiVENT-ASV Settings window, More tab



- 1 More
- 4 Oxygen limit*
- 2 Oxygenation map
- 5 PEEP limit*
- 3 SpO2 Target Shift control
- 6 Back/Continue (if displayed)

^{*} The PEEP and/or Oxygen limit control is displayed only when the associated controller (PEEP, Oxygen) is set to Automatic.

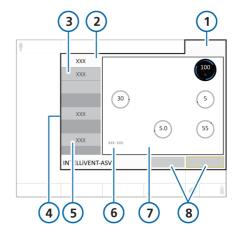
To set a minimum/maximum PEEP and/or minimum Oxygen limit

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 3.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- 2. Touch the **More** tab (Figure 1-7).
- Set options as specified in Table 1-3, if needed.
 - If not needed, continue to step 4.
- 4. If displayed, touch **Continue** to accept the settings and proceed to Section 1.4.8, *Adjusting control settings*.

1.4.8 Adjusting control settings

As with other modes, you can adjust control settings for INTELLIVENT-ASV. The controls are the same as in the ASV mode.

Figure 1-8. INTELLIVENT-ASV Controls window, Basic tab



- I Modes
- 5 Target
- 2 Basic
- 6 Current minute volume
- 3 More
- Controls: Plimit, Flow trigger, %MinVol, PEEP/CPAP, Oxygen

In More window: P-ramp,

ETS, Sigh

4 Patient

8 Cancel/Confirm (if displayed

Reviewing and possibly adjusting the control settings is part of the INTELLIVENT-ASV setup process. You can also adjust settings at any time during ventilation.

To review and adjust INTELLiVENT-ASV control settings

- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process⁵, start with step 2.
- 1. To open the Controls window, touch the Controls button at the bottom right of the display.
 - The **Basic** tab (Figure 1-8) is displayed.
- 2. Adjust any settings as needed.
- 3. Touch the **More** tab to review or adjust additional settings.
- 4. Touch the **Patient** tab (Figure 1-3) to review patient data (height, sex), and ensure the correct IBW is calculated.
 - You can also access the Patient window by touching the Patient icon at the top left of the display, next to the mode name.
- 5. The **Target** button is displayed during active INTELLIVENT-ASV ventilation: touching the button displays the INTELLiVENT-ASV Settings > Target window
- 6. If displayed, touch **Confirm** to accept the settings and proceed to Section 1.4.9, Reviewing and adjusting alarm limits

1.4.9 Adjusting alarm limits

WARNING

- Set all alarms to clinically acceptable values, especially Pressure, ExpMinVol, Vt, Oxygen msg, SpO2, and PetCO2.
- To prevent patient injury, periodically review all alarm settings.

NOTICE

You can suppress the PetCO2 and SpO2 alarms for 2 minutes by pressing the Audio pause key, in the same manner as other alarms on the ventilator.

For details, see the chapter, Responding to alarms, in your ventilator Operator's Manual.

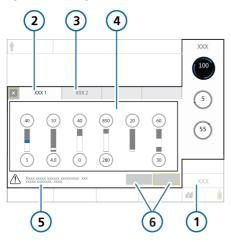
As with other modes, you can adjust alarm limits for INTELLIVENT-ASV, including for SpO2 and PetCO2 levels. The adjustable alarms are accessed on multiple tabs in the Alarms window.

For additional information:

- For troubleshooting, see Section 1.6.
- For detailed information about alarms, including default settings and ranges, see your ventilator Operator's Manual and the Pulse Oximetry Instructions for Use.

⁵ The Controls window is displayed when you touch Continue in the INTELLIVENT-ASV Settings > More window, when available. If both the PEEP and Oxygen controllers are set to Manual, the More window is disabled; in this case, touching Continue in the INTELLIVENT-ASV Settings > Target window displays the Controls window.

Figure 1-9. Setting alarm limits



- 1 Alarms
- 4 Alarm limit controls
- 2 Limits 1
- 5 Safety information
- 3 Limits 2
- 6 Cancel/Confirm (if displayed)

To adjust INTELLiVENT-ASV alarm limits

- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- To open the Alarms window, touch the Alarms button at the bottom right of the display.

The **Limits 1** tab (Figure 1-9) is displayed.

- 2. Adjust any alarm limits as needed.
- 3. Touch the **Limits 2** tab to review and adjust additional alarm limits.
- 4. If displayed, touch **Confirm** to accept the settings.

INTELLIVENT-ASV setup is now complete.

1.4.10 Adjusting settings during active ventilation

During active ventilation, you can adjust INTELLIVENT-ASV settings at any time.

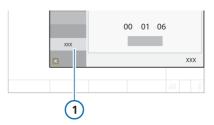
You can also review patient information in multiple scrollable views. For details, see Section 1.5.1.

During active ventilation, all of the tabs in the INTELLiVENT-ASV Settings window are available and function the same way as during initial setup, except that there are no Cancel/Back, Continue/Confirm buttons. Changes are applied as soon as you make them.

You can also adjust control settings and alarm limits at any time, same as with any other ventilation mode. For details, refer to your ventilator *Operator's Manual*.

To adjust INTELLIVENT-ASV settings during ventilation

- At any time during ventilation with INTELLIVENT-ASV, do any of the following:
 - Touch the INTELLIVENT-ASV mode name at the top left of the display.
 - Touch an automated controller on the right of the display, if available.
 - In the Controls window, touchTarget (1) in the left pane.



The INTELLIVENT-ASV Settings window opens.

- Make changes as needed in each window, touching the tabs to display each one; close the window when finished.
 - Changes are applied immediately.
- To review or change control settings, touch Controls and make changes, as needed.
- To review or change alarm settings, touch **Alarms** and make changes, as needed.

1.4.11 About INTELLIVENT-ASV settings

This section provides details about the following additional INTELLIVENT-ASV features:

Settings	See
Specific conditions	Section 1.4.11.1
Target shift	Section 1.4.11.2
Oxygen limit	Section 1.4.11.3
PEEP limit	Section 1.4.11.4
Oxygen level notification (Oxygen msg %)	Section 1.4.11.5

1.4.11.1 How the Specific conditions selections are used

MARNING

- To prevent possible hyper- or hypoventilation, or hyper- or hypoxemia, ensure the patient data is accurate.
- If Brain Injury is selected but the patient is to be ventilated normally, the patient will be slightly hyperventilated and increased peak pressures might occur.

⚠ CAUTION

- Select the Chronic Hypercapnia and/or ARDS condition only if the patient has one of these conditions; in case of doubt, do NOT select either of these options.
- Always select Brain Injury if you are sure that the patient has this condition. If the patient suffers from a brain injury but the Brain Injury option is not selected, increased CO2 levels and high cranial pressure might result. Carefully monitor intracranial pressure when available.

NOTICE

- If Brain Injury is selected, the Ventilation controller (%MinVol) regulates settings in accordance with the measured PetCO2 signal even if the patient is breathing spontaneously.
- The Brain Injury target range has the highest priority of all conditions.
- If either the Chronic Hypercapnia or Brain Injury condition is selected, management of PEEP cannot be set to Automatic; you must manually set the desired PEEP level.
- If Chronic Hypercapnia and ARDS are both selected, PEEP management can be set to Automatic.

The selection of a specific condition is used in INTELLIVENT-ASV to determine:

- Startup settings to use for %MinVol, PEEP, and Oxygen
- Whether PEEP can be set to Automatic or must be manually controlled
- SpO2 and PetCO2 target ranges, and upper and lower target shift limits
- %MinVol for active patients, based on fSpont or PetCO2 (if Brain Injury is selected)
- Whether or not Quick Wean can be activated

For details about selecting a condition, see Section 1.4.4. For patients with mixed conditions, you can select more than one.

Table 1-4 lists the conditions available in the INTELLIVENT-ASV Settings > Auto window.

Table 1-4. Specific conditions, description

Condition	Description
Normal	No condition selected
ARDS	Acute respiratory distress syndrome, which presents as an acute, severe injury to most segments of the lung
Brain Injury	Patients with brain injuries for whom it is critical to maintain CO2 under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range
Chronic Hypercapnia	For patients with chronically high arterial CO2 values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both
Mixed (ARDS and Chronic Hypercapnia)	For patients with both listed conditions. In this case, select both entries.

Table 1-5 provides an overview of the values set for startup and during ventilation. Startup values depend on the condition(s) selected.

For details about changing the SpO2 or PetCO2 target ranges, see Section 1.4.11.2.

In all cases, Quick Wean is disabled at startup.

	Ventilation	Oxygenation	
Condition	%MinVol startup (%)	Oxygen startup (%)	PEEP startup (cmH2O) ⁶
Normal	100	60	5
ARDS	120	100	8
Chronic Hypercapnia	100	60	Manual
ARDS + Chronic Hypercapnia	120	100	8
Brain Injury	100	60	Manual

Table 1-5. Specific condition selections and their startup values for ventilation

As long as Brain Injury is selected, Quick Wean remains disabled

1.4.11.2 Adjusting the SpO2/PetCO2 target range (Target Shift)

CAUTION

- Regularly check the patient after changing the SpO2 or PetCO2 target range to verify that the range is still appropriate for the patient's current condition
- Changing the target range and NOT monitoring the patient's progress can increase risk of hyper- or hypoventilation or hyper- or hypoxemia.

INTELLIVENT-ASV uses SpO2 and PetCO2 as monitoring inputs for regulation of oxygenation and CO2 elimination, and works to keep the patient within the target range for these values.

These target ranges are shown in the Oxygenation and CO2 elimination maps and horizons. INTELLIVENT-ASV adjusts

oxygenation and CO2 elimination controls to bring the patient to the middle of the set range.

In general, SpO2 and PetCO2 values represent a reliable index of partial pressure of dissolved oxygen in the arterial blood (PaO2) and CO2 partial pressure in the arterial blood (PaCO2), respectively (measured using blood gas analysis (BGA)). To get the most accurate approximation of PaCO2, the second highest PetCO2 value (with a reliable quality index) out of 8 breaths is used.

Under normal conditions, PaCO2 is approximately 2-5 mmHg higher than PetCO2; the difference between the values is referred to as the PaCO2-PetCO2 gradient. With diseased or injured lungs, the PaCO2-PetCO2 gradient can increase due to ventilation-perfusion mismatch, requiring adjustment of the PetCO2 targets.

The **Target Shift** control allows you to move the SpO2 and PetCO2 target ranges to the left (lower values) or to the right (higher values), within the limits defined in Tables 1-7 and 1-6

⁶ The control of settings not explicitly marked as Manual can be set to Automatic.

INTELLIVENT-ASV always tries to bring patient values to the middle of the specified range.

Considerations for evaluating the PetCO2 target range

When determining the appropriate PetCO2 target range for your patient, keep the following considerations in mind (with examples):

- Is the displayed PetCO2 target range appropriate for your patient?
- Is the PaCO2-PetCO2 gradient outside of the physiologic normal range?

To get the most appropriate PetCO2 target range, a BGA is required. Collect the BGA sample when the patient's current PetCO2 is in the middle of the target range.

Check whether one of the Specific conditions entries applies to your patient. If so, select the condition. If the range is still inadequate for your patient, use the Target Shift control to adjust the target range as needed to set the appropriate limits.

To evaluate and adjust the PetCO2 target range

- 1. Measure the difference between current PaCO2 and the desired PaCO2.
- Adjust the PetCO2 target range by the same value as the difference between the current and the desired PaCO2.
- If the desired PaCO2 is less than the current value, move the PetCO2 target range to the left.
- 4. If the desired PaCO2 is higher than the current value, move the PetCO2 target range to the right.

Example 17

Say the patient's BGA with PetCO2 in the middle of the target range is 45 mmHg, shows a PaCO2 of 55 mmHg, and the physician-desired PaCO2 is 45 mmHg.

What is a good PetCO2 target range for this patient?

The difference between the current and desired PaCO2 is 55 - 45 = 10

The desired PaCO2 is lower than the current value, so the PetCO2 target range should be shifted to the *left* by 10.

The desired PetCO2 (45 - 10 = 35) will be the middle of the new target range.

Example 27

Say the patient's BGA with PetCO2 in the middle of the target range is 35 mmHg, shows a PaCO2 of 42 mmHg, and the physician-desired PaCO2 is 50 mmHg.

What is a good **PetCO2** target range for this patient?

The difference between the current and desired PaCO2 is 50 - 42 = 8

The desired PaCO2 is higher than the current value, so the PetCO2 target range should be shifted to the *right* by 8.

The desired PetCO2 (35 + 8 = 43) will be the middle of the new target range.

INTELLIVENT-ASV makes adjustments to get the patient's PetCO2 values to the middle of the target range, which in this case should result in PaCO2 values within the desired 40 to 50 mmHg target PaCO2.

You can adjust the **SpO2** target range in the same manner.

⁷ The example situations and values provided here are for illustration purposes only; they are *not* intended to be used as clinical recommendations or guidelines.

Table 1-6. SpO2 target shift limits

SpO2 target shift limits ⁸	
Normal (no condition selected)	-5% to +4%
ARDS	-2% to +4%
Chronic Hypercapnia	-2% to +5%
Mixed (Chronic Hypercap- nia + ARDS)	-2% to +5%
Brain Injury	-5% to +2% ⁹

Table 1-7. PetCO2 target shift limits

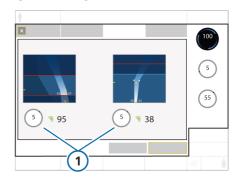
PetCO2 target shift lin	
All conditions	-20 mmHg to
All collations	20 mmHg ¹⁰

To access the SpO2 and PetCO2 Target **Shift controls**

The Target Shift controls are under the associated Oxygenation and CO2 elimination maps in the INTELLiVENT-ASV Settings > Target window.

For details, see Section 1.4.6.

Figure 1-10. Target Shift controls (1)



The PetCO2 Target Shift value and text is displayed in different colors depending on the setting.

Table 1-8. Target shift display

Shift control	rext color and description
O xx xxx	Black text. Target shift is 0; there is no change to the target range values.
5 xx	Yellow text. Target shift is between ±1 and ±5.
-10 xx	Orange text. Target shift is greater than ±5.

⁸ If changing a condition selection causes the existing limits to be exceeded, the target shift is automatically adjusted to comply with the limits for the newly selected condition.

⁹ In some markets, the lower target shift limit is -2%.

¹⁰ In some markets, the upper target shift limit is 10 mmHg.

1.4.11.2.1 About the Target Shift display on the horizons

The Oxygenation and CO2 elimination horizons display the associated Target Shift setting as follows.

Table 1-9. Target Shift setting in Oxygenation and CO2 elimination horizon display

and CO2 emmination nonzon display	
Target Shift setting	Display in Horizon
Target Shift: 0 indicates the target range is unchanged.	In this example, no target shift is set.
	Target Shift: 0
Target Shift: n > indicates the range is shifted to the right.	In this example, the setting is +2. Target Shift: 2 > 95 99
Target Shift: < n indi- cates the range is shifted to the left.	In this example, the setting is -2. Target Shift: < 2

1.4.11.3 Minimum Oxygen limit

When the Oxygen controller is set to Automatic, you can set an absolute lower limit for Oxygen; the Oxygen controller does not allow Oxygen to go below this limit.

To set the minimum Oxygen limit

In the INTELLIVENT-ASV Settings > More window, set the limit to any value between 21% and 30%. See Section 1.4.7

The default setting is 21%.

1.4.11.4 PEEP limit

When the PEEP controller is set to Automatic, the PEEP limit control allows you to define an absolute high limit that the PEEP controller cannot exceed. If enabled, you can also specify an absolute low limit for PEEP; the PEEP controller cannot fall below this limit, listed in Table 1-10.

Note that the minimum difference between the low and high limit is 2 cmH2O

Table 1-10. PEEP limit control settings

PEEP limit control range (cmH2O)	Default (cmH2O)
Low: 5 to 22	Low: 5
High: 7 to 24	High: 15

If the Chronic Hypercapnia or Brain Injury condition is selected, you must set PEEP manually.

To set PEEP limits

 In the INTELLIVENT-ASV Settings > More window, set the desired high and/or low PEEP limits. See Section 1.4.7.

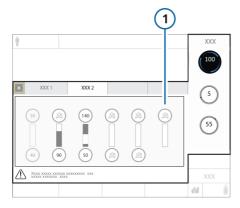
1.4.11.5 Oxygen level notification

When the Oxygen controller is set to Automatic, you can specify an oxygen level that, when exceeded, generates a medium-priority alarm message that is displayed in the message bar.

The Oxygen message control is only a notification tool; it *does not* affect the percentage of delivered oxygen.

This threshold is set using the Oxygen msg control in the Alarms > Limits 2 window.

Figure 1-11. Alarms > Limits 2 window, Oxygen msg control (1)



For alarm details, see Section 1.4.9.

1.5 Monitoring INTELLIVENT-ASV

A CAUTION

Check the patient's condition periodically to assess readiness for weaning.

NOTICE

- If the SpO2 signal is not reliable, the automated PEEP and Oxygen controls freeze after 30 seconds. See Sections 1.8.4.1 and 1.8.4.
- If the PetCO2 signal is not reliable, the automated %MinVol controller freezes after 30 seconds. See Sections 1.7.4.1 and 1.7.4.

INTELLIVENT-ASV provides access to numerical and graphical monitoring data.

Data is shown on the main display in the Monitoring window, in the various graphic panels, as MMPs, and in the INTELLIVENT-ASV-specific windows, called views. These views present the following information:

- Ventilation and Oxygenation horizons
- Capnogram and plethysmogram
- Intelligent panels (Dynamic Lung, Vent Status, Quick Wean (when enabled), and ASV Graph)
- Up to three waveforms
- Trends

Trend graphs for SpO2- and PetCO2- related parameters, as well as for the Ventilation and Oxygenation controller settings, are also available. For details, see Section 1 5 11 1

The following sections provide details about the views

1.5.1 About the INTELLiVENT-ASV windows and views

INTELLIVENT-ASV provides a graphical overview of CO2 elimination (ventilation) and oxygenation, as well as other INTELLIVENT-ASV-related data, on the main display in specialized windows.

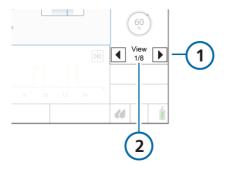
Most of these windows are displayed as a series of views that you can cycle through during ventilation.

To display view windows

► Touch the left or right view navigation arrow to cycle through the views.

The view number is displayed between the arrows.

Figure 1-12. Displaying INTELLiVENT-ASV views



1 View navigation arrows

2 View number

The following table describes the INTELLI-VENT-ASV windows, as well as where they are displayed.

Table 1-11. INTELLiVENT-ASV views and maps, overview

View or man

Description

For details, see ..

Section 153

CO2 elimination horizon, view 1



For a passive patient, the CO2 elimination horizon shows a focused view of the map at the current PetCO2 value and target range.

For an *active* patient, shows the spontaneous breathing rate (fSpont).

The CO2 elimination horizon is shown during active ventilation in views 1 and 2.

Section 152

For details about the rules used to regulate CO2 elimination, see Section 1.7.

CO2 elimination map



The CO2 elimination map shows the current patient PetCO2 value and target range in relation to Ppeak, together with the set limits.

The map is shown in the INTELLIVENT-ASV Settings > Target window.

Oxygenation horizon, view 1

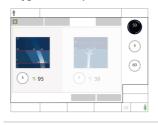


The Oxygenation horizon shows a focused view of the map at the current SpO2 value and target range.

The Oxygenation horizon is shown during active ventilation in views 1 and 3.

Section 155

Oxygenation map



The Oxygenation map shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits.

The map is shown in the INTELLIVENT-ASV Settings > Target and More windows.

Section 1.5.4

For details about the rules used to regulate oxygenation, see Section 1.8

View or map

Description

For details, see ...

Capnogram, view 2



The capnogram provides a real-time CO2 waveform.

Section 1.5.6

Section 1.5.6

It is shown:

- During active ventilation in view 2 together with the CO2 elimination horizon.
- As a waveform on the main display, if selected.

Plethysmogram, view 3

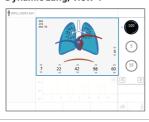


The plethysmogram provides a realtime waveform that represents the pulsating blood volume.

It is shown:

- During active ventilation in view 3 together with the Oxygenation horizon.
- As a waveform on the main display, if selected.

Dynamic Lung, view 4



The Dynamic Lung provides a visual representation, as well as numeric data, for key ventilation data, including tidal volume, lung compliance, patient triggering, and resistance.

The panel is shown during active

ventilation in view 4

Your ventilator *Operator's Manual*

View or man

Description

For details, see ...

Vent Status panel or Quick Wean panel, view 5



Which panel is displayed depends on whether Quick Wean is enabled or disabled, as follows:

- When Quick Wean is *disabled*, the Vent Status panel is displayed.
- When Quick Wean is enabled, the panel is labeled Quick Wean, and shows the status of the monitored weaning criteria.

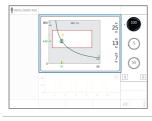
Vent Status panel.
 See your ventilator
 Operator's Manual.

Quick Wean panel.
 See Section 2.2.5.



The panel is shown during active ventilation in view 5.

ASV Graph panel, view 6

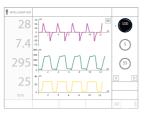


The ASV Graph shows how the adaptive lung controller moves toward its targets. The graph shows both the target and real-time patient data for tidal volume, frequency, pressure, and minute ventilation.

The panel is shown during active ventilation in view 6.

Your ventilator *Operator's Manual*

Waveforms, view 7



The Waveform panel shows the waveforms you have selected in the Graphics > Waveforms window.

By default, the Flow, Volume, and Paw waveforms are displayed.

The panel is shown during active ventilation in view 7.

Section 1.5.10

View or map

Description

For details, see ...

Trend panel, view 8



The Trend panel shows the trends you have selected in the Graphics > Trends window.

By default, the Oxygenation controller combination trends are displayed.

The panel is shown during active ventilation in view 8.

Section 1.5.11

1.5.2 About the CO2 elimination map

The INTELLIVENT-ASV Ventilation controller (CO2 elimination) monitors end-tidal CO2 (PetCO2), and uses this data to adjust %MinVol to regulate CO2 elimination, according to the detailed rules and conditions described in Section 1.7.

The Ventilation controller uses a predefined end-tidal CO2 target schema with peak pressure (Ppeak) on the y-axis and PetCO2 on the x-axis. Peak pressure is the sum of PEEP and the inspiratory pressure set by the controller.

This schema is called the CO2 elimination map. In the map, the yellow cross is the patient symbol denoting the patient's current measured PetCO2 value at the current peak pressure. The boomerang shaped area of the graph is the target range, which denotes a range of values at a given peak pressure.

1.5.2.1 Reviewing the CO2 elimination map

NOTICE

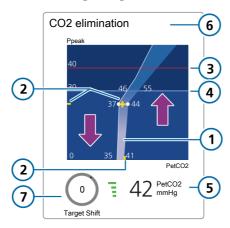
The maximum Ppeak value that can be shown on the CO2 elimination map is 50 cmH2O, so in some cases, the map may not show the patient symbol. INTELLIVENT-ASV is running, however.

The CO2 elimination map is available in the INTELLIVENT-ASV Settings > Target window.

Notes for the following figure: The purple arrows are for clarification purposes only; they do not appear on the display.

- Up arrow: Increase zone (PetCO2 too high, increase %MinVol)
- Down arrow: Decrease zone (PetCO2 too low, decrease %MinVol)

Figure 1-13. CO2 elimination map, INTELLi-VENT-ASV Settings > Target window



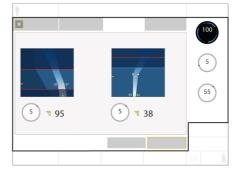
- 1 Target zone
- 5 Current PetCO2 value, quality index
- 2 Patient symbol, patient values
- 6 Map title
- 3 High Pressure alarm limit
- 7 Target Shift control
- 4 Plimit

To view the CO2 elimination map

- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- 2. Touch the **Target** tab, if needed.

 The window shows the both the **Oxygenation** (left) and the **CO2** elimination (right) maps.

Figure 1-14. INTELLiVENT-ASV Settings > Target window



To change the target range, see Section 1.4.11.2.

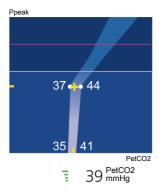
1.5.2.2 About the PetCO2 target zone

At a very basic level, the Ventilation controller (CO2 elimination) attempts to keep the patient in the target zone as described here.

The CO2 elimination map provides examples of each situation: PetCO2 is within, above, or below the target zone.

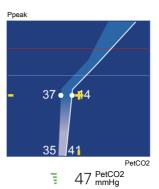
Patient symbol within the PetCO2 target zone

When the patient symbol is within the target zone, the %MinVol is fine tuned to get the patient to the middle of the target range.



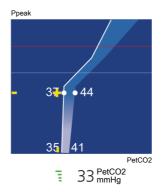
Patient symbol above the PetCO2 target zone

When the patient symbol is to the right of the target zone (in the increase zone, PetCO2 is too high), the %MinVol setting increases.



Patient symbol below the PetCO2 target zone

When the patient symbol is to the left of the target zone (in the decrease zone, PetCO2 is too low), the %MinVol setting decreases.



1.5.3 About the CO2 elimination horizon

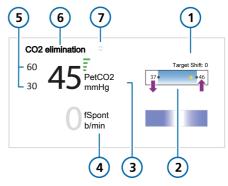
For a passive patient, the CO2 elimination horizon shows a simplified view of the same data as the CO2 elimination map, together with the upper and lower PetCO2 alarm limits.

When the patient is *active*, the horizon shows spontaneous breathing activity (fSpont).

Notes for the following two figures:

- When %MinVol is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, %MinVol is in the target zone.
- The purple arrows are for clarification purposes only; they do not appear on the display.
 - Up arrow: Increase zone (PetCO2 too high, increase %MinVol)
 - Down arrow: Decrease zone (PetCO2 too low, decrease %MinVol)
- When the PetCO2 target range is changed (using the Target Shift control), the setting is shown above the horizon. For details, see Section 1.4.11.2.1.

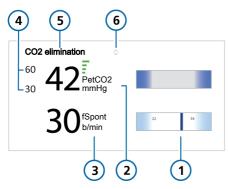
Figure 1-15. CO2 elimination horizon, passive patient



- 1 Target shift setting
- 2 Target zone (blue) and patient symbol (cross)
- 3 Current PetCO2 value, quality index
- 4 fSpont value (0)

- 5 PetCO2 alarm limits
- 6 Horizon title
- 7 %MinVol increase, decrease indicators

Figure 1-16. CO2 elimination horizon, active patient



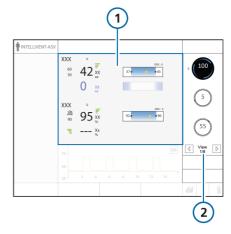
- 1 Spont. breaths target zone, patient symbol
- 4 PetCO2 alarm limits
- 2 Current PetCO2 value, quality index
- 5 Horizon title
- 3 Current fSpont value
- 6 %MinVol increase, decrease indicators

The appropriate CO2 elimination horizon (for *active* or *passive* patient) is shown on the main display during active ventilation, in views 1 and 2.

To display the CO2 elimination horizon

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 1 or 2 is displayed.

Figure 1-17. CO2 elimination horizon during active ventilation, view 1



- 1 CO2 elimination horizon
- 2 View number and arrows

For details about the rules governing automated **%MinVol** adjustments, see Section 1.7.

1.5.4 About the Oxygenation map

The INTELLIVENT-ASV Oxygenation controller monitors SpO2, and uses this data to adjust PEEP and Oxygen to regulate oxygenation, according to the detailed rules and conditions described in Section 1.8

We use the term *treatment* to refer to the joint effect of PEEP and Oxygen:

- Increasing treatment refers to changes to PEEP and/or Oxygen that cause SpO2 to increase. The controller makes these changes based on ARDSnet guidelines.
- Decreasing treatment refers to changes in these control values that cause SpO2 to decrease. The controller makes these changes based on the Open Lung concept.

With the HAMILTON-C1/T1 ventilators, the controller uses the PEEP/SpO2 target predefined schema. The visual presentation of the schema is referred to as an Oxygenation map.

The Oxygenation map shows PEEP on the y-axis and SpO2 on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured SpO2 value at the current PEEP. The boomerang shaped area of the graph is the target zone, which denotes a range of SpO2 values at a given PEEP.

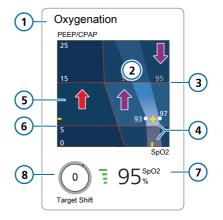
1.5.4.1 Reviewing the Oxygenation maps

The Oxygenation map is displayed in the INTELLIVENT-ASV Settings > Target and More windows (Figures 1-6 and 1-7).

Notes for the following figure: The red/ purple arrows and red dotted lines are for clarification purposes only; they do not appear on the display.

- Purple up arrow: Increase treatment zone
- Purple down arrow: Decrease treatment zone
- Red up arrow: Emergency increase zone (dark blue area), Oxygen set to 100%

Figure 1-18. Oxygenation map in INTELLiVENT-ASV Settings > Target and More windows



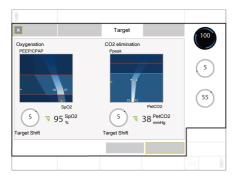
- Map title
- 2 SpO2 target zone
- 3 Upper PEEP limit
- 4 Patient symbol, patient values
- 5 Emergency zone
- 6 Lower PEEP limit
- 7 Current **SpO2** value, quality index
- 8 Target Shift control

To view the Oxygenation map

- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.10).
- 2. Touch either the **Target** or the **More** tab.

The Target window (shown next) shows the both the Oxygenation (left) and the Ventilation (right) maps. The More window shows only the Oxygenation map.

Figure 1-19. INTELLiVENT-ASV Settings > Target window



To change the target range, see Section 1 4 11 2

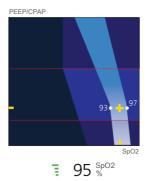
1.5.4.2 About the SpO2 target zone

At a very basic level, the Oxygenation controller attempts to keep the patient in the target zone as described here.

The maps here provide examples of each situation: SpO2 is within, above, or below the target zone.

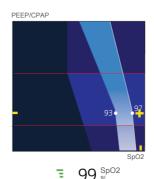
Patient symbol within the SpO2 target zone

When the patient symbol is within the target zone, Oxygen is fine tuned to get the patient to the middle of the target range.



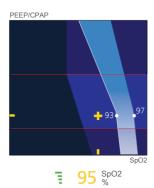
Patient symbol above the target zone

When the patient symbol is to the right of the target zone (in the *decrease zone*, indicating that the treatment is more than sufficient), the treatment is decreased.



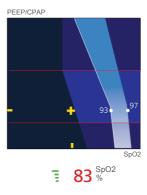
Patient symbol below the SpO2 target zone

When the patient symbol is to the left of the target zone (in the *increase zone*, indicating oxygenation is inadequate), the treatment is increased. As a result of being below the target zone, a medium-priority alarm is generated; the SpO2 parameter is shown in the associated alarm color.



Patient symbol below the SpO2 target zone, in the Emergency zone

If the patient symbol is to the far left of the target zone in the dark blue *emergency zone* indicating hypoxemia, Oxygen is immediately increased to 100%. As a result of being below the target zone, a high-priority alarm is generated; the SpO2 parameter is shown in the associated alarm color.



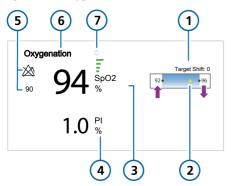
1.5.5 About the Oxygenation horizon

The Oxygenation horizon shows a simplified view of the same data as the SpO2/PEEP Oxygenation map, together with the upper and lower SpO2 alarm limits. With a Masimo SET SpO2 sensor, the horizon also shows the measured perfusion index (PI).

Notes for the following figure:

- When PEEP or Oxygen is increasing (^)
 or decreasing (v), the appropriate indicator is highlighted (7 in the following
 figure). When the arrows are the same
 size, SpO2 is in the target zone.
- The purple arrows in the following figure are for clarification purposes only; they do not appear on the display.
 - Up arrow: Increase treatment zone
 - Down arrow: Decrease treatment zone
- When the SpO2 target range is changed (using the Target Shift control), the setting is shown above the horizon. For details, see Section 1.4.11.2.1.

Figure 1-20. Oxygenation horizon



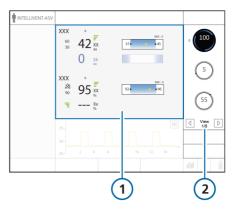
- 1 Target shift setting
- 5 SpO2 alarm limits
- 2 Target zone (blue) and patient symbol (cross)
- 6 Horizon title
- 3 Current SpO2 value, quality index
- 7 PEEP, Oxygen increase/decrease indicator
- 4 Current PI value (Masimo SpO2 sensor only)

The Oxygenation horizon is shown on the main display during active ventilation in views 1 and 3.

To display the Oxygenation horizon

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 1 or 3 is displayed.

Figure 1-21. Oxygenation horizon during active ventilation, view 1



- 1 Oxygenation horizon
- 2 View number and arrows

1.5.6 About the capnogram and plethysmogram

A CO2 capnogram and SpO2 plethysmogram are available as part of the INTELLIVENT-ASV standard views. You can also display them as individual waveforms, in the same manner as other waveforms on the main display.

The time scale displayed is the same as for other waveforms. See your ventilator *Operator's Manual* for details.

About the capnogram

A capnogram is a waveform that represents CO2 levels throughout a breath cycle.

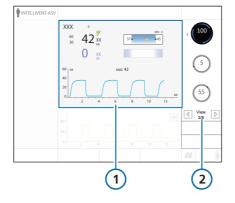
To display the capnogram

During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 2 is displayed.

The capnogram is displayed together with the CO2 elimination horizon.

For details about selecting the capnogram as a waveform on the ventilator main display, see your ventilator Operator's Manual.

Figure 1-22. Capnogram during active ventilation, view 2



- 1 Capnogram and CO₂ elimination horizon
- View number and arrows

About the plethysmogram

A plethysmogram is a waveform that represents the pulsating blood volume; it is generated by the pulse oximeter.

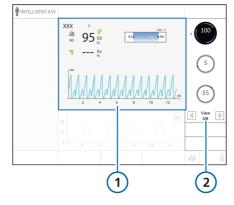
To display the plethysmogram

During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 3 is displayed.

The plethysmogram is displayed together with the Oxygenation horizon

For details about selecting the plethysmogram as a waveform on the ventilator main display, see the Pulse Oximetry Instructions for Use.

Figure 1-23. Plethysmogram during active ventilation, view 3



- Plethysmogram and Oxygenation horizon
- 2 View number and arrows

1.5.7 About the Dynamic Lung

The Dynamic Lung shows an up-to-date visual representation of key ventilation data (Figure 1-24). It visualizes tidal volume, lung compliance, patient triggering, and resistance in real-time.

In addition to the graphic representation, the panel shows numeric data for key parameters.

The **Dynamic Lung** comprises the following components:

- Mechanical breath action
- Respiratory compliance
- Airway resistance
- Patient triggering
- SpO2 data

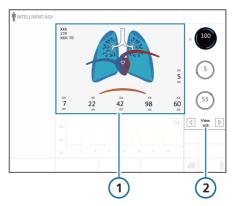
For details about the **Dynamic Lung**, see your ventilator *Operator's Manual*.

In INTELLIVENT-ASV, the Dynamic Lung is provided in view 4.

To display the Dynamic Lung

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 4 is displayed.

Figure 1-24. Dynamic Lung during active ventilation, view 4



- 1 Dynamic Lung
- 2 View number and arrows

1.5.8 About the Vent Status and Quick Wean panels

The panel shown in view 5 is either the Vent Status panel or the Quick Wean panel, depending on whether Quick Wean is enabled in the INTELLIVENT-ASV Settings window, as follows:

- When Quick Wean is disabled (the default), the Vent Status panel is displayed, showing the standard ventilation parameters. For details about this panel, see your ventilator Operator's Manual
- When Quick Wean is enabled, the panel is labeled Quick Wean, and shows the status of the monitored weaning criteria.

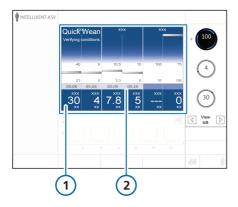
For details, see Sections 2.2.2 and 2.2.5.

48 English | 10098020/00

To display the Vent Status or Quick Wean panel

During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 5 is displayed.

Figure 1-25. Quick Wean panel during active ventilation, view 5



- 1 Monitored parameter, outside the weaning zone
- Monitored parameter, in the weaning zone

When Quick Wean is enabled and the parameters are within their target weaning ranges, that is, in the weaning zone, the Quick Wean panel shows green bars for each of the parameters. A timer is also displayed, showing the length of time the parameters values have been in the weaning zone.

Figure 1-26. Quick Wean panel, all parameters in the weaning zone, timer activated



- Parameter in the weaning zone (with green bar)
- 2 Weaning timer

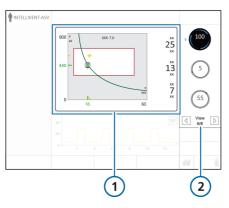
1.5.9 About the ASV Graph

View 6 shows the ASV Graph, the same as in ASV mode. The graph shows both the target and real-time patient data for tidal volume, frequency, pressure, and minute ventilation. For additional details, see your ventilator *Operator's Manual*.

To display the ASV Graph

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 6 is displayed.

Figure 1-27. ASV Graph during active ventilation, view 6



- 1 ASV Graph
- 2 View number and arrows

1.5.10 About the Waveform display

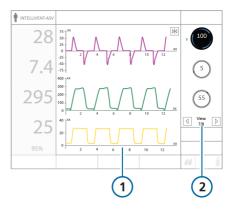
View 7 provides a full display of up to three waveforms during active ventilation. By default, the Paw, flow, and volume waveforms are displayed.

You can change the selection at any time in the same manner as in any other mode. For details, see your ventilator *Operator's Manual*

To display the Waveform view

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 7 is displayed.

Figure 1-28. Waveform display during active ventilation, view 7



- 1 Waveform display
- View number and arrows

1.5.11 About the Trend panel

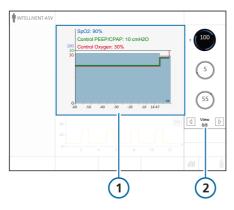
The Trend panel in view 8 displays the selected trend. You can change the selection at any time in the same manner as in any other mode. For details, see your ventilator *Operator's Manual*.

In INTELLIVENT-ASV, two additional trend combinations are available, Oxygenation control and Ventilation control. For details, see Section 1.5.11.1.

To display the Trend view

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view arrow until view 8 is displayed.

Figure 1-29. Trends during active ventilation, view 8



1 Trend graph

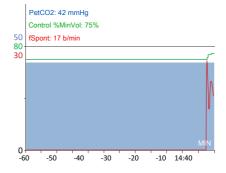
2 View number and arrows

1.5.11.1 About trends

In addition to the trend data available for monitored parameters, you can also trend the actions of the Ventilation and Oxygenation controllers when using INTELLIVENT-ASV. The same time periods are available as for other parameters, namely, 1-, 6-, 12-, 24-, or 72-h trends. Each parameter is represented by a different color, as indicated in the graph legend.¹¹

Ventilation control trend graph

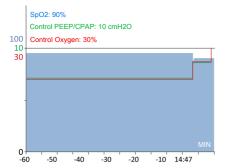
The Ventilation control trend graph provides data for the following parameters: PetCO2, Control %MinVol, and fSpont.



¹¹ Note that the graphs provided here do not represent actual data, they just illustrate how the different parameters are represented.

Oxygenation control trend graph

The Oxygenation control trend graph provides data for the following parameters: SpO2, Control PEEP/CPAP, and Control Oxygen.



1.5.12 INTELLIVENT-ASV symbols

The following table describes important symbols and controls used with INTELLi-VENT-ASV.

Table 1-12. INTELLiVENT-ASV-related symbols and controls

Symbol/Control	Color	Description
View 1/8	White	View selection. During active ventilation, several views are available. The view navigation arrows change the views. See Section 1.5.1.
+	Yellow	Patient symbol. Indicates the current condition of the patient in the graph.
777	Gray (4 bars), Orange (2 bars), Red (1 bar)	Quality index showing unreliable signal quality. Sensor values are not usable, or the sensor is not enabled or connected. When this occurs, the related controller freezes and an alarm is generated indicating automatic management is turned OFF.
33	Green (3 or 4 bars)	Quality index showing stable acceptable signal quality. The data from the sensor is highly stable and reliable.
45 PetCO2 mmHg	White	Measured PetCO2 sensor value and quality index.
Active patient 13 21 Passive patient 22	The inactive component is greyed out.	When the PetCO2 horizon (top) is greyed out, and the fSpont horizon is active, the patient is breathing spontaneously (active). When the PetCO2 horizon is active, and the fSpont horizon is greyed out, the patient meets the passive criteria.
17 fSpont b/min	White	The fSpont measurement is displayed when spontaneous breathing is detected by the flow sensor and used as physiologic input.
83 sp02	Red	Critical SpO2 value. SpO2 is below the set lower alarm limit.

Symbol/Control	Color	Description
=	White	Dashes indicate that no sensor value can be detected.
\$	White	Increase arrow, next to the horizon name and to the left of the automated controllers. Indicates that treatment must be increased.
\$	White	Decrease arrow, next to the horizon name and to the left of the automated controllers. Indicates that treatment must be decreased.
\$	Black	Value is stable, in range. Displayed next to the horizon name and to the left of the automated controllers.
263	White	Time to increase. Counts down the time to the next increase of the control.
<u>\$</u>	White	Time to decrease. Counts down the time to the next decrease of the control.
100 % XXX	Gray circle	Manual management. Indicates that the operator must manage the control.
95 xxx 96	Blue circle rotating clockwise	Management is set to Automatic. Indicates that INTELLiVENT-ASV is dynamically updating the settings, and treatment has been increased (comets moving clockwise). A faster rotation provides a visual indication of ongoing or recent changes.
95 xxx 96	Blue circle rotating counter-clockwise	Management is set to Automatic. Indicates that INTELLIVENT-ASV is dynamically updating the settings, and treatment has been decreased (comets moving counter-clockwise). A faster rotation gives a visual indication of ongoing or recent changes.
100 XXX %	Red circle	No settings management – controller is in a frozen state. A sensor value may be absent.
100 xxx 1:59	Green circle	Oxygen enrichment in progress. For details, see your ventilator Operator's Manual.

1.6 Troubleshooting alarms



You can suppress audible CO2 and SpO2 alarms for 2 minutes by pressing the Audio pause key.

NOTICE

When the device is in Standby, all SpO2related alarms are suppressed.

The following table provides troubleshooting information for alarms related to INTELLIVENT-ASV.

For information about working with alarms, including resetting them, see your ventilator Operator's Manual and SpO2related documentation.

For the following alarm types, see the listed documentation:

- SpO2-related alarms, see the Pulse oximetry Instructions for use.
- PetCO2-related alarms, see your ventilator Operator's Manual.

Table 1-13. INTELLiVENT-ASV alarms, priority, and corrective actions

Alarm/Priority	Definition/Corrective action
FiO2 set to 100% due to low SpO2 Medium priority.	The Oxygenation controller set Oxygen to 100% due to low SpO2 saturation. SpO2 is, or was, in the emergency zone.
	To resolve
	Check patient condition.
	 Open and close the Alarm buffer to reset the alarm (even if the alarm situation changes).
Oscillation PEEP/CPAP	Large variations in PEEP in a short time period.
Medium priority.	To resolve
	Check patient condition.
	• Set PEEP to Manual.
Oscillation %MinVol	Large variations in %MinVoI in a short time period.
Medium priority.	To resolve
	Check patient condition.
	• Set %MinVol to Manual.
Oxygenation adjustment off Medium priority.	The Oxygenation controller is frozen due to poor or absent SpO2 signal.
, ,	To resolve
	Check pulse oximeter connections.
	• Set PEEP and/or Oxygen to Manual.
Oxygen controller at limit Low priority.	PEEP and/or Oxygen are at the defined limit and cannot be increased.
- 19	To resolve
	Check patient condition.
	Verify limit settings.
	• Set PEEP and/or Oxygen to Manual.
Oxygen control limit exceeded Medium priority.	Oxygen exceeds the limit defined by the Oxygen msg alarm (Alarms window).
,	To resolve
	Check patient condition.
	• Open and close the Alarms buffer to reset the alarm (even if the alarm situation changes).

Alarm/Priority	Definition/Corrective action
PetCO2 target range changed Low priority.	Quick Wean has been set to Automatic; it is now active. As a result, the PetCO2 target range is moved +5 mmHg to the right.
	See Section 2.2.4 for details about the workflow.
Ventilation adjustment OFF Medium priority.	The Ventilation controller (CO2 elimination) is frozen when any of the following conditions persists for longer than 30 seconds:
	• Poor or absent CO2 signal
	• fSpont > 60 b/min (> 40 kg IBW)
	• fSpont > 100 b/min (≤ 40 kg IBW)
	To resolve
	Check patient condition.
	• Check CO2 connections.
	• Set %MinVol to Manual.
Ventilation controller at limit Low priority.	%MinVol is at the defined limit (200%) and cannot be increased.
•	To resolve
	Check patient condition.
	• Set %MinVol to Manual.

1.7 Management of minute volume (%MinVol)

MARNING

Regularly inspect CO2 adapters/sensors. Patient secretions and/or condensation in airway adapters can lead to an incorrect PetCO2 reading.

A CAUTION

Do NOT use the sidestream CO2 sensor with automatic management of %MinVol.

Ventilation (%MinVol) management operates in two modes: Automatic and Manual.

Minute volume (%MinVol) management in Automatic mode

When set to Automatic, the INTELLIVENT-ASV Ventilation controller (CO2 elimination) uses the following data to set the minute volume (%MinVol):

- The controller uses different inputs to control the target minute volume, depending on whether the patient is passive or active.
 - Passive patient. The controller uses the measured end-tidal CO2 partial pressure, PetCO2, as described in Section 1.7.1.
 - Active patient. The controller uses the difference between the targeted and actual respiratory rate, as described in Section 1.7.2.

For details on how the controller manages the transition between spontaneous breathing and passive activity, see Section 1.7.3.

- All ASV safety limits are active for prevention of Apnea, baro- and volutrauma, auto-PEEP, and dead space ventilation, including the tidal volume (Vt) limit of 1.5 x (upper Vt alarm limit).
- The target PetCO2 that is set depends on:
 - The patient's treatment level (peak inspiratory pressure)
 - Any specific condition(s) set by the operator (Section 1.4.11.1)
 - Operator-set PetCO2 target shift (Section 1.4.11.2)
 - Whether Quick Wean is enabled (Section 2.2)
- The acceptable spontaneous breathing rate is calculated using the information in Table 1-16.

The %MinVol limits that are in force when minute volume management is set to Automatic are listed in Table 1-14. As soon as the upper limit for the management of %MinVol is reached, a Ventilation controller at limit message is generated.

Table 1-14. %MinVol limits when minute volume management set to Automatic

PetCO2 status	%MinVol
	Minimum %MinVol
PetCO2 available	70
PetCO2 not available	100 (automatic control suspended)
	Maximum %MinVol
PetCO2 available	200

Minute volume (%MinVol) management in Manual mode

In Manual mode, you keep the CO2 elimination within the target range by manually adjusting %MinVol, based on the PetCO2 monitoring values and on clinical practice.

1.7.1 Management of %MinVol, passive patient

When the patient is passive, the ventilator adjusts the target minute ventilation based on the PetCO2 value of the patient.

End-tidal CO2 partial pressure (PetCO2), available when the CO2 sensor is connected, is the maximum partial pressure of CO2 exhaled during a breath, just before the start of inspiration. This represents the final portion of air that was involved in the exchange of gases in the alveolar area, and is generally a reliable index of CO2 partial pressure in the arterial blood.

Under normal conditions, PaCO2 is approximately 2-5 mmHg higher than PetCO2 the difference between the values is referred to as the PaCO2-PetCO2 gradient. Under special clinical conditions (including ventilation/perfusion mismatch, such as shunt), the PaCO2-PetCO2 gradient can increase, requiring adjustment of the ventilation targets (using the Target Shift control). For details, see Section 1.4.11.2.

To get the most accurate approximation of PaCO2, the second highest PetCO2 value out of 8 breaths is used.

The PetCO2 target range depends on:

- Any specific condition(s) set by the operator (Section 1.4.11.1)
- Operator-set PetCO2 target shift (Section 1.4.11.2)
- Current level of ventilator support (Ppeak)

Within these ranges, and based on the PetCO2 response from the patient, %MinVol is adjusted as described in the following table.

Table 1-15. Automated management of %MinVol, passive patient

When these conditions apply	%MinVol change
PetCO2 is above the upper limit of acceptable values	%MinVol increase
PetCO2 is below the lower limit of acceptable values	%MinVol decrease
PetCO2 is within the target range	Minor %MinVol changes
PetCO2 measurement is invalid or unreli- able for at least 30 seconds	%MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

1.7.2 Management of %MinVol, active patient

When a patient is *active*, spontaneously triggering the breaths, the ventilator adjusts the target minute ventilation based on the spontaneous breathing Rate of the patient.

The acceptable range for the spontaneous breathing Rate is determined as follows:

Table 1-16. Spontaneous breathing rate range calculation¹²

Lower limit of range	ASV target rate + 2 When Quick Wean is enabled: ASV target rate + 3
Upper limit of range	ASV target rate + d d = %MinVol * k where
	k = 0.1 Quick Wean disabled
	k = 0.15 Quick Wean enabled

While the patient is *active*, the patient's spontaneous Rate is detected by the flow sensor. The PetCO2 value is only used in the background for additional safety to avoid excessive values.

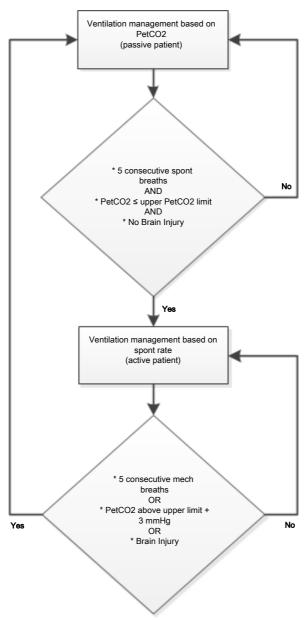
The conditions listed in the following table apply to automated control of **%MinVol** for an *active* patient, and refer to the transition process specified in Section 1.7.3.

¹² For ASV target rate information, see your ventilator Operator's Manual.

Table 1-17. Automated management of %MinVol, active patient

When these conditions apply	%MinVol change
• The patient complies with the <i>Active state conditions</i> in Section 1.7.3 and	%MinVol increase
 The patient's Rate is above the upper limit of the acceptable spontaneous Rate (danger of patient fatigue) 	
• The patient complies with the <i>Active state conditions</i> in Section 1.7.3 and	%MinVol decrease
• The patient's Rate is below the lower limit of the acceptable spontaneous Rate	
• The patient complies with the Active state conditions	No change in %MinVol .
in Section 1.7.3 and	If Quick Wean is enabled, see Section 2.2.4 for details.
• The patient's Rate value is within the target range	
The patient's PetCO2 is invalid for more than 30	%MinVol control is frozen.
seconds	The Ventilation adjustment OFF alarm is generated.
The patient's spontaneous Rate is invalid (> 60 b/min	%MinVol control is frozen.
for patients over 40 kg IBW or > 100 b/min for patients ≤ 40 kg IBW) for more than 30 seconds	The Ventilation adjustment OFF alarm is generated.

1.7.3 How the Ventilation controller transitions between active and passive patient states



Passive patient

For a passive patient, the controller starts adjusting the %MinVol based on PetCO2 when ANY of the following are true:

- Five consecutive mechanical breaths occur or
- The PetCO2 value exceeds the upper limit by at least 3 mmHg or
- The Brain Injury condition is selected

In this case, the %MinVoI is adjusted based on the PetCO2 input.

When a reliable PetCO2 measurement is not available (Table 1-19), the Ventilation controller suspends dynamic management of the control, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

Active patient

For an active patient, the Ventilation controller starts adjusting the %MinVol based on the Rate when ALL of the following are true.

- Five consecutive patient-triggered breaths occur and
- The PetCO2 value is below the upper limit and
- The Brain Injury condition is NOT selected

The controller continuously checks the passive patient conditions since it uses Rate as input criteria.

If the passive patient conditions do not apply, the controller continues to adjust the %MinVol based on the spontaneous breathing Rate of the patient.

If the patient's spontaneous Rate is invalid¹³ for more than 30 seconds, the Ventilation controller suspends automated management and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

When a reliable PetCO2 measurement is not available (Table 1-19), the Ventilation controller suspends automated management, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

¹³ fSpont > 60 b/min (> 40 kg IBW) or fSpont > 100 b/min (\leq 40 kg IBW)

1.7.4 Important notes about ventilation management

When ventilating with INTELLIVENT-ASV, pay particular attention to important notes listed in the following table:

Table 1-18. Important notes about ventilation management

For	See
Quality index and ventilation	Section 1.7.4.1
Actions that temporarily halt automatic ventilation management	Section 1.7.4.2
PetCO2 is not available	Section 1.7.4.3
Disconnection or flow sensor failure resolved in 5 minutes or less	Section 1.7.4.4
Disconnection or flow sensor failure resolved in more than 5 minutes	Section 1.7.4.5
Returning to active venti- lation from Standby	Section 1.7.4.6

1.7.4.1 Quality index and ventilation management

The following table summarizes INTELLI-VENT-ASV operation depending on the PetCO2 quality index.

Table 1-19. PetCO2 quality index and automated ventilation management

Quality indicator	These conditions apply
The data from the sensor is unavailable or not reliable for more than 30 seconds Gray or red bars	 The %MinVol control is a solid red circle; it is frozen. The Ventilation adjustment OFF alarm is generated. The minute volume adjustment works as it does in ASV, with a constant minute ventilation equal to the last valid automatic %MinVol setting. For details, see your ventilator Operator's Manual.
The data from the sensor is reliable Green bars	 The %MinVol control is a blue rotating circle. The Ventilation adjust- ment OFF alarm is reset. Automated ventilation management resumes.

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1.7.4.2 Actions that temporarily halt automatic ventilation management

Automated ventilation management pauses during the following actions:

- Disconnection
- Flow sensor calibration
- Leak test
- Suctioning

In some cases, the controller remains displayed with a blue rotating circle, and when the action is completed, it resumes automated management with the lastused setting.

Ventilation continues using the last %MinVol setting before the automated management was paused.

1.7.4.3 PetCO2 is not available

Any time the PetCO2 measurement is unavailable or unreliable, the minute volume adjustment is the same as in ASV mode, using the %MinVol setting in effect at the time that the PetCO2 signal became unusable

Note that if the last %MinVol setting was below 100%, %MinVol is set to 100%.

- The Ventilation controller display changes from blue to red.
- The alarm, Ventilation adjustment OFF, is generated. The ventilator provides constant minute ventilation.

When PetCO2 is again available, the alarm is resolved and the minute volume adjustment switches back to Automatic mode.

- The controller changes from red to a blue rotating circle again.
- %MinVol is adjusted automatically.

1.7.4.4 Disconnection or flow sensor failure resolved in 5 minutes or less

When a disconnection or flow sensor failure situation is resolved in 5 minutes or less:

- The %MinVol management adjustment pauses for 10 breaths.
- The ASV adjustment (ΔPinsp and ASV target rate) pauses for 4 breaths after reconnection
- If the adjustment is in its initialization phase, it remains there for at least 3 more breaths

For details, see your ventilator Operator's Manual

1 7 4 5 Disconnection or flow sensor failure resolved in more than 5 minutes

When a disconnection or flow sensor failure is resolved in more than 5 minutes:

- The Ventilation controller adjustment pauses for 2 minutes.
- The ASV adjustment re-initializes. If the adjustment is in its initialization phase, it remains there for at least 3 more breaths

1.7.4.6 Starting active ventilation from Standby

When starting ventilation with a new patient selected and INTELLIVENT-ASV activated, the %MinVol adjustment initializes with the default settings.

If Last Patient was selected, the system assumes the patient settings, in addition to the %MinVol values from the last patient.

In the event the PetCO2 quality index is below 50, the %MinVol control changes from a blue rotating circle to a red non-pulsing circle. Ventilation management does not start

When the PetCO2 quality index is above 50, ventilation management starts in Automatic mode. The %MinVol control is a blue rotating circle.

1.8 Management of PEEP and Oxygen

As INTELLIVENT-ASV relies on the measurements provided by the SpO2 sensor, be sure to carefully review the safety messages provided in this guide, as well as those provided in the *Pulse oximetry Instructions for use*.

NOTICE

- The emergency increase of oxygen rules remain in place for all cases as long as the Oxygen control is set to Automatic.
- The Oxygenation controller can only adjust the Oxygen between 21% and 100%.
- When the minimum Oxygen limit is set above 21%, a red line indicating the limit appears on the Oxygenation map.
- The PEEP controller can only operate between 5 and 24 cmH2O.
- If the PEEP control is set to Automatic, the set PEEP high and low limit controls are activated. The Oxygenation map shows two red lines, one showing the upper PEEP limit and one showing the lower.

Oxygenation (PEEP/Oxygen) management operates in two modes: Automatic and Manual

Automatic oxygenation (PEEP and Oxygen) management

Automated PEEP/Oxygen management sets the Oxygen and PEEP values according to the following inputs, which determine the expected SpO2 range for the patient:

- Measured oxygen saturation (SpO2)
- Any specific condition(s) set by the operator (Section 1.4.11.1)
- Operator-set Target Shift (Section 1.4.11.2)

The lung-protective rules for oxygenation management, used during automated PEEP/Oxygen management, are based on the ARDSnet guidance when *increasing* the therapy, and the Open Lung concept when *decreasing* the treatment. See Section 1.8.1

Manual oxygenation management

In Manual mode, you keep the SpO2 within the target range by manually adjusting PEEP and/or Oxygen, based on the SpO2 monitoring values and on clinical practice.

1.8.1 Management of PEEP/Oxygen for all patients

Using the SpO2 signal retrieved from the pulse oximeter, the system calculates the difference between the current and the target SpO2 value. This calculation, together with the operator's input, is used to determine the treatment action.

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Automated PEEP/Oxygen management comprises two steps:

- The operator's input and the current treatment (PEEP) define the SpO2 target range. The ranges differ based on the selected specific condition(s), if any (Section 1.4.11.1). The SpO2 signal and the SpO2 target range are used to define the treatment action (increase, decrease, no change of treatment).
- The system decides, depending on the current combination of PEEP and Oxygen on the PEEP/Oxygen curve, whether PEEP and/or Oxygen are increased.

For increasing therapy, the relationship between PEEP and Oxygen is based on the ARDSnet guidance (Figure 1-30, the target path is the bold line).

For decreasing therapy, the relationship is based on the Open Lung concept (Figure 1-31, the target path are the bold lines).

Figure 1-30. Increase of oxygenation support, ARDSnet guidance

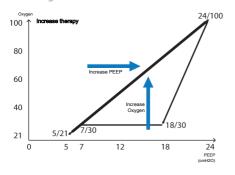
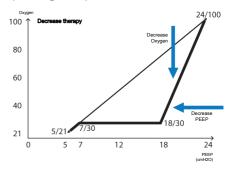


Figure 1-31. Decrease of oxygenation support, Open Lung concept



The device adjusts PEEP and Oxygen, which affect the oxygenation of the patient. Section 1.8.3 provides an overview of the controllers' actions depending on the measured SpO2 value.

1.8.2 Emergency increase of Oxygen

When Oxygen is set to Automatic, the device provides a safety feature that continuously monitors the patient's SpO2 to avoid dangerous desaturation. Upon detecting an inadequate SpO2 level, the device reacts immediately to deliver 100% Oxygen to the patient.

This feature is activated when the physiologic SpO2 value of the patient falls below the lowest acceptable value, thus triggering the 100% Oxygen response. The FiO2 set to 100% due to low SpO2 alarm is generated.

1.8.3 Oxygenation management rules

When set to Automatic, the Oxygenation controller adjusts PEEP and Oxygen as described here

SpO2 is in range (within the target zone limits) and the Oxygen setting is above the PEEP/Oxygen curve

The controller decreases Oxygen support as long as ALL of the following conditions are met:

- SpO2 remains in range AND
- Oxygen was last increased over 10 minutes ago AND
- There is no change in PEEP

SpO2 is too low (below the lower SpO2 target zone limit)

The controller increases oxygenation support.

map, relative to the ARDSnet curve	
Above the curve	The controller changes PEEP stepwise to the PEEP/Oxygen curve.
On the curve	The controller increases PEEP and Oxygen stepwise at the same time to follow the curve.
Below the curve	The controller increases Oxygen stepwise to the curve.

SpO2 is critically low (in the Emergency zone)

The controller *performs* an emergency Oxygen increase.

The Oxygen control displays the value 100%. See Section 1.8.2.

SpO2 measurement is unavailable

The controller is frozen.

The PEEP and Oxygen controls are frozen, displayed as solid red circles, and the Oxygenation adjustment OFF alarm is generated. Oxygenation management is no longer automated.

SpO2 is high, above the target zone limit

Position of patient symbol in the FiO2/PEEP

The controller decreases oxygenation support.

map, relativ	re to the Open Lung curve
Above the curve	The controller decreases Oxygen stepwise to the PEEP/ Oxygen curve.
On the curve	The controller first decreases Oxygen, then PEEP to follow the curve.
Below the curve	The controller automatically decreases PEEP stepwise to the curve.

1.8.3.1 How the controller adjusts Oxygen and PEEP

NOTICE

If an upper PEEP limit is specified, the controller will not exceed the limit.

If a lower PEEP and/or Oxygen limit is specified, the controller will not go below the limit

The following table describes the rules the controller follows to adjust the oxygenation parameters.

Table 1-20. Increase/decrease increments of Oxygen and PEEP by automated Oxygenation controller14

Oxygenation management/Action	Takes place when
Increase Oxygen step- wise: Increases Oxygen by 10% of current Oxygen value every 30 seconds	 Oxygen automatically managed Increasing Oxygen support
Decrease Oxygen stepwise: Decreases Oxygen by 5% of current Oxygen value every 60 seconds	 Oxygen automatically managed Decreasing Oxygen support
Increase PEEP step- wise: Increases PEEP by 1 cmH2O every 6 minutes	 PEEP automatically managed Increasing PEEP support
Decrease PEEP step- wise: Decreases PEEP by 1 cmH2O every 6 minutes	 PEEP automatically managed Decreasing PEEP support
Decrease PEEP step- wise quickly: Exception: Decreases PEEP by 1 cmH2O quickly every 30 seconds	PEEP automatically managed

1.8.4 Important notes about oxygenation management

When ventilating with INTELLIVENT-ASV, pay particular attention to important notes listed in the following table.

Table 1-21. Important notes about oxygenation management

For	See
Quality index and oxygenation management	Section 1.8.4.1
Actions that temporarily halt automatic oxygenation management	Section 1.8.4.2
Oxygen level notification	Section 1.8.4.3
Returning to active ventilation from Standby	Section 1.8.4.4

1.8.4.1 Quality index and oxygenation

The following table summarizes INTELLi-**VENT-ASV** operation depending on the quality of the SpO2 signal.

Note that the controllers may also be frozen as a result of various SpO2- and Oxygen-related alarms.

The automatic emergency increase of Oxygen is inactive when Oxygen is controlled manually.

¹⁴ When the PEEP and/or Oxygen control setting is manually changed and then control is again set to Automatic, these rules still apply. The time interval starts from the time of the last manual change.

Table 1-22. SpO2 quality index and automated oxygenation management

Qua	THAT	[6]2	[[[0]]]

These conditions apply ...

The data from the sensor is unavailable or unreliable for more than 30 seconds

Gray, red, or orange bars



 The PEEP and Oxygen controls are solid red circles; they are frozen.

- The Oxygenation adjustment OFF alarm is generated.
- The ventilator uses the same oxygenation rules as when in ASV mode. For details, see your ventilator Operator's Manual.
- Automatic emergency increase of oxygen management is inactive (Section 1.8.2).

The data from the sensor is reliable

Green bars



- The PEEP and Oxygen controls are blue rotating circles.
- The Oxygenation adjustment OFF alarm is reset.
- Automated oxygenation management resumes.
- Automatic emergency increase of oxygen management is active (Section 1.8.2)

1.8.4.2 Actions that temporarily halt automated oxygenation management

Automated oxygenation management pauses during the following actions:

- Disconnection
- Oxygen enrichment
- Flow sensor calibration
- Leak test
- Suctioning
- Oxygen sensor calibration
- Oxygen supply failure

In some cases, the controller remains displayed with a blue rotating circle, and when the action is completed, it resumes automated management with the last-used setting.

1.8.4.3 Oxygen level notification

When the Oxygenation controller is set to Automatic and is active, you can set the ventilator to display a message if the Oxygen concentration exceeds a specific limit that you specify. For details, see Section 1.4.11.5.

If the notification threshold is reached, an alarm is generated and the message Oxygen control limit exceeded is displayed.

1.8.4.4 Starting active ventilation from Standby

When starting ventilation with a new patient selected and INTELLIVENT-ASV activated, the PEEP and Oxygen adjustments initialize with the default settings.

If Last Patient is selected, the system uses the patient settings, as well as the PEEP and Oxygen values, from the last patient.

1.9 Manual control of ventilation and oxygenation

With INTELLIVENT-ASV, you can manage minute volume (%MinVol), Oxygen, and/or PEEP automatically or manually.

In some cases, automated management is not available, as described in the following sections

1.9.1 Manual control of ventilation

When %MinVol is controlled manually, the device uses the same rules as when in ASV mode. For details, see your ventilator Operator's Manual.

Table 1-23. Conditions for manual control of %MinVol

When these conditions are met	This control must be adjusted MANU- ALLY by the opera- tor
CO2 monitoring is	%MinVol is set to Manual

For control to be automated, you must set %MinVol to Automatic in the INTELLIVENT-ASV Settings > Auto window.

1.9.2 Manual control of oxygenation

You must control PEEP and/or Oxygen manually when any of the conditions listed in the following table occur.

Table 1-24. Conditions for manual control of PEEP and/or Oxygen

When these conditions are met	This control must be adjust- ed MANUALLY by the operator	
PEEP	PEEP is set to	
• The Chronic Hypercap- nia or Brain injury con- dition is selected	Manual	
 The ventilator is using a low pressure oxygen (LPO) supply 		
• SpO2 monitoring is disabled		
Oxygen	Oxygen is set to	
 The ventilator is using a low pressure oxygen (LPO) supply 	Manual	
• Oxygen monitoring (O2 sensor) is disabled		
• SpO2 monitoring is dis-		

When PEEP or Oxygen is controlled manually, the device uses the same rules as when in ASV mode. For details, see your ventilator *Operator's Manual*.

abled

For control to be automated, you must set the PEEP and/or Oxygen controls to Automatic in the INTELLIVENT-ASV Settings > Auto window.

1.10 Assessing results

After the calculated targets are reached, the ventilation management results need to be assessed. Use the monitored parameters for this purpose. To assess respiratory acid-base status, it is recommended that arterial blood gases be measured to monitor the minute volume adjustment.

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Quick Wean

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2.1 Overview

WARNING

Additional ventilator-independent patient monitoring (for example, bedside vital monitoring or a blood gas analyzer) must be used during INTELLIVENT-ASV ventilation. Check PaCO2 against displayed PetCO2, and SaO2 against SpO2.

↑ CAUTION

Responsibility for final decisions regarding weaning and extubation rests solely with the physician/operator. Additional criteria not provided by the ventilator must be taken into account

Quick Wean is integrated into INTELLIVENT-ASV, and when activated, provides continuous dynamic monitoring and control of patient conditions to assess the patient's potential readiness for discontinuing mechanical ventilation.

Together with the clinician and the patient. Quick Wean is part of a complex care cycle that has as its goal a spontaneously breathing patient with good respiratory function.

Discontinuation of mechanical ventilation involves three general steps:

- Measurement and assessment of weaning predictors during a screening phase
- A spontaneous breathing trial (SBT)
- An extubation trial

Quick Wean helps with this first phase.

2.2 Quick Wean in clinical use

This section provides a brief overview of the Quick Wean support indications for use, key parameters, and clinical workflow

2.2.1 Indications for use

NOTICE

When the Brain Injury condition is selected in INTELLIVENT-ASV, Quick Wean is unavailable

A clinical assessment of the patient's readiness for weaning prior to enabling Quick Wean is mandatory!

Once the patient is deemed ready, Quick Wean can be enabled at any time.

2.2.2 About the Quick Wean parameters

Quick Wean monitors a key set of parameters to help you identify patients who may be ready for your facility's weaning protocol and eventual extubation.

The default settings for these parameters are consensus based. However, you can change them to suit your facility's protocols. Once modified, they are generally set once and then used as the defaults. Settings are defined in Configuration. Some parameters are calculated and are not user modifiable.

The monitored weaning parameters are:

- Oxygen
- Vt/IBW
- PFFP
- RSB or PetCO2 (depending on patient IBW), not configurable
- Rate
 - APsupport max

For details about each of these parameters, see Section 2.4, which lists where each one is displayed, default settings, and value ranges.

2.2.3 Quick Wean key terms

Table 2-1. Quick Wean key terms

Term/Parameter	Description
For parameter details,	see Table 2-3.
fSpont (b/min)	fSpont is the absolute number of spontaneous breaths taken. See Rate .
RSB (1 / (I*min))	Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE).
%MinVol (%)	When Quick Wean is enabled, as long as the patient is active and the patient's Rate is below the upper limit of the target range (Section 1.7.2), the device gradually reduces %MinVoI to 70%, if it is above this level.
Oxygen (%)	Inspired oxygen. The target Oxygen is configurable.
PEEP (cmH2O)	Positive end-expiratory pressure. Airway pressure at the end of exhalation. The target PEEP is configurable.
PetCO2 (mmHg)	End-tidal CO2 pressure.
ΔPsupport max (cmH2O)	The maximum pressure support allowed. The target ΔP support max is configurable.
Quick Wean panel	When Quick Wean is active, view 5 displays the Quick Wean panel showing the monitored weaning parameters and their status. When all parameters are in the weaning zone, the timer is also displayed in this panel.
Rate (b/min)	Respiratory rate, as number of breaths per minute. Shown on the Quick Wean panel as fSpont.
	Defines the maximum Rate allowed. The target Rate is configurable.
SpO2 (%)	Measurement of oxygen saturation in the blood.
Timer	When all 6 monitored weaning parameters are in the weaning zone, a timer becomes active in the Quick Wean panel. For details, see Section 2.2.5.

Term/Parameter	Description
Tolerance time (s)	The length of time a parameter value can be out of range without affecting the timer.
	If any one parameter is out of range for longer than the specified time period (180 s for patients over 40 kg, 60 s for patients \leq 40 kg), the timer is reset to zero and starts over again once all parameters are in the weaning zone.
Vt/IBW (ml/kg)	Tidal volume per kilogram of ideal body weight.

2.2.4 Quick Wean workflow

Upon enabling Quick Wean, the device does the following:

- Shifts the PetCO2 range to the right by up to +5 mmHg to support spontaneous breathing.
 - This shift remains in place as long as Quick Wean is enabled.
- Increases the spontaneous respiratory rate target range limits.
- As long as the patient is active and their Rate is below the upper limit of the target range, the device gradually reduces %MinVol to 70% as follows:
 - If %MinVol is already at 70%, the device does nothing.
 - If %MinVol is above 70%, the device decreases %MinVol to 70% in steps of no more than 1% per breath.
- If the patient is passive, INTELLIVENT-ASV continues ventilating the patient. When the patient becomes active, the ventilator proceeds with the %MinVol reduction process described above.
- Starts screening the readiness-to-wean criteria, and shows the Quick Wean panel in view 5 on the main display.

For details about:

- How the Quick Wean panel indicates progress, see Section 2.2.5
- How the device controls minute volume, see Sections 1.7.2 and 1.7.1

2.2.5 Monitoring progress with the Ouick Wean panel

When enabled, Quick Wean continuously screens the readiness-to-wean criteria that can help the physician assess whether the patient might be ready for the hospital's SBT and extubation protocols.

The ventilator monitors a set of weaning parameters and their values, and once all parameters are within the weaning ranges, starts a Weaning timer. Once the timer has started, the nonconfigurable Tolerance time determines the length of time a weaning parameter can be out of range before causing the timer to reset. For details, see Table 2-2.

These parameters are displayed in the Quick Wean panel in view 5.

The following table describes how this panel displays the status of the weaning parameters.

Table 2-2. Vent Status or Quick Wean panel

When	Vent Status or Quick Wean panel	
Quick Wean is disabled	INTELLIVENT-ASV displays the Vent Status panel, showing the ventilation parameters. For details, see your ventilator Operator's Manual.	
Quick Wean is enabled	INTELLIVENT-ASV displays the Quick Wean panel, showing the monitored weaning parameters (Table 2-3).	
One or more parameter values are in the weaning zone	Parameters that are within their target weaning ranges are in their weaning zone, and are marked with a green bar above and below the zone (1 below).	
	In addition, parameters with values within the weaning zone show a timer indicating the amount of time that parameter has been in the weaning zone.	
	*** INTELLIMENT-ASV** *********************************	

All of the parameter values are in the weaning zone

The Quick Wean panel displays:

- A green bar for each of the parameters.
- A timer (HH:MM:SS) showing how long the patient values have been in the weaning zone.



Any of the weaning parameters can be out of range for up to the time specified by the Tolerance time parameter without affecting the timer progress.

For example, with a Tolerance time of 180 seconds, any parameter can be out of range for up to 3 minutes with no effect.

If a parameter value remains out of range for 181 or more seconds, the process resets. The timer disappears, as does the green bar for the affected parameter(s). Monitoring continues, and once all of the bars are green again, the timer restarts.

For Tolerance time details, see Table 2-3.

2.3 Configuring Quick Wean parameters

You configure Quick Wean using the Configuration windows, in Standby mode. These settings cannot be modified while ventilating a patient.

You can configure the following control settings: PEEP, Oxygen, \(\Delta Psupport \) max, and Rate

The following parameters are set by the ventilator and are nonconfigurable: Tolerance time, Vt/IBW, and RSB.

For parameter ranges and default settings, see Section 2.4. While the default parameter values are all based on the currently available literature, you can change the settings if you prefer to use a different protocol.

The system monitors patient conditions against these parameter thresholds to determine whether the patient is ready for weaning activities.

For details on putting the ventilator into Standby and accessing Configuration mode, refer to your ventilator Operator's Manual.

2.3.1 Adjusting values in Configuration

The Quick Wean criteria are set in Configuration. You can change the default settings to match your institution's protocol. if needed.

To change the Quick Wean criteria

- 1. Without a patient connected, put the ventilator in Standby.
- 2. Access the Configuration windows, and on the left side, touch **Setups** > Adult/Ped x > Status > Ouick Wean.

Note that Adult/Ped x is any of the three Quick Setups for which you wish to define Quick Wean settings.

The Quick Wean window displays the user-configurable weaning-related parameters.

- 3. Make changes as desired to the parameter thresholds
- 4. Touch the **Back** button to return to the main Configuration window.
- 5. When finished, exit Configuration.

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2.3.2 Restoring factory default settings

To reset the Ouick Wean criteria to the factory default settings

- 1. Without a patient connected, put the ventilator in Standby.
- 2. Access the Configuration windows, and on the left side, touch Setups > Adult/Ped x > Status > Quick Wean. Note that Adult/Ped x is any of the three Quick Setups for which you wish to define Quick Wean settings.
- 3. Touch the Use factory settings button, and when prompted to confirm, touch Yes

Touch **No** to cancel the reset.

- 4 Touch the **Back** button to return to the main Configuration window.
- 5. When finished, exit Configuration.

2.4 Quick Wean parameter specifications

For the definition of a parameter, see Section 2.2.3.

Table 2-3. Quick Wean parameters, default settings, and ranges

Parameter	Default values	Where displayed/Where set	Range
%MinVol (%)	Quick Wean enabled: 70	Displayed in: INTELLIVENT-ASV main display in the %MinVol control	
fSpont		Displayed in: • Quick Wean panel • Monitoring window	
Oxygen (%)	≤ 40	Displayed in: INTELLIVENT-ASV main display in the Oxygen control Quick Wean panel Monitoring window Set in: Configuration > Setups > Adult/Ped x > Status > Quick Wean	30 to 50
PEEP (cmH2O)	Patient IBW > 40 kg: ≤ 8 Patient IBW ≤ 40 kg: ≤ 6	Displayed in: INTELLIVENT-ASV main display in the PEEP control Quick Wean panel Monitoring window Set in: Configuration > Setups > Adult/Ped x > Status > Quick Wean	5 to 10

Danamatan	Defaulturalises	and an discharge days	D
Parameter	Default values	Where displayed/Where set	Range
PetCO2 (mmHg)	PetCO2 < (upper limit INTELLiVENT-ASV PetCO2 target range + 3 mmHg)	 Patient IBW ≤ 40 kg: Quick Wean panel. For patients with IBW over 40 kg, RSB is used instead. Ventilation horizon and map Monitoring > CO2 window Dynamic Lung panel PetCO2 is only used for patients with IBW ≤ 40 kg. This value is not configured. You can, however, shift the target range, if needed. See Section 1.4.11.2. 	Depends on PetCO2 target range
Rate (b/min)	Patient IBW > 30 kg: ≤ 35 Patient IBW ≤ 30 kg: ≤ 45	Displayed in: Quick Wean panel (as fSpont) Set in: Configuration > Setups > Adult/Ped x > Status > Quick Wean	25 to 65
RSB (1 /(l*min))	≤ 105	Displayed in: Patient IBW over 40 kg: Quick Wean panel For patients with IBW ≤ 40 kg, PetCO2 is used instead. RSB is only used for patients with IBW over 40 kg. This value is not configured.	105

Parameter	Default values	Where displayed/Where set	Range
SpO2 (%)	Within or above the INTELLIVENT-ASV SpO2 target range	Displayed in: Oxygenation horizon and map Monitoring > SpO2 window Dynamic Lung panel Main display under MMP list This value is not configured. You can, however, shift the target range, if needed. See Section 1.4.11.2.	Depends on the SpO2 target range
Tolerance time (s)	Patient IBW > 40 kg: 180 s Except for %fSpont, which is 60 s Patient IBW ≤ 40 kg: 60 s Except for Rate and Vt/IBW, which is 180 s	This value is not configured.	
Vt/IBW (ml/kg)	≥ 5 ml/kg	 Displayed in: Quick Wean panel Monitoring window Set in: Configuration > Setups > Adult/Ped x > Status > Quick Wean 	3 to 6
ΔPsupport max (cmH2O)	≤ 12	Displayed in: Quick Wean panel Set in: Configuration > Setups > Adult/Ped x > Status > Quick Wean	6 to 25

Specifications

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3.1 Intended use

The INTELLIVENT-ASV software is an option for the HAMILTON-C1/T1 ventilators, and is, for all legal purposes, subject to the Intended Use as stated in the current ventilator Operator's Manuals.

Table 3-1. INTELLiVENT-ASV technical data

3.2 Technical data

The following table provides technical data related to INTELLiVENT-ASV.

Operator settings	
Patient height (cm)	30 to 250 (adult, pediatric)
%MinVol (%)	25 to 350 (manual) 70 to 200 (automatic)
Oxygen (%)	21 to 100 (manual and automatic)
PEEP (cmH2O)	0 to 50 (manual) 5 to 24 (automatic)

Internal calculations		
Ideal body weight, IBW (kg)	Calculation based on patient height and sex. For details, see your ventilator <i>Operator's Manual</i> .	
	INTELLIVENT-ASV can only be used for patients weighing more than 7 kg.	
MinVol (target)	Target MinVol is calculated as:	
(l/min)	IBW x NormMinVent x %MinVol/100	
	where NormMinVent (l/kg/min) is the normal minute ventilation (not valid for pediatric patients < 30 kg). For details, see your ventilator <i>Operator's Manual</i> .	
ASV target respiratory rate (b/min)	Calculated as described in Section 1.7.2.	
VDaw (ml/kg)	Calculation of the dead space: IBW x 2.2	
Vt (target)	MinVol/f (target)	

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Monitoring		
Values (numerical)	PetCO2 target range, depending on patient condition and treatment (Ppeak); SpO2 target range, depending on patient condition and treatment (PEEP)	
Current ventilation settings	ExpMinVol, fTotal, fControl, Ppeak (ΔPinsp + PEEP), Oxygen, PEEP	
Patient status	fSpont, PetCO2, SpO2	
Graphics	f (target)/Vt, PetCO2/target, PEEP/SpO2	
Trend parameters	Ventilation control, Oxygenation control	

Performance specifications, Ventilation controller		
Settling time	< 5 minutes	
Response time (90% of steady state)	< 5 minutes (typical)	
(Rel./command) Overshoot/ undershoot	< 20%	
Steady state deviation	5%	
Maximum change of %MinVol per breath	1%	

Performance specifications, Oxygenation controller	Oxygen	PEEP
Settling time	The settling time depends on the patient condition relative to the SpO2 target, as defined by the appropriate approach (ARDSnet or Open Lung concept) for the current treatment. Note that if SpO2 enters the emergency zone, the system immediately sets Oxygen to 100%.	6 minutes
Response time (90% of steady state)	N/A, only target range for SpO2 specified	6 minutes

Performance specifications, Oxygenation controller	Oxygen	PEEP	
Rel/Command over- shoot	none	N/A, SpO2 of some patients does not respond at all to PEEP changes. In this case, Oxygen is also changed if it is set to Automatic.	
Command overshoot	none	N/A, SpO2 of some patients does not respond at all to PEEP changes. Upper PEEP limit, 24 cmH2O, user can set lower limit.	
Steady state deviation	N/A, only target range for SpO2 speci- fied	N/A, only target range for SpO2 specified	
Tracking error	N/A	N/A, only target range for SpO2 specified	
Maximum change	Decrease: 5% of current Oxygen setting every 60 s Increase: 10% of current Oxygen setting every 30 s	1 cmH2O every 6 min	

Lung-protective ventilation, Ventilation controller		
Minimum %MinVol	70% (100% if no PetCO2 is available)	
Maximum %MinVol	200%	

Lung-protective ventilation, Oxygenation controller		
Minimum Oxygen	21% to 30%, depending on what is selected in the Oxygen limit control in the INTELLIVENT-ASV Settings > More window.	
	Default: 21%	
Maximum Oxygen	100%	
PEEP limits	Low: 5 to 22 (Default: 5)	
	High: 7 to 24 (Default: 15)	

3.3 Data logging

Breath-by-breath data representing the actual values of these listed monitoring values and settings are saved by the ventilation unit of the processor.

Table 3-2. Data log inputs

Saved parameters	Unit
ARDS	N/A
Brain injury	N/A
Chronic hypercapnia	N/A
Chronic hypercapnia	N/A
Controller ventilation	N/A
Controller oxygena- tion	N/A
Controller PEEP	N/A
Date	N/A
Recruitment passive	N/A
Recruitment running	N/A
Time	N/A
Weaning	N/A
RRIMV	breaths per min
RRtot	breaths per min
RRtarget	breaths per min
fSpont	breaths per min
PEEP limit	cmH2O
%MinVol	%
ExpMinVol	l/min
Ti	S
ΔPinsp	cmH2O

Saved parameters	Unit
SpO2	%
PetCO2	mmHg
Oxygen	%
PEEP/CPAP	cmH2O
Pulse	bpm (beats per minute)
QI-SpO2	%
VtTarget	ml
RCexp	S

The memory reserved for breath-by-breath data allows storage of at least 10 days of recording. The data is saved breath-bybreath, but at most one time per second.

Data is exported using the test software. Refer to the ventilator Service Manual.

3 4 References

References are available on the Hamilton Medical website, www.hamilton-medical.com.

%MinVol

When Quick Wean is enabled, as long as the patient is active and the patient's rate is below the upper limit of the target range, the device gradually reduces MinVol to 70%

active patient

An active patient is one who is making inspiratory efforts. Active breathing is identified as the occurrence of at least five (5) consecutive spontaneous breaths. Spontaneous breaths are those for which inspiration is both patient triggered and patient cycled. In addition to spontaneous breaths as described, an active patient must also meet the requirements described in the rules for transitioning between active and passive states.

alarm buffer

Contains information on recent alarm occurrences

ARDS

Acute respiratory distress syndrome, which presents as an acute, severe injury to most segments of the lung

brain injury

Patients with brain injuries with whom it is critical to maintain CO2 under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range

chronic hypercapnia

For patients with chronically high arterial CO2 values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both

Dynamic Lung

Intelligent panel that graphically represents tidal volume, lung compliance, patient triggering, and resistance in real time

fSpont

The absolute number of spontaneous breaths taken. %fSpont is the percentage of spontaneous breaths to total breaths taken

IBW

Ideal body weight, a calculated value for adult and pediatric patients based on the patient's sex and height; used as the basis for initial settings of various parameters

Oxygen

Inspired oxygen

Oxygenation controller

Automated PEEP and Oxygen controller, available in INTELLIVENT-ASV

Oxygenation horizon

Shows a zoom into the Oxygenation map at the current SpO2 value and target range. Displayed during active ventilation in INTELLIVENT-ASV

Oxygenation map

The PEEP/SpO2 view shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits

PaCO2-PetCO2 gradient

The difference between the PaCO2 measured in the blood (using blood gas analysis) and the PetCO2 measured using a noninvasive CO2 sensor. Under normal conditions, PaCO2 is approximately 2-5 mmHg higher than PetCO2.

passive patient

A passive patient is one who is not making inspiratory efforts. Passive breathing is identified as the occurrence of at least five (5) consecutive mandatory breaths. In general, mandatory breaths are those for which inspiration is either machine triggered or machine cycled. In INTELLIVENT-ASV, mandatory inspirations are both machine triggered and machine cycled. In addition to mandatory breaths as described, a passive patient must also meet the requirements described in the rules for transitioning between active and passive status.

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.

PetCO2

Measured end-tidal CO2 partial pressure

Plethysmogram

The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter

Rate

Respiratory rate, as number of breaths per minute. Defines the maximum rate allowed.

RSB

Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE). The RSB parameter is only used for patients weighing >40 kg. For patients weighing less, the PetCO2 parameter is used.

SpO₂

Measurement of oxygen saturation in the blood.

Tolerance time

The length of time a parameter value can be out of range without affecting the timer

Ventilation controller

Automated %MinVol controller, available in INTELLiVENT-ASV. The controller uses different inputs to control the target minute volume, depending on whether the patient is passive or active.

Ventilation horizon

For a passive patient, shows a zoom into the Ventilation map at the current PetCO2 value and target range. For an active patient, shows the spontaneous breathing rate (fSpont). Displayed during active ventilation in INTELLIVENT-ASV.

Vt/IBW

Tidal volume per kilogram of ideal body weight.

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Intelligent Ventilation since 1983



Hamilton Medical AG Via Crusch 8, 7402 Bonaduz, Switzerland

2 +41 (0)58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com



EC REP medin Innovations GmbH Adam-Geisler-Strasse 1 DE - 82140 Olching