



# INTELLiVENT-ASV

## Operator's Manual

### HAMILTON-C6

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**MEDICAL**



# Operator's Manual

## INTELLiVENT-ASV

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## About this guide

This guide describes the features and functions of INTELLiVENT®-ASV® for HAMILTON-C6, and is designed for use with the following documentation:

- Your ventilator *Operator's Manual* (PN 624945)
- *Pulse oximetry Instructions for use* for your ventilator (PN 624963)
- *INTELLiVENT-ASV Quick Guide*

Be sure to read all relevant documentation, including safety information, before using the device or accessories. For the list of related Hamilton Medical documentation, see the *Documentation suite* table in the ventilator *Operator's Manual*.

## Conventions used in this guide

In this manual:

- Button and tab names are shown in a **bold** font.
- The notation **ICON > ICON** shows the following sequence:

Icon to touch in the toolbar on the bottom of the display, followed by the icon/element to touch in the window that is opened.

For example,  >  means touch the Applications icon in the toolbar, then touch the O2 enrichment icon in the Applications window.

- The notation **XX > XX** shows the sequence of buttons/tabs to touch to open the associated window. For example, the text "Touch **Alarms > Limits 2**" means touch the **Alarms** button, then touch the **Limits 2** tab.
- Similarly, window names are shown using the sequence of buttons/tabs used to open them. For example, "Alarms > Limits 2 window" means the window is accessed by touching the **Alarms** button, then the **Limits 2** 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  indicates a selected item or feature.
- The graphics shown in this manual may *not* exactly match what you see in your environment.
- For the Adult/Pediatric patient group, the ventilator uses sex and patient height to calculate the predicted body weight (PBW).<sup>1</sup>
- *Software version*: The software version for the ventilator is displayed in the Info window ( > ) and should match the version on the title page of this manual.

<sup>1</sup> Martin DC and Richards GN. Predicted body weight relationships for protective ventilation – unisex proposals from pre-term through to adult. *BMC Pulmonary Medicine* (2017) 17:85

- 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 figure 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.
  - A These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- All patient-related pressure, volume, and flow measurements are expressed in BTPS (body temperature and pressure saturated).
- Pneumatic-related pressure, volume, and flow measurements are expressed in STPD (standard temperature and pressure dry).
- PI and PVI<sup>2</sup> are only available with a Masimo SET<sup>®</sup> pulse oximeter.
- The terms *user* and *operator* are used interchangeably and refer to the operator of the device.
- Unless otherwise indicated, the information in this manual applies to both the HAMILTON-C6 PN 1600210 and PN 160021.
- 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.

 **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!**

<sup>2</sup> Available as an option.

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## Active and passive patients definition

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 1.9.3.

- 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 described, a *passive* patient must also meet the requirements described in Section 1.9.3.



# 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 CO<sub>2</sub> elimination and oxygenation for both *passive* and *active* patients, using both physiologic data from the patient and clinician-set targets and limits.

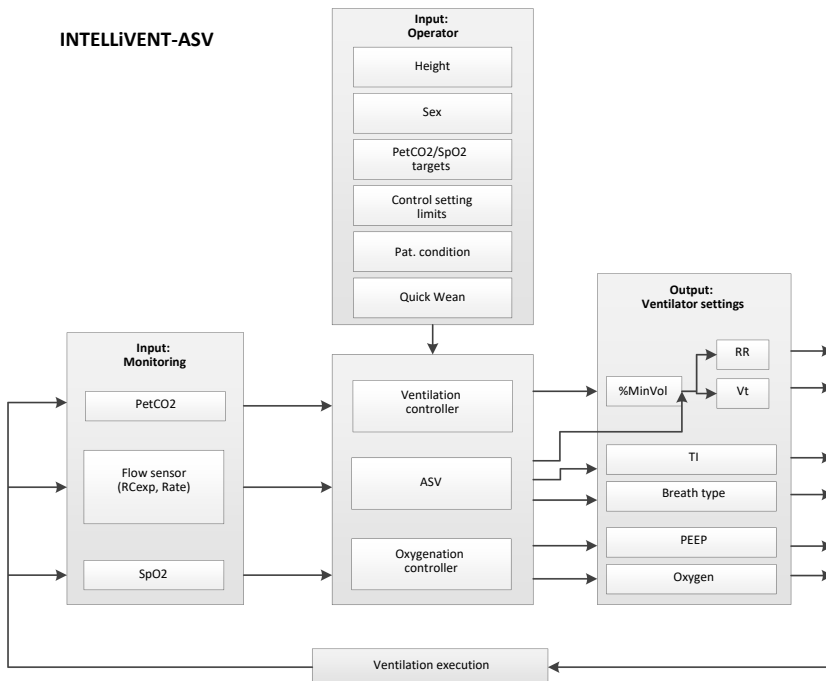
With this mode, the clinician sets targets for PetCO<sub>2</sub> and SpO<sub>2</sub>, as well as limits for various controls, including PEEP, Oxygen, and %MinVol, for the patient. INTELLiVENT-ASV then manages

the controls for CO<sub>2</sub> elimination (%MinVol), and oxygenation (PEEP and Oxygen) based on these targets, clinician-defined limits, and on the physiologic input from the patient (PetCO<sub>2</sub> and SpO<sub>2</sub>).

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 help promote early weaning using the Quick Wean function.

Figure 1-1. INTELLiVENT-ASV workflow



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

- Section 1.9, Management of minute volume
- Section 1.10, 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 contraindications for use, as well as all safety-related messages.

## 1.2 Intended use

### Intended medical purpose

INTELLiVENT-ASV is a medical device software (MDSW) intended for automated adjustment of ventilation and/or oxygenation variables to assist the user in maintaining the patient's PetCO<sub>2</sub> and/or SpO<sub>2</sub> values within the target ranges and limits set and monitored by healthcare professionals.

INTELLiVENT-ASV includes the following features that can be activated:

1. Ventilation controller (automated adjustment of %MinVol)
2. Oxygenation controller (automated adjustment of Oxygen and/or PEEP)
3. Quick Wean (evaluation of the patient's readiness for weaning, including optional spontaneous breathing trials (SBT))

INTELLiVENT-ASV is intended for use only within the limits of its stated technical specifications.

### Intended patient group

INTELLiVENT-ASV is intended to be used for intubated adult and pediatric patients (with a predicted body weight (PBW) of 7 kg or more) requiring invasive mechanical ventilation.

### Intended user

INTELLiVENT-ASV is intended for use only by healthcare professionals trained on the use of INTELLiVENT-ASV.

### Intended environment

INTELLiVENT-ASV is only intended to be used on compatible Hamilton Medical ventilators in their respective intended-use environments.

## 1.3 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.
- Be sure you are familiar with the use of the CO<sub>2</sub> and SpO<sub>2</sub> sensors. See your ventilator *Operator's Manual*, the *Pulse Oximetry Instructions for Use*, and documentation provided with the sensors.

Intubated adult and pediatric patients (with a predicted body weight (PBW) of 7 kg or more) requiring invasive mechanical ventilation.

## Contraindications for use

### WARNING

Do *not* use the INTELLiVENT-ASV automated PEEP/Oxygen adjustment if dyshemoglobin is expected or clearly evidenced, or if the difference between SaO<sub>2</sub> and SpO<sub>2</sub> is greater than 5%.<sup>1</sup>

### CAUTION

*Do NOT use SpO<sub>2</sub> measurement and automated PEEP/Oxygen adjustments with patients being treated with intravenous dyes.*

Do NOT use INTELLiVENT-ASV if:

- The patient PBW is under 7 kg
- Oxygenation controller:
  - Dyshemoglobinemia
  - Patients having intravenous dyes
- Ventilation controller:
  - NIV
  - Ventilation through an uncuffed tube resulting in a high leak
  - The existence of a bronchopleural fistula with high airflow through the fistula
  - Veno-Arterial ECMO
  - Cardiac arrest

## Limitations for use

INTELLiVENT-ASV is limited in the following cases:

- Target ranges for PetCO<sub>2</sub> and SpO<sub>2</sub> cannot be set according to the hospital protocol or to the patient's condition
- Oxygenation controller:
  - A low peripheral perfusion causing unreliable SpO<sub>2</sub> sensor readings
  - Difference between SaO<sub>2</sub> and SpO<sub>2</sub> greater than 5%
- Ventilation controller:
  - An irregular drive, for example, Cheyne-Stokes respiration
  - Need for PetCO<sub>2</sub> target shift > 20 mmHg
  - Veno-Venous ECMO with high CO<sub>2</sub>-removal

<sup>1</sup> You can compensate for differences between SaO<sub>2</sub>/SpO<sub>2</sub> and PaCO<sub>2</sub>/PetCO<sub>2</sub> up to set limits. For details, see information about Target shift.

## 1.4 Navigating the windows and controls

When in INTELLiVENT-ASV mode:

- Swipe left/right in the INTELLiVENT-ASV panels that are displayed during active ventilation (horizons, maps, plethysmogram/capnogram, SBT history) to cycle through the panel options.  
Alternatively, touch the left and right View arrows above the **Controls** button to cycle through the panels.
- Swipe left/right within the Oxygenation map panel to switch between the PEEP/SpO<sub>2</sub> and FiO<sub>2</sub>/PEEP maps.  
Alternatively, touch the button for the map to display.
- Swipe left/right within the SBT history panel (Section 2.4.4.2) to cycle through previous SBT data.

## 1.5 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 INTELLiVENT-ASV ventilation. Check PaCO<sub>2</sub> against displayed PetCO<sub>2</sub>, and SaO<sub>2</sub> against SpO<sub>2</sub>.
- The physician is responsible for deciding which settings are managed by INTELLiVENT-ASV, the acceptable ranges, and alarm limits.
- Use *only* parts and accessories specified in the ventilator *Operator's Manual* and in the product e-catalog, or that are specified as being compatible with this ventilator. Doing so ensures proper ventilation operation, avoids degraded performance, and keeps your warranty in force.

### NOTICE

Any incident with the device leading to serious patient injury, death, or a potential threat to public health must be reported to the manufacturer and the relevant authorities.

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

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

| To ...                                                                              | See ...                                                                                                                                                                            |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Set up and enable the CO2 and SpO2 sensors                                          | <ul style="list-style-type: none"><li>• Ventilator <i>Operator's Manual</i></li><li>• Pulse oximetry documentation</li><li>• Documentation provided with the CO2 sensors</li></ul> |
| Prepare the ventilator for operation, including performing the preoperational check | <ul style="list-style-type: none"><li>• Ventilator <i>Operator's Manual</i></li><li>• <i>Preoperational Check Quick Reference</i></li></ul>                                        |
| Set up and connect the patient                                                      | <i>Ventilator Operator's Manual</i>                                                                                                                                                |
| Specify and confirm INTELLiVENT-ASV settings                                        | Section 1.6                                                                                                                                                                        |
| Start ventilation and monitor the patient                                           | <i>Ventilator Operator's Manual</i>                                                                                                                                                |

1.6 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 provides access to most of the INTELLiVENT-ASV settings and controls. It is organized into the following tabs: Auto, SBT, Target, and More.

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)
- Enable or disable Quick Wean
- Enable or disable automatic SBTs
- Define SBT settings
- Review SpO2 and PetCO2 target ranges, and adjust if needed
- If the Oxygenation controller is set to Automatic, set Oxygen and PEEP limits for the controller, as well as an oxygen level notification

You can further fine tune control settings in the Controls window, and alarm limits in the Alarms window.

## Navigating the INTELLiVENT-ASV Settings window

Navigating the window differs depending on whether you are setting up INTELLiVENT-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 the **Back** button returns you to the previously displayed window.
    - Touching the **X** or **Cancel** buttons, or doing nothing for one (1) minute, closes the INTELLiVENT-ASV Settings window and returns you to the previously selected mode.
  - During active ventilation with INTELLiVENT-ASV, 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 **Back/Cancel/Continue/Confirm** buttons. Changes are applied as soon as you make them.
- You can also adjust control settings and alarm limits at any time, as with any other ventilation mode.

## Specifying INTELLiVENT-ASV settings

Setting up INTELLiVENT-ASV for use comprises the following steps.

Table 1-2. Specifying INTELLiVENT-ASV settings

| To ...                                                                                                          | See ...        |
|-----------------------------------------------------------------------------------------------------------------|----------------|
| Specify the patient settings in the Standby window.                                                             | Section 1.6.1  |
| Select the INTELLiVENT-ASV mode.                                                                                | Section 1.6.2  |
| Select control management options (automatic or manual).                                                        | Section 1.6.3  |
| Select one or more specific conditions (ARDS, Brain Injury, Chronic Hypercapnia), if applicable.                | Section 1.6.4  |
| Enable or disable Quick Wean.                                                                                   | Section 1.6.5  |
| Enable or disable automated SBTs.                                                                               | Section 1.6.6  |
| Review and adjust SpO <sub>2</sub> and PetCO <sub>2</sub> target ranges, if needed.                             | Section 1.6.8  |
| Specify additional settings (minimum Oxygen limit, and upper and lower PEEP limits), oxygen notification level. | Section 1.6.9  |
| Review and adjust control settings.                                                                             | Section 1.6.10 |
| Review and adjust alarm limits.                                                                                 | Section 1.6.11 |
| Adjust settings during active ventilation, if needed.                                                           | Section 1.6.12 |

### 1.6.1 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.  
You can adjust these settings during ventilation in the Controls > Patient window.

Be sure the patient data is accurate. It is used to calculate the patient's PBW, 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*.

#### 1.6.1.1 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.

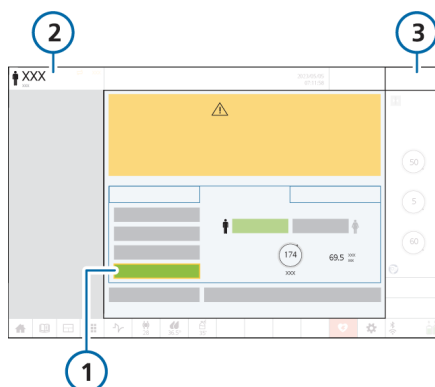
If you select Last patient in the Standby window and start ventilating the patient, the system assumes the same settings that were in place before entering Standby.

### 1.6.2 Selecting the INTELLiVENT-ASV mode

You can select the INTELLiVENT-ASV mode from the following locations:

- Standby window
- Modes window

Figure 1-2. Selecting the INTELLiVENT-ASV mode (Standby window shown)



- 1 INTELLiVENT-ASV
- 2 Selected mode and patient group
- 3 Modes

#### To select INTELLiVENT-ASV from Standby

- ▶ In the Standby window, touch **INTELLiVENT-ASV** (Figure 1-2).<sup>1</sup>  
The INTELLiVENT-ASV Settings window (Figure 1-3) opens, displaying the **Auto** tab.

You can now configure INTELLiVENT-ASV options. Continue to the next step, selecting control management options.

<sup>1</sup> This button accesses settings saved with the INTELLiVENT-ASV Quick setup. For Quick setup configuration, see the ventilator *Operator's Manual*.

### To select INTELLiVENT-ASV from the Modes window

1. Open the Modes window by doing either of the following (Figure 1-2):
  - 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 **INTELLiVENT-ASV**.
3. Touch **Confirm**.  
The INTELLiVENT-ASV Settings window (Figure 1-3) opens, displaying the **Auto** tab.

You can now configure INTELLiVENT-ASV options. Continue to the next step, selecting control management options.

### 1.6.3 Selecting control management options (Auto/Manual)

#### NOTICE

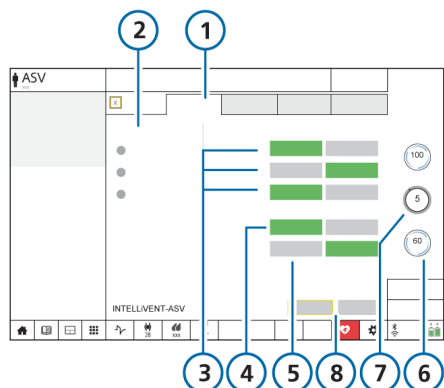
- Only Manual mode is available for %MinVol when the CO<sub>2</sub> sensor hardware option is *deactivated* in Configuration.<sup>1</sup>
- Only Manual mode is available for PEEP when:
  - Either the Chronic Hypercapnia or Brain Injury condition is selected.
  - The SpO<sub>2</sub> sensor hardware option is *deactivated* in Configuration.<sup>1</sup>
  - If Chronic Hypercapnia and ARDS are *both* selected, PEEP management can be set to Automatic.
- Only Manual mode is available for Oxygen when the SpO<sub>2</sub> sensor hardware option is *deactivated* in Configuration.<sup>1</sup>

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 1.9 and 1.10 in this guide provide detailed information about how INTELLiVENT-ASV regulates these controls automatically.
- Select one or more conditions (ARDS, Brain injury, or Chronic Hypercapnia), if appropriate.
- Enable or disable Quick Wean
- Enable or disable automatic SBTs

<sup>1</sup> 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 CO<sub>2</sub> and/or SpO<sub>2</sub> sensor in the Sensors window. If a sensor is *not* connected, a medium-priority sensor-related alarm is generated.

Figure 1-3. INTELLiVENT-ASV Settings window, Auto tab



- |                                                                                 |                                                                        |
|---------------------------------------------------------------------------------|------------------------------------------------------------------------|
| 1 Auto                                                                          | 5 Automatic SBT: On, Off                                               |
| 2 Specific condition options                                                    | 6 Automated management indicator with rotating comets, parameter value |
| 3 Controller settings: Automatic, Manual buttons for %MinVol, PEEP/CPAP, Oxygen | 7 Manual management indicator, parameter value                         |
| 4 Quick Wean settings: On, Off                                                  | 8 Cancel, Continue (if displayed)                                      |

### 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 1.6.12).
2. For each of the controls, %MinVol, PEEP, and Oxygen, choose whether they are managed automatically by the device or manually by the operator:
  - Touch **Automatic** to have INTELLiVENT-ASV automatically regulate the control setting to keep the patient within the target range.<sup>1</sup>
  - 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. In all cases, the selected button turns green.
3. Select a specific condition (such as ARDS), if needed. See Section 1.6.4. Otherwise, continue to step 4.
4. Enable (or disable) Quick Wean, if desired. See Section 1.6.5. Otherwise, continue to step 5.
5. Enable (or disable) automatic SBTs, if desired. See Section 1.6.6. Otherwise, continue to step 6.

<sup>1</sup> 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 *Sensors* window. If a sensor is *not* connected, a medium-priority sensor-related alarm is generated.

6. Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen) and, if desired, make any adjustments.
7. If displayed, touch **Continue** to accept the settings and proceed to the next step.

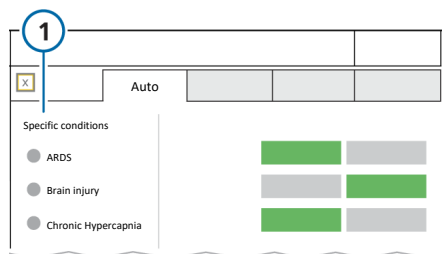
### 1.6.4 Adjusting for Specific conditions

If appropriate for the patient, you can select one or more of the following conditions: ARDS, Brain Injury, and Chronic Hypercapnia (*passive* patients only). These selections are in the Auto window, under Specific conditions.

Selecting a condition may affect ventilation and oxygenation control setting startup values, and PetCO<sub>2</sub> and SpO<sub>2</sub> target ranges, as well as the upper and lower target shift limits. For details on the use of specific conditions, see Section 1.6.13.1.

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 ranges of the associated CO<sub>2</sub> elimination and Oxygenation maps.

Figure 1-4. Specific conditions (1)



### 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 1.6.12).
  2. Before proceeding, be sure to read the safety information related to selecting specific conditions, in Section 1.6.13.1.
  3. *Only* if the patient has any special condition, select one or more of the following entries: ARDS, Chronic Hypercapnia, or Brain injury. See Figure 1-4.  
Selecting a condition may change the startup settings and targets for CO<sub>2</sub> 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 1-6 in Section 1.6.13.1.
  4. Set control management options (Automatic, Manual), as needed, if you have not already done so.
  5. Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen) and, if needed, make any adjustments.
  6. If displayed, touch **Continue** to accept the settings and proceed to the next step.

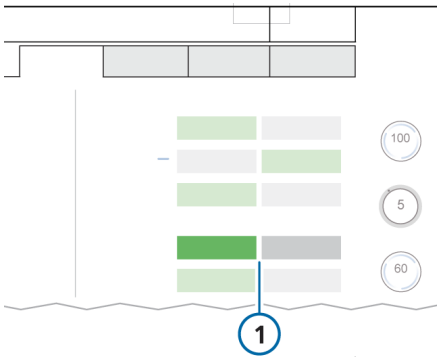
### 1.6.5 Enabling/disabling Quick Wean

#### NOTICE

Quick Wean remains disabled when either of the following occurs:

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

Figure 1-5. INTELLiVENT-ASV Settings > Auto window, Quick Wean On/Off buttons (1)



#### To enable/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 1.6.12).
2. In the Auto window, enable Quick Wean by touching **On**.

The button turns green.

A low-priority alarm, PetCO<sub>2</sub> 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.

The **SBT** tab is enabled.

To disable Quick Wean, touch **Off**.

The button turns green. The **SBT** tab is disabled.

3. If displayed, touch **Continue** to confirm the settings and proceed to the next step.

### 1.6.6 Enabling/disabling automatic SBTs

Use the INTELLiVENT-ASV Settings > Auto window to enable/disable automatic spontaneous breathing trials (SBTs).

When Quick Wean is enabled, the device decreases ventilatory support, and, if automatic SBTs are also enabled, performs an SBT when criteria are met.

You can fine tune the SBT settings, as well as timing options for when to perform them. For details, see Section 1.6.7.

Quick Wean and automatic SBTs are both disabled by default, and can be enabled at any time during ventilation.

#### To enable/disable automated SBTs

Note that to enable SBTs, Quick Wean must be set to On in the INTELLiVENT-ASV Settings > Auto window (Section 1.6.5).

- ✓ 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 1.6.12).
2. In the Auto tab, enable automatic SBTs by touching On.<sup>1</sup>

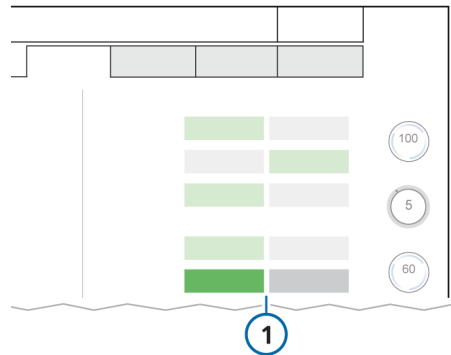
The button turns green. When the *To start SBT* criteria are met, the ventilator initiates a trial. For details, see Section 2.4.

You can adjust SBT settings in the **SBT** tab (Section 1.6.7).

To disable automatic SBTs, touch **Off**. The button turns green.

3. Review and adjust control settings as appropriate. For details, see Section 2.3.
4. If displayed, touch **Continue** to confirm the settings and proceed to the next step.

Figure 1-6. INTELLiVENT-ASV Settings > Auto window, Automatic SBT On/Off buttons (1)



<sup>1</sup> If the button cannot be selected, Quick Wean is set to Off; set it to On to proceed.

1.6.7 Defining SBT settings

Default SBT settings are defined in Configuration (Section 2.9).

You can adjust key SBT-related settings that determine when to start and stop an SBT, active SBT settings, and timing-related controls.

- SBT settings:
  - To start SBT:  $\Delta P_{\text{support}}$  max value required before an SBT can start
  - To stop SBT:  $\Delta P_{\text{support}}$  max and Rate values that determine an SBT should be stopped
  - SBT settings:  $\Delta P_{\text{support}}$  min value to deliver during the SBT
- Timing controls (apply only to automated SBTs):
  - How long the criteria must be met and maintained before starting an SBT (Time before starting SBT)
  - The time period within which an SBT can take place (by default, set to between 8 am and 8 pm)
  - The minimum time interval between two SBTs

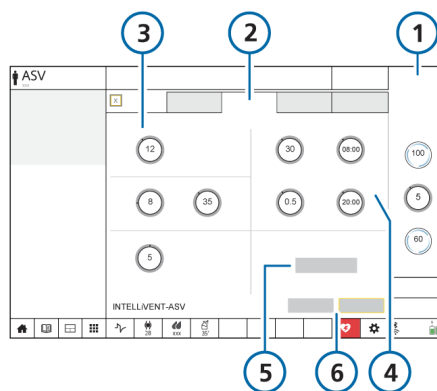
These values can be modified during ventilation and in Standby, as appropriate. For details, see Table 1-3.

Table 1-3. SBT settings, available during ventilation

| SBT setting             | Description                                                                                                                                                                                                                                                                                                                        |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SBT time range          | Hours between which an SBT can be started.<br><br>Even if clinical conditions match the specified SBT starting criteria, if the start time for the SBT is outside of the range specified here, the SBT will <i>not</i> take place.<br><br>To allow automatic SBTs to start at any time, set both controls to the same time.        |
| Manually start/stop SBT | Manually start/stop an SBT. Only available when the patient is <i>active</i> and the patient's Rate is below the upper limit of the target range.                                                                                                                                                                                  |
| Start SBT               | Touch to immediately start an SBT.<br><br>The system: <ul style="list-style-type: none"><li>• Adjusts %MinVol to the configured setting</li><li>• Adjusts PEEP to the configured setting (if automatically controlled)</li><li>• Displays the SBT history panel</li><li>• Displays the Quick Wean &amp; SBT status panel</li></ul> |

| SBT setting                                | Description                                                                                                                                                                                                                                                                                                                                                | SBT setting                                | Description                                                                                                                                                                                                                                                                                     |
|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Stop SBT                                   | Select to immediately stop an ongoing SBT.<br><br>The system returns to the previous INTELLiVENT-ASV settings and monitors patient conditions for the next possible SBT.                                                                                                                                                                                   | $\Delta$ Psupport min (cmH <sub>2</sub> O) | The bottom limit of the pressure support applied during an SBT; that is, the pressure support will <i>not</i> fall below this value.<br><br>The target $\Delta$ Psupport min is configurable (Section 2.9).<br><br>Shown as the lower $\Delta$ Psup limit in the Quick Wean & SBT Status panel. |
| Time before starting SBT (min)             | Length of time that <i>To start SBT</i> parameters must remain within specified limits before an SBT can start. See Section 2.4.2. Available only when automatic SBTs are on.                                                                                                                                                                              | Rate (b/min)                               | The maximum rate allowed before starting an SBT, and an absolute upper limit that it cannot exceed during an SBT.                                                                                                                                                                               |
| Time between 2 SBTs (min)                  | The minimum length of time after an automatic SBT is executed before another automatic SBT can be started. By default, set to 30 minutes; can be increased up to 24 hours or turned off.                                                                                                                                                                   |                                            |                                                                                                                                                                                                                                                                                                 |
| $\Delta$ Psupport max (cmH <sub>2</sub> O) | The maximum pressure support allowed before starting an SBT, and an absolute upper limit that it cannot exceed during the SBT. If the upper limit is reached during an SBT, the SBT is stopped.<br><br>The target $\Delta$ Psupport max is configurable (Section 2.9).<br><br>Shown as the upper $\Delta$ Psup limit in the Quick Wean & SBT Status panel. |                                            |                                                                                                                                                                                                                                                                                                 |

Figure 1-7. INTELLiVENT-ASV Settings &gt; SBT window



- |                |                                    |
|----------------|------------------------------------|
| 1 Modes        | 4 SBT timing controls <sup>1</sup> |
| 2 SBT          | 5 Manually start/stop SBT          |
| 3 SBT controls | 6 Back, Continue (if displayed)    |

<sup>1</sup> Timing controls apply only to automatic SBTs; when automatic SBTs are turned off, this panel is disabled.

## To update SBT settings

The **SBT** tab is enabled when Quick Wean is set to On.

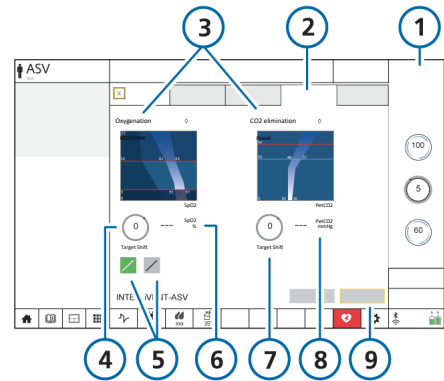
- ✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLiVENT-ASV Settings window (Section 1.6.12).
- 2. Touch the **SBT** tab.
- 3. Review and adjust the settings as appropriate.  
For details about running an SBT, see Section 2.3 and related sections in Chapter 2.
- 4. If displayed, touch **Continue** to confirm the settings and proceed to the next step.

## 1.6.8 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.

Figure 1-8. INTELLiVENT-ASV Settings window, Target tab



- |                                              |                                       |
|----------------------------------------------|---------------------------------------|
| 1 Modes                                      | 6 Current SpO2 value, quality index   |
| 2 Target                                     | 7 Target Shift control (PetCO2)       |
| 3 Oxygenation and CO2 elimination maps       | 8 Current PetCO2 value, quality index |
| 4 Target Shift control (SpO2)                | 9 Back, Continue (if displayed)       |
| 5 PEEP/SpO2, FiO2/PEEP map selection buttons |                                       |

## To review the SpO2 and PetCO2 target ranges

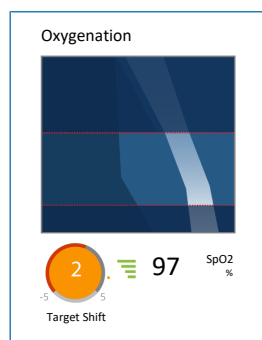
- ✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 3.
1. Open the INTELLiVENT-ASV Settings window (Section 1.6.12).
  2. To display the SpO2 and PetCO2 target ranges, touch the **Target** tab (Figure 1-8).
  3. Carefully review the target ranges.  
Note that 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.  
*If you have changed the condition selection, carefully review the target ranges.*  
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 next.
  5. When finished, if displayed, touch **Continue** to confirm the settings, and proceed to the next step.

## To adjust the SpO2 target range

For details on target shift limits associated with specific conditions, see Tables 1-9 and 1-8 in Section 1.6.13.2.

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. See Figure 1-9.
2. Turn the P&T knob clockwise or counterclockwise to move the target range as described next, then press the P&T knob to confirm 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.

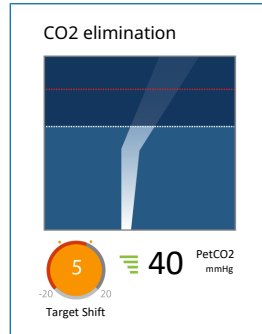
Figure 1-9. Target shift active: SpO2



### To adjust the PetCO<sub>2</sub> target range

- Under the CO<sub>2</sub> elimination map, touch **Target Shift** next to the PetCO<sub>2</sub> value.  
The button turns orange, and the limits appear on either side of the control. See Figure 1-10.
- Turn the P&T knob clockwise or counterclockwise to move the target range as described below, then press the P&T knob to confirm the setting. The control turns gray again.
  - Setting the value to a positive number moves the target range to the right, targeting a higher PetCO<sub>2</sub>.
  - Setting the value to a negative number moves the target range to the left, targeting a lower PetCO<sub>2</sub>.
- To shift the PetCO<sub>2</sub> target range to a value beyond  $\pm 5$  mmHg:
  - Set the value now to +5 or -5, as needed, and press the P&T knob to confirm the setting.
  - Touch the **Target Shift** control again and set the value beyond  $\pm 5$ , as needed, and press the P&T knob to confirm the setting.

Figure 1-10. Target shift active: PetCO<sub>2</sub>



### 1.6.9 Specifying additional settings

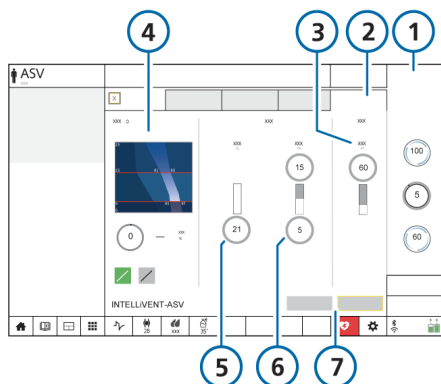
The INTELLiVENT-ASV Settings > More window provides access to additional INTELLiVENT-ASV options:<sup>1</sup>

- Set the minimum Oxygen limit (between 21% and 30%)
- Set an upper and/or lower PEEP limit
- Set an oxygen level notification limit (Oxygen alert)

The Oxygenation map is also displayed in the window.

<sup>1</sup> When PEEP and Oxygen are both set to Manual, the More tab is grayed out and unavailable.

Figure 1-11. INTELLiVENT-ASV Settings window, More tab



- |                                 |                                 |
|---------------------------------|---------------------------------|
| 1 Modes                         | 5 Oxygen limit                  |
| 2 More                          | 6 PEEP limit                    |
| 3 Oxygen alert                  | 7 Back, Continue (if displayed) |
| 4 Oxygenation map, Target shift |                                 |

### To set minimum oxygen limit, PEEP limits, and oxygen level notification

- ✓ 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 1.6.12).
  2. Touch the **More** tab (Figure 1-11).
  3. Set options, described in Table 1-4, as desired.
  4. If displayed, touch **Continue** to confirm the settings and proceed to the next step, reviewing and adjusting control settings.

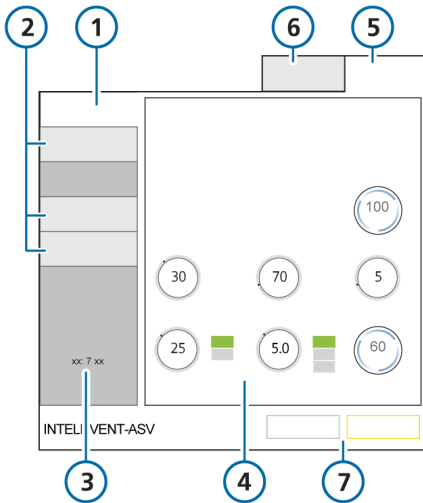
Table 1-4. More window settings

| Setting            | Description                                                                                                                                                                                                                                                                                                         |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oxygen limit (%)   | <p>When the Oxygen control is set to Automatic, you can set an absolute lower limit that the Oxygen controller cannot fall below.</p> <p>The limit can be set between 21% (the default) and 30%. See Section 1.6.13.3.</p>                                                                                          |
| PEEP limit (cmH2O) | <p>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 two (2) cmH2O.</p> <p>See Section 1.6.13.4.</p>            |
| Oxygen alert (%)   | <p>When the Oxygen control 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.</p> <p>The Oxygen alert control is only a notification tool; <i>it does not affect the percentage of delivered oxygen.</i></p> |

### 1.6.10 Adjusting control settings

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. The controls are the same as in the ASV mode.

Figure 1-12. INTELLiVENT-ASV Controls window, Basic tab



- |                           |                                 |
|---------------------------|---------------------------------|
| 1 Basic                   | 5 Modes                         |
| 2 More, TRC, Patient tabs | 6 Target                        |
| 3 Current minute volume   | 7 Back, Continue (if displayed) |
| 4 Control settings        |                                 |

### To adjust INTELLiVENT-ASV control settings

- ✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.

1. To open the Controls window, touch the **Controls** button at the bottom right of the display.

The contents of the **Basic** tab are displayed by default.

2. Adjust any settings as needed.
3. Touch the **More** tab to enable or disable Sigh, as needed.

4. Touch the **TRC** tab to adjust any tube resistance compensation settings if needed.

For details on TRC, see your ventilator *Operator's Manual*.

5. Touch the **Patient** tab to review patient data (height, sex), and ensure the correct PBW is calculated.

You can also access the Patient window by touching the Patient icon at the top left of the display (Figure 1-14).

6. If displayed, touch **Confirm** to confirm the settings and proceed to the next step, reviewing and adjusting alarm limits.

### 1.6.11 Adjusting alarm limits

#### **WARNING**

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

#### **NOTICE**

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

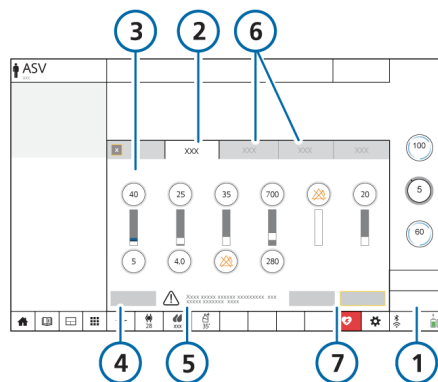
For details, see the chapter, *Responding to alarms*, in your ventilator *Operator's Manual*.

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.

Additional information:

- For troubleshooting, see Section 1.8.
- For detailed information about alarms, including default settings and ranges, see your ventilator *Operator's Manual* and the *Pulse Oximetry Instructions for Use*.

Figure 1-13. Setting alarm limits



- |                        |                                   |
|------------------------|-----------------------------------|
| 1 Alarms               | 5 Safety notice                   |
| 2 Limits 1             | 6 Limits 2, Limits 3 <sup>1</sup> |
| 3 Alarm limit controls | 7 Cancel, Confirm (if displayed)  |
| 4 Auto                 |                                   |

#### 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.
1. To open the Alarms window, touch the **Alarms** button at the bottom right of the display.  
The contents of the **Limits 1** tab are displayed by default.
  2. Adjust any limits as needed.
  3. Touch the **Limits 2** and **Limits 3** (if displayed) tabs to review and adjust additional alarm limits.

<sup>1</sup> When Masimo rainbow SET SpO2 parameters are enabled, additional alarm limit settings are available in the Limits 3 window.

4. To set alarm limits automatically, touch the **Auto** button.  
Selecting **Auto** automatically sets alarm limits around the current monitoring parameter values, except for the following alarm limits: Apnea, Vt, SpO2, Pulse, and PI. These alarm limits remain unchanged, and must be set manually to the desired level.
5. If displayed, touch **Confirm** to accept the settings.

INTELLiVENT-ASV setup is now complete.

### 1.6.12 Adjusting settings during active ventilation

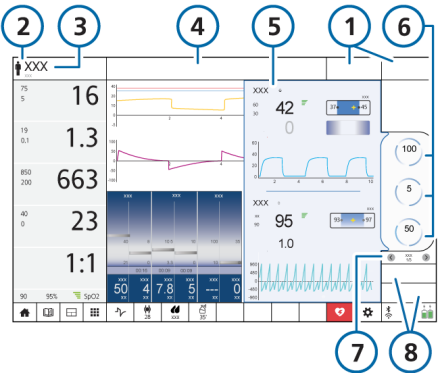
During active ventilation, you can adjust INTELLiVENT-ASV settings at any time.

You can also review patient information in multiple scrollable views. For details, see Section 1.7.1.

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 **Back/Continue** buttons. Changes are applied at the end of the current breath cycle.

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

Figure 1-14. Active ventilation with INTELLiVENT-ASV



- |                                                               |                                                                       |
|---------------------------------------------------------------|-----------------------------------------------------------------------|
| 1 Target, Modes                                               | 5 Selected INTELLiVENT-ASV view                                       |
| 2 Touch patient icon to open the Patient window               | 6 Controls managed by INTELLiVENT-ASV shown with rotating blue comets |
| 3 Touch mode name to open the INTELLiVENT-ASV Settings window | 7 View number and navigation arrows                                   |
| 4 Alarm message bar                                           | 8 Controls, Alarms bar                                                |

To display the INTELLiVENT-ASV Settings window

- When INTELLiVENT-ASV is the active mode, access the INTELLiVENT-ASV Settings window at any time by doing 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.
  - Touch **Target** at the top right of the display.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 at the end of the current breath cycle.
- 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.

1.6.13 About INTELLiVENT-ASV settings

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

| Settings                                 | See ...          |
|------------------------------------------|------------------|
| Specific conditions                      | Section 1.6.13.1 |
| Target shift                             | Section 1.6.13.2 |
| Oxygen limit                             | Section 1.6.13.3 |
| PEEP limit                               | Section 1.6.13.4 |
| Oxygen level notification (Oxygen alert) | Section 1.6.13.5 |

1.6.13.1 How the Specific conditions selections are used

 **WARNING**

- 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 CO<sub>2</sub> levels and high cranial pressure might result. Carefully monitor intracranial pressure when data is available.*

**NOTICE**

- If Brain Injury is selected, the Ventilation controller (%MinVol) regulates settings in accordance with the measured PetCO<sub>2</sub> 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, as well as upper and lower alarm limits
- Whether PEEP can be set to Automatic or must be manually controlled
- SpO<sub>2</sub> and PetCO<sub>2</sub> target ranges, and upper and lower target shift limits
- %MinVol for *active* patients based on fSpont, or, based on PetCO<sub>2</sub> for *passive* patients when the Brain injury condition is selected
- Whether or not Quick Wean can be enabled

Table 1-5 lists the conditions available in the INTELLiVENT-ASV Settings > Auto window.

For details about selecting a condition, see Section 1.6.4. For patients with mixed conditions, you can select more than one.

Table 1-5. 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                         | For patients with brain injuries for whom it is critical to maintain CO <sub>2</sub> under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range.<br><br>When selected, Quick Wean remains disabled. |
| Chronic Hypercapnia                  | For patients with chronically high arterial CO <sub>2</sub> 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 1-6 provides an overview of the values set for startup and during ventilation. Startup values depend on the condition(s) selected.

Changing the specific condition selection can trigger a change to any of the settings listed in the table to match the specified startup settings.

If the Pressure alarm or Plimit setting is modified, the Pressure limit has changed alarm is generated.

Be sure to carefully review all settings to ensure they are appropriate for the patient.

You can change these settings at any time, as appropriate.

For details about changing the SpO<sub>2</sub> or PetCO<sub>2</sub> target ranges, see Section 1.6.13.2.

In all cases, Quick Wean is disabled at startup.

When PEEP is set to Manual, the PEEP limit controls are disabled.

Table 1-6. Specific condition selections and associated startup values for ventilation

| Condition                  | Ventilation |                             | Oxygenation |                           |
|----------------------------|-------------|-----------------------------|-------------|---------------------------|
|                            | %MinVol (%) | Plimit (cmH2O) <sup>1</sup> | Oxygen (%)  | PEEP (cmH2O) <sup>2</sup> |
| Normal                     | 100         | 30                          | 60          | 5                         |
| ARDS                       | 120         | 35                          | 100         | 8                         |
| Chronic Hypercapnia        | 100         | 35                          | 60          | Manual                    |
| ARDS + Chronic Hypercapnia | 120         | 35                          | 100         | 8                         |
| Brain Injury <sup>3</sup>  | 100         | 30                          | 60          | Manual                    |

Table 1-7. Specific conditions and associated startup alarm limits

| Condition                  | Pressure high <sup>4</sup> (cmH2O) | ExpMinVol high (l/min) | Rate high (1/min) | Vt high/low <sup>5</sup> (ml/kg) | PetCO2 high/low (mmHg) | SpO2 low (%) |
|----------------------------|------------------------------------|------------------------|-------------------|----------------------------------|------------------------|--------------|
| Normal                     | 40                                 | 25                     | 35                | 10/4                             | 50/30                  | 90           |
| ARDS                       | 45                                 | 25                     | 35                | 10/4                             | 50/30                  | 90           |
| Chronic Hypercapnia        | 45                                 | 25                     | 35                | 12/4                             | 60/25                  | 88           |
| ARDS + Chronic Hypercapnia | 45                                 | 25                     | 35                | 10/4                             | 60/25                  | 88           |
| Brain Injury               | 40                                 | 25                     | 35                | 10/4                             | 40/30                  | 92           |

<sup>1</sup> The Plimit control setting is directly related to the high Pressure alarm limit. The high Pressure alarm limit is always 10 cmH2O greater than Plimit.

<sup>2</sup> The control of settings not explicitly marked as Manual can be set to Automatic.

<sup>3</sup> Any combination of conditions that includes Brain injury uses the Brain injury settings for Plimit.

<sup>4</sup> Changing Plimit or the high Pressure alarm limit automatically changes the other: the high Pressure alarm limit is always 10 cmH2O greater than Plimit.

<sup>5</sup> The value shown is the multiplier to use for milliliters (ml) per kilogram (kg) PBW, which the ventilator uses to calculate the default Vt high and low alarm limit settings. For example, in the Normal condition, with PBW = 70, the Vt high limit is 70\*10 = 700, and the Vt low limit is 70\*4 = 280.

### 1.6.13.2 Adjusting the SpO<sub>2</sub>/PetCO<sub>2</sub> target range (Target Shift)

#### CAUTION

- Regularly check the patient after changing the SpO<sub>2</sub> or PetCO<sub>2</sub> 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 SpO<sub>2</sub> and PetCO<sub>2</sub> as monitoring inputs for regulation of oxygenation and CO<sub>2</sub> elimination, and works to keep the patient within the target range for these values.

These target ranges are shown in the Oxygenation and CO<sub>2</sub> elimination maps and horizons. INTELLiVENT-ASV adjusts the associated controls to bring the patient to the middle of the set range.

In general, SpO<sub>2</sub> and PetCO<sub>2</sub> values represent a reliable index of partial pressure of dissolved oxygen in the arterial blood (PaO<sub>2</sub>) and CO<sub>2</sub> partial pressure in the arterial blood (PaCO<sub>2</sub>), respectively (measured using blood gas analysis (BGA)). To get the most accurate approximation of PaCO<sub>2</sub>, the second highest PetCO<sub>2</sub> value (with a reliable quality index) out of 8 breaths is used.

Under normal conditions, PaCO<sub>2</sub> is approximately 2 to 5 mmHg higher than PetCO<sub>2</sub> — the difference between the values is referred to as the *PaCO<sub>2</sub>-PetCO<sub>2</sub> gradient*. With diseased or

injured lungs, the PaCO<sub>2</sub>-PetCO<sub>2</sub> gradient can increase due to ventilation-perfusion mismatch, requiring adjustment of the PetCO<sub>2</sub> targets.

The **Target Shift** control allows you to move the SpO<sub>2</sub> and PetCO<sub>2</sub> target ranges to the left (lower values) or to the right (higher values), within the limits defined in Tables 1-8 and 1-9.

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

#### Considerations for evaluating the PetCO<sub>2</sub> target range

When determining the appropriate PetCO<sub>2</sub> target range for your patient, keep the following considerations in mind (with examples):

- Is the displayed PetCO<sub>2</sub> target range appropriate for your patient?
- Is the PaCO<sub>2</sub>-PetCO<sub>2</sub> gradient outside of the physiologic normal range?

To get the most appropriate PetCO<sub>2</sub> target range, a BGA is required. Collect the BGA sample when the patient's current PetCO<sub>2</sub> is in the middle of the target range.

Check whether one of the specific conditions 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.
2. Adjust the PetCO2 target range by the same value as the difference between the current and the desired PaCO2.
3. 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 1<sup>1</sup>

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 2<sup>1</sup>

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 adjust the SpO2 target range in the same manner.

Table 1-8. PetCO2 target shift limits

| PetCO2 target shift limits |                                  |
|----------------------------|----------------------------------|
| All conditions             | -20 mmHg to 20 mmHg <sup>2</sup> |

<sup>1</sup> The example situations and values provided here are for illustration purposes only; they are *not* intended to be used as clinical recommendations or guidelines.  
<sup>2</sup> In some markets, the upper target shift limit is 10 mmHg.

Table 1-9. SpO2 target shift limits

| SpO2 target shift limits <sup>1</sup> |                         |
|---------------------------------------|-------------------------|
| Normal<br>(no condition selected)     | -5% to +4%              |
| ARDS                                  | -5% to +4% <sup>2</sup> |
| Chronic Hypercapnia                   | -2% to +5%              |
| Mixed (Chronic Hypercapnia + ARDS)    | -2% to +5%              |
| Brain Injury                          | -5% to +2% <sup>3</sup> |

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

Table 1-10. PetCO2 Target shift display

| Target Shift control                                                                | Text color and description                                                       |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|    | White text.<br>Target shift is 0; there is no change to the target range values. |
|   | Yellow text.<br>Target shift is between $\pm 1$ and $\pm 5$ .                    |
|  | Orange text.<br>Target shift is greater than $\pm 5$ .                           |

### 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 1.6.8.

### To shift the target zone to the left or to the right

1. To open the INTELLiVENT-ASV Settings window, touch the **INTELLiVENT** button or an automated controller.
2. Display the appropriate map: Ventilation (PetCO2 target range) or Oxygenation (SpO2 target range) using the View arrows in the INTELLiVENT-ASV Settings window.
3. Touch the **Target Shift** control to activate it, and turn the P&T knob clockwise or counter-clockwise to adjust the target range limits in increments of 1.
  - Setting the value to a positive number shifts the target range to the right, targeting a higher PetCO2 or SpO2.
  - Setting the value to a negative number shifts the target range to the left, targeting a lower PetCO2 or SpO2.
  - To shift the PetCO2 target range to a value beyond  $\pm 5$  mmHg, set the value now to +5 or -5, as needed.
4. Press the P&T knob to confirm the changed setting.

<sup>1</sup> 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.

<sup>2</sup> In some markets, the lower target shift limit is -2% when the ARDS condition is selected.

<sup>3</sup> In some markets, the lower target shift limit is -2% when the Brain Injury condition is selected.

- 5. To shift the PetCO<sub>2</sub> target range beyond  $\pm 5$  mmHg:
  - Touch the **Target Shift** control again, and turn the P&T knob to set the value as desired.
  - Press the P&T knob to confirm the changed setting.

The change is applied immediately and is visible in the associated Ventilation or Oxygenation map. During ventilation, the applied target shift is displayed on the associated map (see Figures 1-15 and 1-21).

1.6.13.2.1 About the Target Shift display on the horizons

The Oxygenation and CO<sub>2</sub> elimination horizons display the associated Target Shift setting as follows.

Table 1-11. Target Shift setting in Oxygenation and CO<sub>2</sub> elimination horizon display

| Target Shift setting                                           | Display in Horizon                                                                                                                                         |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Target Shift: 0 indicates the target range is unchanged.       | In this example, no target shift is set.<br><div>Target Shift: 0</div>  |
| Target Shift: n > indicates the range is shifted to the right. | In this example, the setting is +2.<br><div>Target Shift: 2 &gt;</div>  |
| Target Shift: < n indicates the range is shifted to the left.  | In this example, the setting is -2.<br><div>Target Shift: &lt; 2</div>  |

1.6.13.3 Minimum Oxygen limit

When the Oxygen control is set to Auto-matic, 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% (default) and 30%.

1.6.13.4 PEEP limit

When the PEEP control is set to Auto-matic, 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 1-12.

Note that the minimum difference between the low and high limit is 2 cmH<sub>2</sub>O.

Table 1-12. PEEP limit settings

| PEEP limit range (cmH <sub>2</sub> O) | Default (cmH <sub>2</sub> O) |
|---------------------------------------|------------------------------|
| 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 Figure 1-11.

### 1.6.13.5 Oxygen level notification

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

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

This threshold is set using the Oxygen alert control in the INTELLiVENT-ASV Settings > More window.

## 1.7 Monitoring INTELLiVENT-ASV

### CAUTION

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

### NOTICE

- If the SpO<sub>2</sub> signal is *not* reliable, the automated PEEP and Oxygen controls freeze after 30 seconds. See Sections 1.10.4 and 1.10.4.1.
- If the PetCO<sub>2</sub> signal is *not* reliable, the automated %MinVol control freezes after 30 seconds. See Sections 1.9.4 and 1.9.4.1.

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 main monitoring parameters (MMPs) and secondary monitoring parameters (SMPs), and in the INTELLiVENT-ASV windows, called views.

These views present the following information:

- CO<sub>2</sub> elimination and Oxygenation horizons
- Capnogram and plethysmogram
- Intelligent panels (QuickWean (when enabled), Dynamic Lung, Lung impact, Vent Status, Monitoring, ASV Graph)
- Waveforms
- Trends

Trend graphs for PetCO<sub>2</sub>- and SpO<sub>2</sub>-related parameters, as well as for the CO<sub>2</sub> elimination and Oxygenation controller settings, are also available. For details, see Section 1.7.8.

1.7.1 About the INTELLiVENT-ASV windows and views

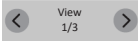
INTELLiVENT-ASV provides a graphical overview of CO2 elimination (ventilation) and oxygenation, as well as other INTELLiVENT-ASV-related data, on the main display in specialized windows.

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 button to cycle through the views.

The view number is displayed between the buttons.



The following table describes the INTELLiVENT-ASV views, as well as where they are displayed.

Table 1-13. INTELLiVENT-ASV views, overview

| View                    | Description                                                                                                                                                                                                                                                                                    | See ...                                                                                                    |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| CO2 elimination horizon | <p>For a <i>passive</i> patient, shows a zoom into the map at the current PetCO2 value and target range.</p> <p>For an <i>active</i> patient, shows the spontaneous breathing rate (fSpont).</p> <p>The horizon is shown during active ventilation in view 1.</p>                              | Section 1.7.4                                                                                              |
| CO2 elimination map     | <p>Shows the current patient PetCO2 value and target range in relation to Ppeak, together with the set limits.</p> <p>The map is shown:</p> <ul style="list-style-type: none"><li>• In the INTELLiVENT-ASV Settings &gt; Target window</li><li>• During active ventilation in view 2</li></ul> | <p>Section 1.7.3</p> <p>For details about the rules used to regulate CO2 elimination, see Section 1.9.</p> |
| Oxygenation horizon     | <p>Shows a zoom into the map at the current SpO2 value and target range.</p> <p>The horizon is shown during active ventilation in view 1.</p>                                                                                                                                                  | Section 1.7.6                                                                                              |

| View                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | See ...                                                                                                 |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Oxygenation maps                    | <p>Two maps are available:</p> <ul style="list-style-type: none"> <li>• The PEEP/SpO2 view shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits.</li> <li>• The FiO2/PEEP view shows the patient's current combination of Oxygen/PEEP values, together with the set limits.</li> </ul> <p>The selected map is shown:</p> <ul style="list-style-type: none"> <li>• In the INTELLiVENT-ASV Settings &gt; Target window</li> <li>• During active ventilation in view 2</li> </ul> | <p>Section 1.7.5</p> <p>For details about the rules used to regulate oxygenation, see Section 1.10.</p> |
| Plethysmogram                       | <p>Provides a real-time waveform that represents the pulsating blood volume.</p> <p>A plethysmogram is shown:</p> <ul style="list-style-type: none"> <li>• During active ventilation in views 1 and 3</li> <li>• As a waveform on the main display, if selected</li> </ul>                                                                                                                                                                                                                                                            | Section 1.7.7                                                                                           |
| Capnogram                           | <p>Provides a real-time end-tidal CO2 waveform.</p> <p>A capnogram is shown:</p> <ul style="list-style-type: none"> <li>• During active ventilation in views 1 and 3</li> <li>• As a waveform on the main display, if selected</li> </ul>                                                                                                                                                                                                                                                                                             | Section 1.7.7                                                                                           |
| <b>Quick Wean related</b>           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                         |
| Quick Wean, Quick Wean & SBT status | Shows the status for SBT- and weaning-related parameters.                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Section 2.4.4.1                                                                                         |
| SBT history                         | The SBT history panel is shown during active ventilation in view 3.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Section 2.4.4.2                                                                                         |

## 1.7.2 Navigating the views

When in INTELLiVENT-ASV mode:

- Swipe left/right in the INTELLiVENT-ASV panels that are displayed during active ventilation (horizons, maps, plethysmogram/capnogram, SBT history) to cycle through the panel options.

Alternatively, touch the left and right View arrows above the **Controls** button to cycle through the panels.

- Swipe left/right within the Oxygenation map panel to switch between the PEEP/SpO<sub>2</sub> and FiO<sub>2</sub>/PEEP maps. Alternatively, touch the button for the map to display.
- Swipe left/right within the SBT history panel (Section 2.4.4.2) to cycle through previous SBT data.

### 1.7.3 About the CO<sub>2</sub> elimination map

The INTELLiVENT-ASV Ventilation (CO<sub>2</sub> elimination) controller monitors end-tidal CO<sub>2</sub> (PetCO<sub>2</sub>), and uses this data to adjust %MinVol to regulate CO<sub>2</sub> elimination, according to the detailed rules and conditions described in Section 1.9.

The Ventilation controller uses a predefined end-tidal CO<sub>2</sub> target schema with peak pressure (Ppeak) on the y-axis and PetCO<sub>2</sub> on the x-axis. Peak pressure is the sum of PEEP and the inspiratory pressure set by the controller.

This schema is called the CO<sub>2</sub> elimination map. In the map, the yellow cross is the patient symbol denoting the patient's current measured PetCO<sub>2</sub> 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.

#### 1.7.3.1 Reviewing the CO<sub>2</sub> elimination map

##### NOTICE

The maximum Ppeak value that can be shown on the CO<sub>2</sub> elimination map is 50 cmH<sub>2</sub>O, so in some cases, the map may not show the patient symbol. INTELLiVENT-ASV is running, however.

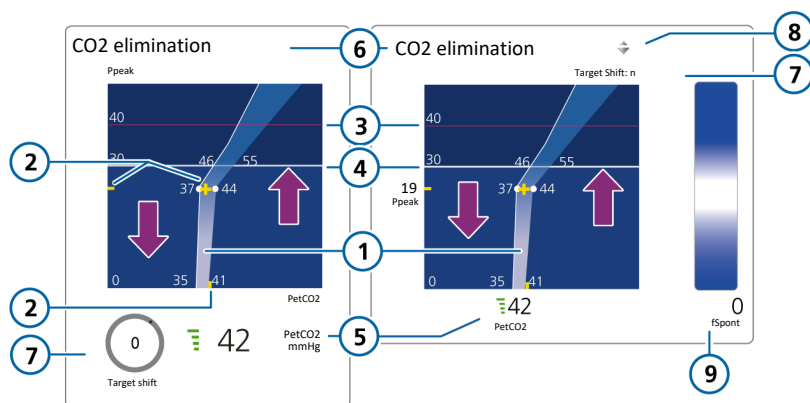
The CO<sub>2</sub> elimination map is available in two locations:

- INTELLiVENT-ASV Settings > Target window
- During active ventilation with INTELLiVENT-ASV, in view 2

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

- *Up arrow*: Increase zone (PetCO<sub>2</sub> too high, increase %MinVol)
- *Down arrow*: Decrease zone (PetCO<sub>2</sub> too low, decrease %MinVol)

Figure 1-15. CO<sub>2</sub> elimination map, INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)



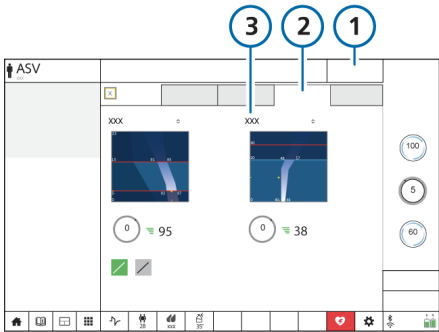
- |   |                                                 |   |                                                                                                                                                    |
|---|-------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Target zone                                     | 6 | Map title                                                                                                                                          |
| 2 | Patient symbol, patient values                  | 7 | Target Shift control and setting                                                                                                                   |
| 3 | High Pressure alarm limit                       | 8 | When %MinVol is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, %MinVol is in target zone. |
| 4 | Pressure limitation: Plimit                     | 9 | For <i>active</i> patient: target range and current fSpont value                                                                                   |
| 5 | Current PetCO <sub>2</sub> value, quality index |   |                                                                                                                                                    |

To display the CO2 elimination map in the INTELLiVENT-ASV Settings window

- ▶ To open the INTELLiVENT-ASV Settings > Target window, touch the **Target** button at the top right of the main display.
- The Settings window opens, with the **Target** tab selected.

The panel shows the CO2 elimination map, measured PetCO2 value, and the Target Shift control.

Figure 1-16. CO2 elimination map, INTELLiVENT-ASV Settings window



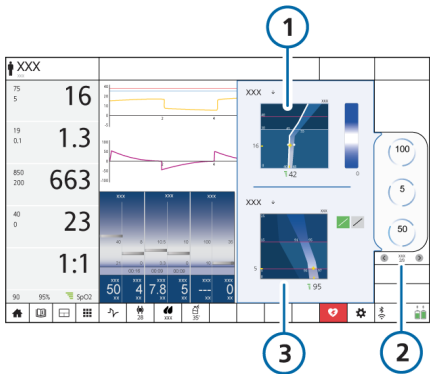
- 1 Target
- 2 Target
- 3 CO2 elimination map

To display the CO2 elimination map while INTELLiVENT-ASV is running

- ▶ If it is not already displayed, touch the view navigation arrows at the right of the display or swipe right on the display until view 2 is displayed.

View 2 shows the CO2 elimination map and measured PetCO2 value.

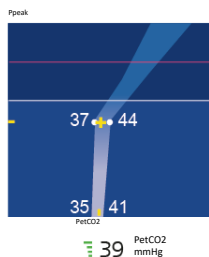
Figure 1-17. CO2 elimination map, in main display during active ventilation



- 1 CO2 elimination map
- 2 View number and arrows
- 3 Oxygenation map

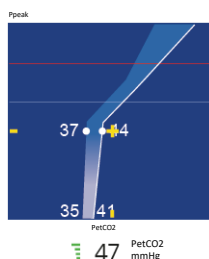
### 1.7.3.2 About the PetCO2 target zone

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



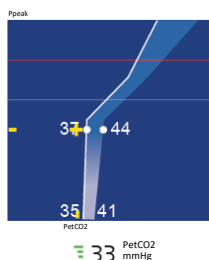
#### Patient symbol within the PetCO2 target zone

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.

### 1.7.4 About the CO2 elimination horizon

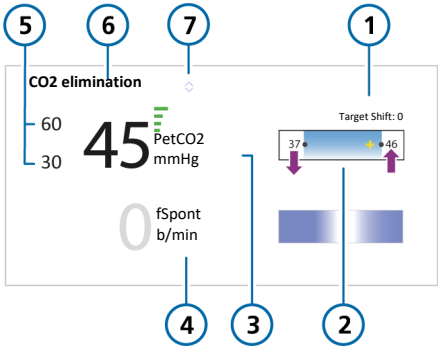
For a *passive* patient, the CO2 elimination horizon shows a simplified view of the same data as the CO2 elimination map, together with the upper and lower PetCO2 alarm limits.

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

Notes for the following two figures:

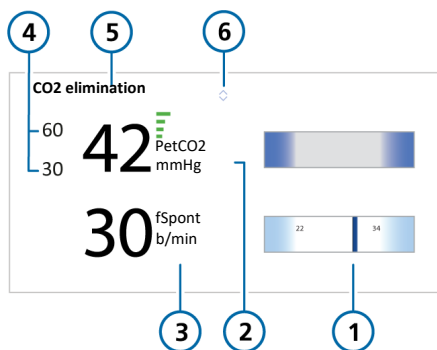
- When %MinVol is increasing (^) or decreasing (v), the appropriate indicator is highlighted (7 in the following figure). When the arrows are the same size, %MinVol is in the target zone.
- The purple arrows are for illustrative purposes only; they do not appear on the display.
  - *Up arrow*: Increase 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 1.6.13.2.1.

Figure 1-18. CO2 elimination horizon, passive patient



- |                                                 |                                         |
|-------------------------------------------------|-----------------------------------------|
| 1 Target shift setting                          | 5 PetCO2 alarm limits                   |
| 2 Target zone (blue) and patient symbol (cross) | 6 Horizon title                         |
| 3 Current PetCO2 value, quality index           | 7 %MinVol increase, decrease indicators |
| 4 fSpont value (0)                              |                                         |

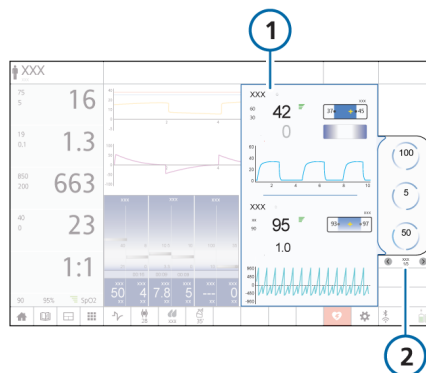
Figure 1-19. CO<sub>2</sub> elimination horizon, active patient



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

The appropriate CO<sub>2</sub> elimination horizon (for *active* or *passive* patient) is shown on the main display during active ventilation, in view 1.

Figure 1-20. CO<sub>2</sub> elimination horizon, during active ventilation



- |                                       |                          |
|---------------------------------------|--------------------------|
| 1 CO <sub>2</sub> elimination horizon | 2 View number and arrows |
|---------------------------------------|--------------------------|

### 1.7.5 About the Oxygenation map

The INTELLiVENT-ASV Oxygenation controller monitors SpO<sub>2</sub>, and uses this data to adjust PEEP and Oxygen to regulate oxygenation, according to the detailed rules and conditions described in Section 1.10.

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 SpO<sub>2</sub> to increase. The controller makes these changes based on ARDSnet guidelines.
- *Decreasing treatment* refers to changes in these control values that cause SpO<sub>2</sub> to decrease. The controller makes these changes based on the Open Lung concept.

The controller uses two predefined schemas. The visual representation of the schema is referred to as an Oxygenation map.

The *PEEP/SpO<sub>2</sub> target* schema shows PEEP on the y-axis and SpO<sub>2</sub> on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured SpO<sub>2</sub> value at the current PEEP. The boomerang shaped area of the graph is the target zone, which denotes a range of SpO<sub>2</sub> values at a given PEEP.

The *FiO<sub>2</sub>/PEEP* schema shows Oxygen on the y-axis and PEEP on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured combination of Oxygen/PEEP values. The triangular PEEP/Oxygen curve shows the target treatment levels, depending on whether treatment remains unchanged, increases, or decreases.

#### 1.7.5.1 Reviewing the Oxygenation maps

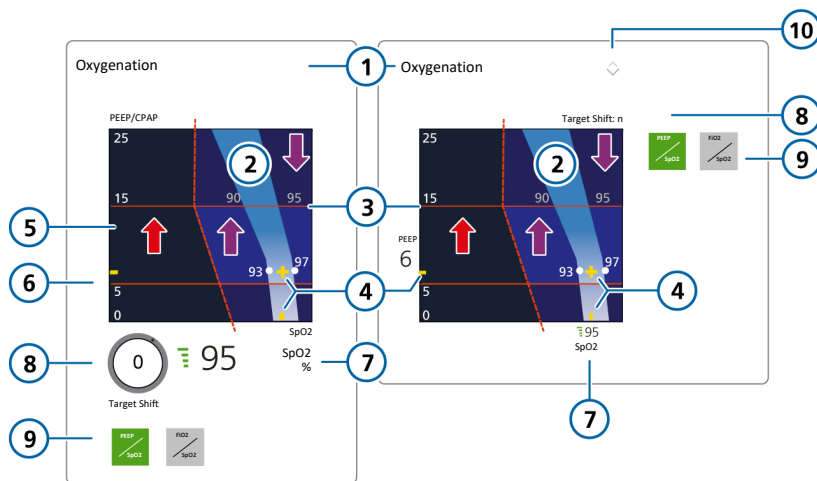
The Oxygenation maps (PEEP/SpO<sub>2</sub> and FiO<sub>2</sub>/PEEP) are available in two locations:

- INTELLiVENT-ASV Settings > Target window
- During active ventilation with INTELLiVENT-ASV, on the main display in view 2

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

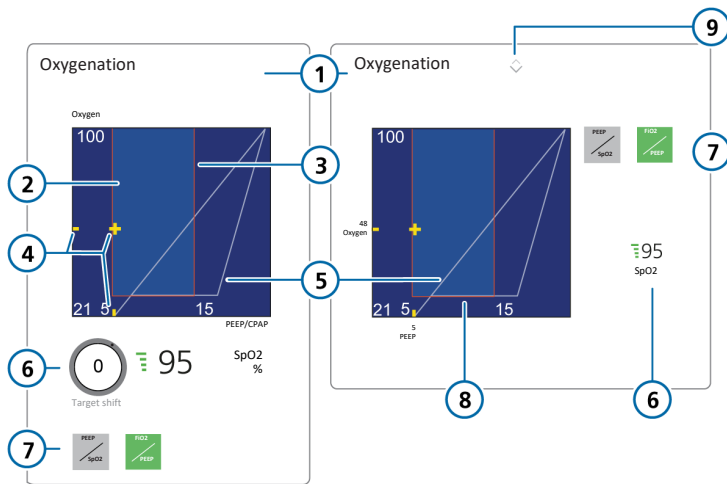
- *Purple up arrow*: Increase treatment zone
- *Purple down arrow*: Decrease treatment zone
- *Red up arrow*: Emergency increase zone (dark blue area), Oxygen set to 100%

Figure 1-21. Oxygenation map, PEEP/SpO<sub>2</sub>, in INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)



- |   |                                |    |                                                                                                                                                        |
|---|--------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Map title                      | 6  | Lower PEEP limit                                                                                                                                       |
| 2 | SpO2 target zone               | 7  | Current SpO2 value, quality index                                                                                                                      |
| 3 | Upper PEEP limit               | 8  | Target Shift control and setting                                                                                                                       |
| 4 | Patient symbol, patient values | 9  | Oxygenation map selection buttons (PEEP/SpO2 selected)                                                                                                 |
| 5 | Emergency zone                 | 10 | When PEEP or Oxygen is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, SpO2 is in target zone. |

Figure 1-22. Oxygenation map, FiO2/PEEP, in INTELLIVENT-ASV Settings window (left), main display during active ventilation (right)



- |                                  |                                                                                                                                                          |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 Map title                      | 6 Current SpO2 value, quality index                                                                                                                      |
| 2 Lower PEEP limit               | 7 Oxygenation map selection buttons (FiO2/PEEP selected)                                                                                                 |
| 3 Upper PEEP limit               | 8 Lower Oxygen limit                                                                                                                                     |
| 4 Patient symbol, patient values | 9 When PEEP or Oxygen is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, SpO2 is in target zone. |
| 5 PEEP/Oxygen curve              |                                                                                                                                                          |

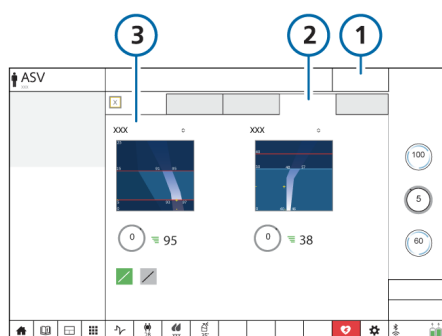
### To display the Oxygenation map in the INTELLiVENT-ASV Settings window

1. To open the INTELLiVENT-ASV Settings > Target window, touch the **Target** button at the top right of the main display.  
The Settings window opens, with the **Target** tab selected.  
The panel shows the PEEP/SpO<sub>2</sub> Oxygenation map, measured SpO<sub>2</sub> value, and the Target Shift control.
2. To display the FiO<sub>2</sub>/PEEP map, touch the **FiO<sub>2</sub>/PEEP** button.

### To display the Oxygenation maps while INTELLiVENT-ASV is running

1. If it is not already displayed, touch the view navigation arrows at the right of the display until view 2 is displayed.  
View 2 shows the Oxygenation map and the measured SpO<sub>2</sub> value. See Figure 1-17.
2. To display the FiO<sub>2</sub>/PEEP map, touch the **FiO<sub>2</sub>/PEEP** button.  
To display the PEEP/SpO<sub>2</sub> map, touch the **PEEP/SpO<sub>2</sub>** button.

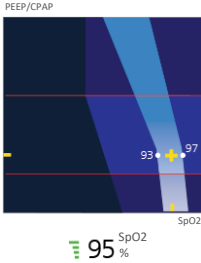
Figure 1-23. Oxygenation map, INTELLiVENT-ASV Settings window



- 1 Target
- 2 Target
- 3 Oxygenation map

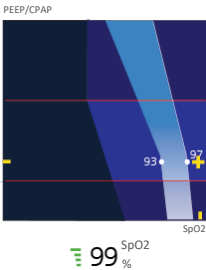
### 1.7.5.2 About the SpO2 target zone

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



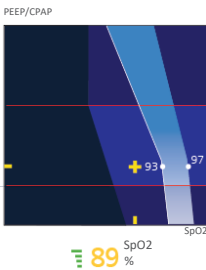
#### Patient symbol within the SpO2 target zone

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



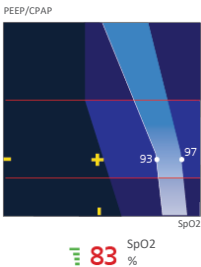
#### Patient symbol above the SpO2 target zone

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 yellow.



#### 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 red.

### 1.7.6 About the Oxygenation horizon

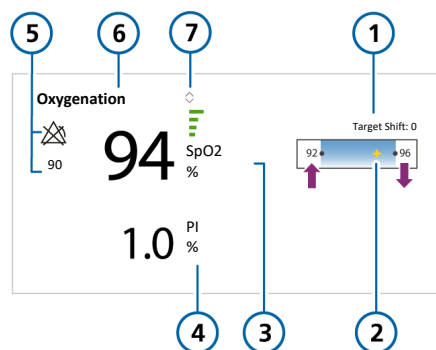
The Oxygenation horizon shows a simplified view of the same data as the SpO2/PEEP Oxygenation map, together with the upper and lower SpO2 alarm limits.

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 illustrative 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 1.6.13.2.1.

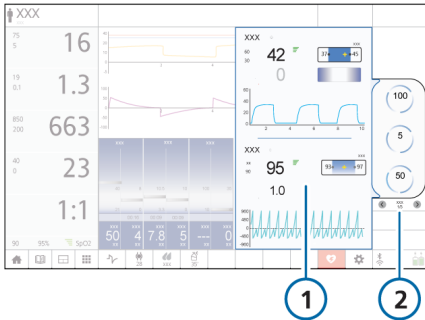
Figure 1-24. Oxygenation horizon



- |                                                 |                                            |
|-------------------------------------------------|--------------------------------------------|
| 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 view 1.

Figure 1-25. Oxygenation horizon during active ventilation



- 1 Oxygenation horizon
- 2 View number and arrows

### 1.7.7 About the capnogram and plethysmogram

A CO<sub>2</sub> capnogram and SpO<sub>2</sub> 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 CO<sub>2</sub> levels throughout a breath cycle.

#### To display the capnogram

- ▶ During active ventilation with INTELLiVENT-ASV, touch the left or right view button until the capnogram is displayed.

Figure 1-25 shows the capnogram in the top part of the display.

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

#### 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 INTELLiVENT-ASV, touch the left or right view button until the plethysmogram is displayed.

Figure 1-25 shows the plethysmogram in the bottom part of the display.

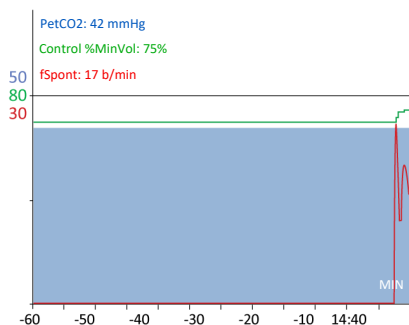
For details about selecting the plethysmogram as a waveform on the ventilator main display, see your ventilator *Operator's Manual*.

### 1.7.8 About the Trend panel

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.<sup>1</sup>

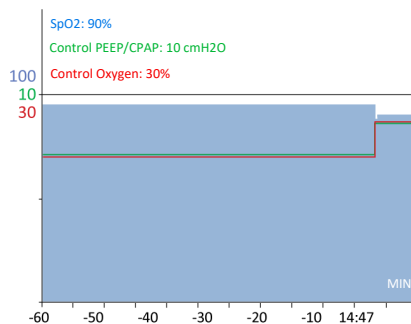
For details about working with trends, see your ventilator *Operator's Manual*.

#### Ventilation controller trend graph



The Ventilation controller trend graph provides data for the following parameters: PetCO<sub>2</sub>, Control %MinVol, and fSpont.

#### Oxygenation controller trend graph

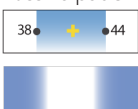


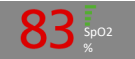
The Oxygenation controller trend graph provides data for the following parameters: SpO<sub>2</sub>, Control PEEP/CPAP, and Control Oxygen.

<sup>1</sup> Note that the graphs provided here do not represent actual data, they just illustrate how the different parameters are represented.

### 1.7.9 INTELLiVENT-ASV symbols

Table 1-14. INTELLiVENT-ASV-related symbols and controls

| Symbol/Control                                                                                                                                                                                                    | Color                                       | Description                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                   | White                                       | View selection.<br>During active ventilation, several views are available; the view navigation arrows change the view between those described in Section 1.7.1.                                                                                                     |
|                                                                                                                                   | Yellow                                      | Patient symbol. Indicates the current condition of the patient in the graph.                                                                                                                                                                                        |
|                                                                                                                                  | Gray (4 bars), Orange (2 bars), Red (1 bar) | Quality index showing unreliable signal quality. Sensor values are not usable or sensor not enabled or connected.<br>When this occurs, the related controller freezes and an alarm is generated indicating the automatic management is turned OFF.                  |
|                                                                                                                                  | Green (3 or 4 bars)                         | Quality index showing stable acceptable signal quality. The data from the sensor is highly stable and reliable.                                                                                                                                                     |
|                                                                                                                                   | White                                       | Measured PetCO2 sensor value and quality index.                                                                                                                                                                                                                     |
| <p>Active patient</p>  <p>Passive patient</p>  | 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 ( <i>active</i> ).<br>When the PetCO2 horizon is active, and the fSpont horizon is greyed out, the patient meets the <i>passive</i> criteria. |
|                                                                                                                                 | White                                       | The fSpont measurement is displayed when spontaneous breathing is detected by the flow sensor, and is used as physiologic input.                                                                                                                                    |

| Symbol/Control                                                                      | Color                          | Description                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Yellow                         | Low SpO2 value. SpO2 is below the set lower alarm limit. A medium-priority Low SpO2 alarm is active.<br><br>For details, see the <i>Pulse Oximetry Instructions for Use</i> .                                         |
|    | Red                            | Critical SpO2 value. SpO2 is well below the set lower alarm limit. A high-priority Low SpO2 alarm is active.<br><br>For details, see the <i>Pulse Oximetry Instructions for Use</i> .                                 |
|    | Black or 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.                                                                                    |
|    | Blue                           | Value is stable, in range. Displayed next to the horizon name and to the left of the automated controllers.                                                                                                           |
|    | White                          | Time to increase. Counts down the time to the next increase of the control.                                                                                                                                           |
|  | White                          | Time to decrease. Counts down the time to the next decrease of the control.                                                                                                                                           |
|  | Gray circle                    | Manual management. Indicates that the ventilator operator must manage the control.                                                                                                                                    |
|  | Blue comets rotating clockwise | Automatic management. Indicates that INTELLiVENT-ASV is managing the patient and treatment has been increased (comets moving clockwise). A faster rotation provides a visual indication of ongoing or recent changes. |

| Symbol/Control                                                                   | Color                                  | Description                                                                                                                                                                                                                |
|----------------------------------------------------------------------------------|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Blue comets rotating counter-clockwise | Automatic management. Indicates that INTELLiVENT-ASV is managing the patient and treatment has been decreased (comets moving counter-clockwise). A faster rotation gives a visual indication of ongoing or recent changes. |
|  | Red circle                             | No automatic management – controller is in a frozen state. A sensor value may be absent.                                                                                                                                   |
|  | Green circle                           | Oxygen enrichment in progress. For details, see your ventilator <i>Operator's Manual</i> .                                                                                                                                 |

# 1.8 Troubleshooting alarms

## ⚠ CAUTION

You can suppress audible CO<sub>2</sub> and SpO<sub>2</sub> alarms for 2 minutes by pressing the Audio pause key.

## NOTICE

When the device is in Standby, all SpO<sub>2</sub>-related 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 SpO<sub>2</sub>-related documentation.

For the following alarm types, see the listed documentation:

- *Quick Wean/SBT-related alarms*, see Section 2.8.
- *SpO<sub>2</sub>-related alarms*, see the *Pulse oximetry Instructions for use*.
- *PetCO<sub>2</sub>-related alarms*, see your ventilator *Operator's Manual*.

Table 1-15. INTELLiVENT-ASV alarms, priority, and corrective actions

| Alarm/Priority                                                                      | Definition/Corrective action                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FiO <sub>2</sub> set to 100% due to low SpO <sub>2</sub><br><i>Medium priority.</i> | <p>The Oxygenation controller set Oxygen to 100% due to low SpO<sub>2</sub> saturation. SpO<sub>2</sub> is, or was, in the emergency zone.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).</li> </ul> |
| Oscillation PEEP/CPAP<br><i>High priority.</i>                                      | <p>Large variations in PEEP in a short time period.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Set PEEP to Manual.</li> </ul>                                                                                                                                                              |
| Oscillation %MinVol<br><i>High priority.</i>                                        | <p>Large variations in %MinVol in a short time period.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Set %MinVol to Manual.</li> </ul>                                                                                                                                                        |

| Alarm/Priority                                          | Definition/Corrective action                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oxygenation adjustment off<br><i>Medium priority.</i>   | <p>The Oxygenation controller is frozen due to poor or absent SpO<sub>2</sub> signal.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check pulse oximeter connections.</li> <li>• Set PEEP and/or Oxygen to Manual.</li> </ul>                                                                             |
| Oxygenation controller at limit<br><i>Low priority.</i> | <p>PEEP and/or Oxygen are at the defined limit and cannot be increased.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Verify limit settings.</li> <li>• Set PEEP and/or Oxygen to Manual.</li> </ul>                                                                  |
| Oxygen alert limit exceeded<br><i>Medium priority.</i>  | <p>Oxygen exceeds the limit defined by the Oxygen alert control (INTELLiVENT-ASV Settings &gt; More window).</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).</li> </ul>       |
| Oxygen supply failed<br><i>High priority.</i>           | <p>Oxygen source flow is lower than expected.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Check oxygen supply; change supply if necessary.</li> <li>• Check oxygen supply for leaks.</li> <li>• Provide alternative ventilation until issue is resolved.</li> </ul> |

| Alarm/Priority                                          | Definition/Corrective action                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ventilation adjustment OFF<br><i>Medium priority.</i>   | <p>The Ventilation controller is frozen when any of the following conditions persists for longer than 30 seconds:</p> <ul style="list-style-type: none"> <li>• Poor or absent CO2 signal</li> <li>• fSpont &gt; 60 b/min (&gt; 40 kg PBW)</li> <li>• fSpont &gt; 100 b/min (≤ 40 kg PBW)</li> </ul> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Check CO2 connections.</li> <li>• Set %MinVol to Manual.</li> </ul> |
| Ventilation controller at limit<br><i>Low priority.</i> | <p>%MinVol is at the defined limit (200%) and cannot be increased.</p> <p><b>To resolve</b></p> <ul style="list-style-type: none"> <li>• Check patient condition.</li> <li>• Verify limit settings.</li> <li>• Set %MinVol to Manual.</li> </ul>                                                                                                                                                                                                                              |

## 1.9 Management of minute volume (%MinVol)

### WARNING

Regularly inspect CO<sub>2</sub> adapters/sensors. Patient secretions and/or condensation in airway adapters can lead to an incorrect PetCO<sub>2</sub> reading.

### CAUTION

*Do NOT use the sidestream CO<sub>2</sub> sensor with automatic management of %MinVol.*

During automated management of ventilation, the lung-protective strategy principles inherent in ASV are always applied. For details, see the section, *Working with ASV*, in your ventilator *Operator's Manual*.

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 (CO<sub>2</sub> 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 CO<sub>2</sub> partial pressure, PetCO<sub>2</sub>, as described in Section 1.9.1.
  - **Active patient.** The controller uses the difference between the targeted and actual respiratory rates, as described in Section 1.9.2.

For details on how the controller manages the transition between spontaneous breathing and passive activity, see Section 1.9.3.

- 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 PetCO<sub>2</sub> that is set depends on:
  - The patient's treatment level (peak inspiratory pressure)
  - Any specific condition(s) set by the operator (Section 1.6.13.1)
  - Operator-set PetCO<sub>2</sub> target shift (Section 1.6.13.2)
  - Whether Quick Wean is enabled (Section 2.2)
- The acceptable spontaneous breathing rate is calculated using the information in Table 1-18.

The %MinVol limits that are in force when minute volume management is set to Automatic are listed in Table 1-16. As soon as the upper limit for the management of %MinVol is reached, a Ventilation controller at limit message is generated.

Table 1-16. %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                               |
| PetCO2 not available | 200 (automatic control suspended) |

### 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 clinical practice.

### 1.9.1 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 to 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 1.6.13.2.

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

The PetCO2 target range depends on:

- Any specific condition(s) set by the operator (Section 1.6.13.1)
- Operator-set PetCO2 target shift (Section 1.6.13.2)
- 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 1-17. Automated management of %MinVol, *passive* patient

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

1.9.2 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 1-18. Spontaneous breathing rate range calculation<sup>1</sup>

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

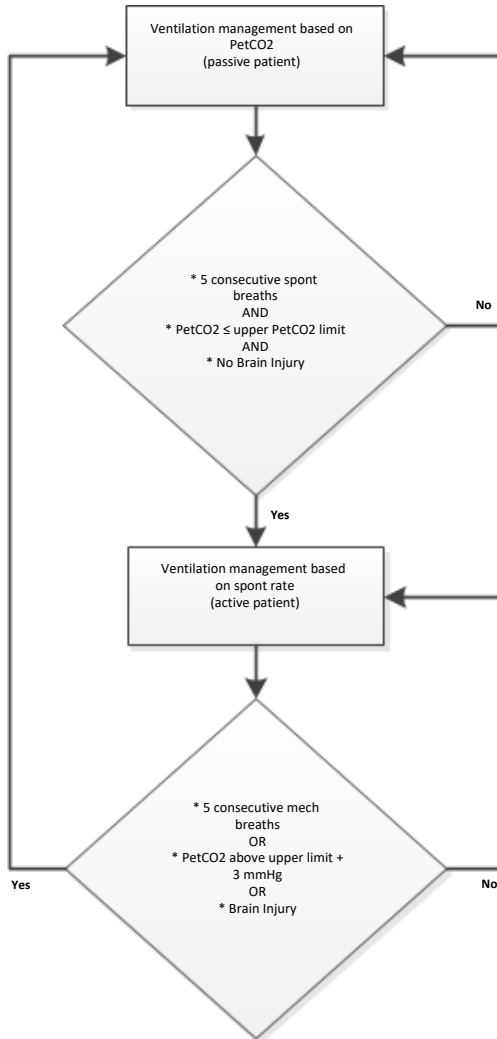
The conditions listed in the following table apply to automated control of %MinVol for an *active* patient, and refer to the transition process specified in Section 1.9.3.

<sup>1</sup> For ASV target rate information, see your ventilator *Operator's Manual*.

Table 1-19. Automated management of %MinVol, *active* patient

| When these conditions apply ...                                                                                                                                                                                                                                    | %MinVol change                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>The patient complies with the <i>Active state conditions</i> in Section 1.9.3<br/><i>and</i></li> <li>The patient's Rate is above the upper limit of the acceptable spontaneous rate (danger of patient fatigue)</li> </ul> | %MinVol increase                                                                             |
| <ul style="list-style-type: none"> <li>The patient complies with the <i>Active state conditions</i> in Section 1.9.3<br/><i>and</i></li> <li>The patient's Rate is below the lower limit of the acceptable spontaneous rate</li> </ul>                             | %MinVol decrease                                                                             |
| <ul style="list-style-type: none"> <li>The patient complies with the <i>Active state conditions</i> in Section 1.9.3<br/><i>and</i></li> <li>The patient's Rate value is within the target range</li> </ul>                                                        | <p>No change in %MinVol.</p> <p>If Quick Wean is enabled, see Section 2.4.1 for details.</p> |
| The patient's PetCO <sub>2</sub> is invalid for more than 30 seconds                                                                                                                                                                                               | <p>%MinVol control is frozen.</p> <p>The Ventilation adjustment OFF alarm is generated.</p>  |
| The patient's spontaneous Rate is invalid (> 60 b/min for patients > 40 kg PBW or > 100 b/min for patients ≤ 40 kg PBW) for more than 30 seconds                                                                                                                   | <p>%MinVol control is frozen.</p> <p>The Ventilation adjustment OFF alarm is generated.</p>  |

### 1.9.3 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 PetCO<sub>2</sub> when ANY of the following are true:

- Five (5) consecutive mechanical breaths occur *or*
- The PetCO<sub>2</sub> value exceeds the upper limit by at least three (3) mmHg *or*
- The Brain Injury condition is selected

When a reliable PetCO<sub>2</sub> measurement is not available (Table 1-21), 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 (5) consecutive patient-triggered breaths occur *and*
- The PetCO<sub>2</sub> 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 invalid<sup>1</sup> 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 PetCO<sub>2</sub> measurement is not available (Table 1-21), the Ventilation controller suspends automated management, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

<sup>1</sup> fSpont > 60 b/min (> 40 kg PBW) or fSpont > 100 b/min (≤ 40 kg PBW)

1.9.4 Important notes about ventilation management

When ventilating with INTELLiVENT-ASV, pay particular attention to the following important notes.

Table 1-20. Important notes about ventilation management

| For ...                                                                     | See ...         |
|-----------------------------------------------------------------------------|-----------------|
| Quality index and ventilation                                               | Section 1.9.4.1 |
| Actions that temporarily halt automatic ventilation management              | Section 1.9.4.2 |
| PetCO2 is not available                                                     | Section 1.9.4.3 |
| Disconnection or flow sensor failure resolved in five (5) minutes or less   | Section 1.9.4.4 |
| Disconnection or flow sensor failure resolved in more than five (5) minutes | Section 1.9.4.5 |
| Returning to active ventilation from Standby                                | Section 1.9.4.6 |

1.9.4.1 Quality index and ventilation management

If the signal quality is unreliable, the PetCO2 quality index can show gray, red, or orange bars.

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

Table 1-21. PetCO2 quality index and automated ventilation management

| Quality indicator                                                                                                                                                                                          | These conditions apply ...                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>The data from the sensor is unavailable or not reliable for more than 30 seconds</p> <p>Gray, red, or orange bars</p>  | <ul style="list-style-type: none"><li>• The %MinVol control is a solid red circle; it is frozen.</li><li>• The Ventilation adjustment OFF alarm is generated.</li><li>• 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 <i>Operator's Manual</i>.</li></ul> |
| <p>The data from the sensor is reliable</p> <p>Green bars</p>                                                           | <ul style="list-style-type: none"><li>• The %MinVol control is a blue rotating circle.</li><li>• The Ventilation adjustment OFF alarm is reset.</li><li>• Automated ventilation management resumes.</li></ul>                                                                                                                                                                            |

### 1.9.4.2 Actions that temporarily halt automated ventilation management

Automated ventilation management pauses during the following actions:

- Disconnection
- Flow sensor calibration
- Leak test
- Suctioning
- P/V Tool maneuver
- Inspiratory/expiratory hold maneuver

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

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

### 1.9.4.3 PetCO<sub>2</sub> is not available

Any time the PetCO<sub>2</sub> 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 PetCO<sub>2</sub> signal became unusable.<sup>1</sup>

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

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

When PetCO<sub>2</sub> is again available, the alarm is resolved and the minute volume adjustment switches back to Automatic mode.

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

### 1.9.4.4 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 (P<sub>insp</sub> 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*.

### 1.9.4.5 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.

<sup>1</sup> If the PetCO<sub>2</sub> value falls below 10 mmHg, the quality indicator bar is red; the value is considered unreliable.

### 1.9.4.6 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.

If the PetCO<sub>2</sub> quality index is below 50, the %MinVol control changes from a blue rotating circle to a red static circle. Ventilation management does *not* start.

When the PetCO<sub>2</sub> quality index is above 50, ventilation management starts in Automatic mode. The %MinVol control is a blue rotating circle.

## 1.10 Management of PEEP and Oxygen

As INTELLiVENT-ASV relies on the measurements provided by the SpO<sub>2</sub> 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 maps.
- The PEEP controller can only operate between 5 and 24 cmH<sub>2</sub>O, unless an SBT is currently being performed.
- If the PEEP control is set to Automatic, the set PEEP high and low limit controls are activated. The Oxygenation maps show two red lines, one showing the upper PEEP limit and one showing the lower.

During automated management of oxygenation, the lung-protective strategy principles inherent in ASV are always applied. For details, see the section, *Working with ASV*, in your ventilator *Operator's Manual*.

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 SpO<sub>2</sub> range for the patient:

- Measured oxygen saturation (SpO<sub>2</sub>)
- Any specific condition(s) set by the operator (Section 1.6.13.1)
- Operator-set Target Shift (Section 1.6.13.2)

The lung-protective rules for oxygenation management, used during automated PEEP/Oxygen management, are based on the following guidelines:

- ARDSnet guidance when *increasing* therapy
- Open Lung concept when *decreasing* therapy

For details, see Section 1.10.1.

### Manual oxygenation management

In Manual mode, you keep the SpO<sub>2</sub> within the target range by manually adjusting PEEP and/or Oxygen, based on the SpO<sub>2</sub> monitoring values and clinical practice.

#### 1.10.1 Management of PEEP/Oxygen for all patients

Using the SpO<sub>2</sub> signal retrieved from the pulse oximeter, the system calculates the difference between the current and the target SpO<sub>2</sub> values. This calculation, together with the operator's input, is used to determine the treatment action.

Automated PEEP/Oxygen management comprises two steps:

- The operator's input and the current treatment (PEEP) define the SpO<sub>2</sub> target range. The ranges differ based on the selected specific condition(s), if any (Section 1.6.13.1). The SpO<sub>2</sub> signal and the SpO<sub>2</sub> 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 treatment*, the relationship between PEEP and Oxygen is based on the ARDSnet guidance (Figure 1-26, the target path is the bold line).

*For decreasing treatment*, the relationship is based on the Open Lung concept (Figure 1-27, the target path is the bold lines).

Figure 1-26. Increase of oxygenation support, ARDSnet guidance

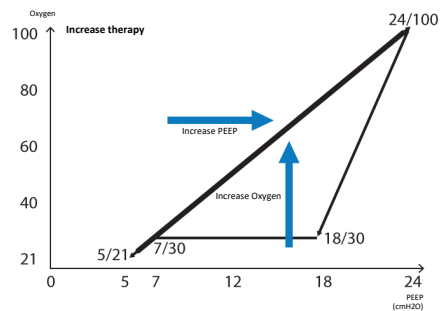
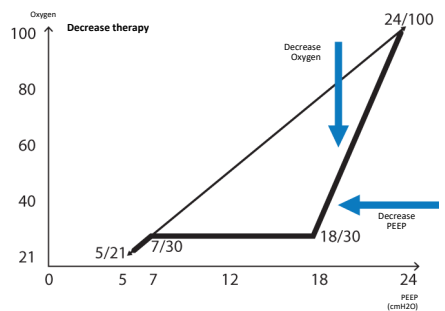


Figure 1-27. Decrease of oxygenation support, Open Lung concept



The device adjusts PEEP and Oxygen, which affects the oxygenation of the patient. Section 1.10.3 provides an overview of the controllers' actions depending on the measured SpO2 value.

1.10.2 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 immediately delivers 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.

1.10.3 Oxygenation management rules

The Oxygenation controller adjusts PEEP and Oxygen as described here, when they are set to Automatic.

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
- PEEP is automatic and in range AND
- Oxygen has been automatic and not frozen for at least six (6) minutes

If PEEP is automatic and at the upper limit, the controller fine tunes Oxygen.

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

The controller *increases oxygenation support* as follows:

| Position of patient symbol in the FiO2/PEEP 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 1.10.2.

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.

**SpO<sub>2</sub> is high, above the target zone limit**

The controller *decreases oxygenation support* as follows:

| Position of patient symbol in the FiO <sub>2</sub> /PEEP map, relative 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.    |

**1.10.3.1 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 1-22. Increase/decrease increments of Oxygen and PEEP by automated Oxygenation controller<sup>1</sup>

| Oxygenation management/ Action                                                                                                 | Takes place when ...                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Increase Oxygen stepwise:<br>Increases Oxygen by 10% of current Oxygen value every <b>30 seconds</b>                           | <ul style="list-style-type: none"> <li>• Oxygen automatically managed</li> <li>• Increasing Oxygen support</li> </ul>                                                   |
| Decrease Oxygen stepwise:<br>Decreases Oxygen by 5% of current Oxygen value every <b>60 seconds</b>                            | <ul style="list-style-type: none"> <li>• Oxygen automatically managed</li> <li>• Decreasing Oxygen support</li> </ul>                                                   |
| Increase PEEP stepwise:<br>Increases PEEP by 1 cmH <sub>2</sub> O every <b>6 minutes</b>                                       | <ul style="list-style-type: none"> <li>• PEEP automatically managed</li> <li>• Increasing PEEP support</li> </ul>                                                       |
| Decrease PEEP stepwise:<br>Decreases PEEP by 1 cmH <sub>2</sub> O every <b>6 minutes</b>                                       | <ul style="list-style-type: none"> <li>• PEEP automatically managed</li> <li>• Decreasing PEEP support</li> </ul>                                                       |
| Decrease PEEP stepwise quickly:<br><b>Exception:</b><br>Decreases PEEP by 1 cmH <sub>2</sub> O quickly every <b>30 seconds</b> | <ul style="list-style-type: none"> <li>• PEEP automatically managed</li> <li>• PEEP is above the upper PEEP limit (if PEEP was set manually above the limit)</li> </ul> |

<sup>1</sup> These rules still apply when the PEEP and/or Oxygen control setting is manually changed and then control is again set to Automatic. The time interval starts from the time of the last manual change.

1.10.4 Important notes about oxygenation management

When ventilating with INTELLiVENT-ASV, pay particular attention to the following important notes.

Table 1-23. Important notes about oxygenation management

| For ...                                                        | See ...          |
|----------------------------------------------------------------|------------------|
| Quality index and oxygenation management                       | Section 1.10.4.1 |
| Actions that temporarily halt automatic oxygenation management | Section 1.10.4.2 |
| Oxygen level notification                                      | Section 1.10.4.3 |
| Returning to active ventilation from Standby                   | Section 1.10.4.4 |

1.10.4.1 Quality index and oxygenation management

The following table summarizes INTELLiVENT-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.

Table 1-24. SpO2 quality index and automated oxygenation management

| Quality indicator                                                                                                                                                                                                           | These conditions apply ...                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div>The data from the sensor is unavailable or unreliable for more than 30 seconds</div> <div>Gray, red, or orange bars</div> <div></div> | <ul style="list-style-type: none"><li>• The PEEP and Oxygen controls are solid red circles; they are frozen.</li><li>• The Oxygenation adjustment OFF alarm is generated.</li><li>• The ventilator uses the same oxygenation rules as when in ASV mode. For details, see your ventilator <i>Operator's Manual</i>.</li><li>• Automatic emergency increase of oxygen management is <i>inactive</i> (Section 1.10.2).</li></ul> |
| <div>The data from the sensor is reliable</div> <div>Green bars</div> <div></div>                                                        | <ul style="list-style-type: none"><li>• The PEEP and Oxygen controls are blue rotating circles.</li><li>• The Oxygenation adjustment OFF alarm is reset.</li><li>• Automated oxygenation management resumes.</li><li>• Automatic emergency increase of oxygen management is <i>active</i> (Section 1.10.2)</li></ul>                                                                                                          |

### 1.10.4.2 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
- P/V Tool maneuver
- Inspiratory/Expiratory hold maneuver

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.

### 1.10.4.3 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 specified limit using the Oxygen alert control in the INTELLiVENT-ASV Settings > More window. For details, see Section 1.6.13.5.

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

### 1.10.4.4 Returning to 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.

## 1.11 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.

### 1.11.1 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 1-25. Conditions for manual control of %MinVol

| When these conditions are met ...                                                | This control must be adjusted MANUALLY by the operator |
|----------------------------------------------------------------------------------|--------------------------------------------------------|
| CO <sub>2</sub> monitoring is disabled or CO <sub>2</sub> sensor is disconnected | %MinVol is set to Manual                               |

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

1.11.2 Manual control of oxygenation

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

Table 1-26. Conditions for manual control of PEEP and/or Oxygen

| When these conditions are met ...                                                                                                                                                                               | This control must be adjusted MANUALLY by the operator |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>PEEP</b> <ul style="list-style-type: none"><li>• The Chronic Hypercapnia or Brain injury patient condition is selected</li><li>• SpO2 monitoring is disabled</li><li>• SpO2 sensor is disconnected</li></ul> | PEEP is set to Manual                                  |
| <b>Oxygen</b> <ul style="list-style-type: none"><li>• Oxygen monitoring (O2 sensor) is disabled</li><li>• SpO2 monitoring is disabled</li><li>• SpO2 sensor is disconnected</li></ul>                           | Oxygen is set to Manual                                |

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*.

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

1.12 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.

# 2

## 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 PaCO<sub>2</sub> against displayed PetCO<sub>2</sub>, and SaO<sub>2</sub> against SpO<sub>2</sub>.

### 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 of the patient's potential readiness for discontinuing mechanical ventilation, as well as control of the applied %MinVol.

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 phases:

- Measurement and assessment of weaning predictors during a screening phase
- A spontaneous breathing trial (SBT), a diagnostic tool that can help determine whether the patient is ready to be removed from ventilator support and can breathe on their own
- An extubation trial

Quick Wean helps with the first and second phases.

## 2.2 Quick Wean in clinical use

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

### 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.

Conducting an SBT, however, is only possible when:

- The patient is *active*
- Quick Wean is enabled

### 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
- PEEP
- Rate
- $\Delta P_{\text{insp}}$
- $V_t/\text{kg}$
- RSB or PetCO<sub>2</sub> (depending on patient PBW), not configurable

Parameters are further grouped into three categories:

- *To start SBT*, the group of parameters that are monitored to determine whether an SBT can be started
- *SBT settings*, the group of parameters that determine the settings for an SBT
- *To stop SBT*, the group of parameters that are monitored to determine whether to stop an ongoing SBT

### 2.2.3 About Quick Wean use modes

The following use modes are available:

- Quick Wean disabled
- Quick Wean enabled, without automatic SBTs
- Quick Wean enabled, with automatic SBTs

An overview is provided here. For detailed information, see the referenced sections.

#### Quick Wean disabled

Default setting. No continuous monitoring against defined weaning criteria occurs.

#### Quick Wean enabled (set to Automatic)

The device does the following:

- Shifts the PetCO<sub>2</sub> range to the right by up to +5 mmHg to support spontaneous breathing.

The 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.

As long as these conditions are met, 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 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, displaying them on the Quick Wean panel.

For details about:

- How the Quick Wean panel indicates progress, see Section 2.4
- How the device controls minute volume, see Section 1.9

When Quick Wean is enabled, two SBT-related options are available: Automatic SBTs enabled or disabled

### Automatic SBTs disabled (set to Off)

This is the default setting. You can manually start an SBT any time the patient is *active*.

- The device continuously screens readiness-to-wean criteria.
- As long as the patient is breathing spontaneously and the patient's Rate is below the upper limit of the target range, the %MinVol is decreased to and/or maintained at 70%.
- The SBT parameters are configurable, and some can be fine-tuned during ventilation.
- You can manually start an SBT any time the patient is *active*.

For details about manually performing an SBT, see Section 2.5.

### Automatic SBTs enabled (set to On)

Automatic SBTs offer all of the benefits of providing standardized, protocolized care.

- The device continuously monitors the patient against weaning criteria.
- When defined criteria are met, the device automatically initiates an SBT.
- The SBT parameters are configurable, and some can be fine-tuned during ventilation.
- You can manually start an SBT any time the patient is *active*.

For details about automatic SBTs, see Sections 2.3 and 2.5.

### 2.2.4 Quick Wean key terms

| Term/<br>Parameter                      | Description                                                                                                                                                                                                                                                                                               |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SBT                                     | <i>Spontaneous breathing trial.</i><br>Diagnostic test to help determine whether patients are ready to be removed from ventilator support and can breathe on their own.                                                                                                                                   |
| Automatic SBT                           | When enabled, the device performs an SBT when specified criteria are met. By default, disabled (turned off).                                                                                                                                                                                              |
| <i>To start SBT group of parameters</i> | A list of parameters that must all be within a predefined range for a specific amount of time for the patient to be considered ready for an SBT.<br><br>This set of parameters and values is referred to as the <i>To start SBT criteria</i> .                                                            |
| <i>To stop SBT group of parameters</i>  | A list of parameters that are monitored during an SBT, to determine whether to stop the SBT. If any of the values is outside the predefined range for a specified period of time, an ongoing SBT is stopped.<br><br>This set of parameters and values is referred to as the <i>To stop SBT criteria</i> . |

| Term/<br>Parameter        | Description                                                                                                                                                                                                                                                                                         |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| fSpont / %fSpont          | fSpont is the absolute number of spontaneous breaths taken. %fSpont is the percentage of spontaneous breaths to total breaths taken.<br><br>The Quick Wean panel shows fSpont; the SBT history panel shows %fSpont.                                                                                 |
| Max. duration (min)       | Defines the length of time the SBT can run. If the patient conditions continue to stay within defined thresholds, the SBT ends after the time specified by this parameter.<br><br>Only applies during an SBT.                                                                                       |
| %MinVol (%)               | When Quick Wean is enabled, as long as the patient is <i>active</i> and the patient's rate is below the upper limit of the target range (Section 1.9.2), the device gradually reduces %MinVol to 70%.<br><br>When SBTs are enabled and an SBT starts, %MinVol is reduced to a default value of 25%. |
| Oxygen (%)                | Inspired oxygen.                                                                                                                                                                                                                                                                                    |
| PEEP (cmH <sub>2</sub> O) | Positive end-expiratory pressure. Airway pressure at the end of exhalation.                                                                                                                                                                                                                         |

| Term/<br>Parameter                               | Description                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PetCO <sub>2</sub><br>(mmHg)                     | End-tidal CO <sub>2</sub> pressure.                                                                                                                                                                                                                                                                                                                                                                                       |
| PetCO <sub>2</sub> inc<br>(mmHg)                 | The absolute increase in PetCO <sub>2</sub> (relative to an average calculated prior to the start of the SBT) that is permitted during an SBT.<br>Only applies during an SBT.                                                                                                                                                                                                                                             |
| $\Delta$ Psupport<br>max<br>(cmH <sub>2</sub> O) | The maximum pressure support allowed before starting an SBT, and an absolute upper limit that it cannot exceed during the SBT. If the upper limit is reached during an SBT, the SBT is aborted.<br><br>The target $\Delta$ Psupport max is configurable; you can change the setting in the INTELLiVENT-ASV Settings > SBT window.<br><br>Shown as the upper P <sub>insp</sub> limit in the Quick Wean & SBT Status panel. |
| $\Delta$ Psupport<br>min<br>(cmH <sub>2</sub> O) | The minimum pressure support that will be applied during an SBT.<br><br>The target $\Delta$ Psupport min is configurable; you can change the setting in the INTELLiVENT-ASV Settings > SBT window.<br><br>Shown as the lower P <sub>insp</sub> limit in the Quick Wean & SBT Status panel.                                                                                                                                |

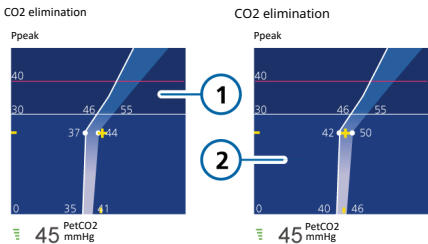
| Term/<br>Parameter | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate<br>(b/min)    | Respiratory rate, as number of breaths per minute.<br><br>Defines the maximum rate allowed before an SBT can take place, as well as an absolute upper limit that cannot be exceeded during an SBT.<br><br>The target Rate is configurable; you can change the setting in the INTELLiVENT-ASV Settings > SBT window.<br><br>If the upper limit is reached during an SBT, the SBT is stopped.                                                                                                             |
| SBT time<br>range  | Defines the hours between which an SBT can be started.<br><br>Even if the <i>To start SBT</i> criteria are met, the SBT will not take place until the current time of day is inside the specified range, if criteria are still met.<br><br>The time range is configurable; you can change it in the INTELLiVENT-ASV Settings > SBT window.<br><br>If an SBT is in progress when the time is out of range, the SBT continues until it is completed.<br><br>Only applies when automatic SBTs are enabled. |

| Term/<br>Parameter                      | Description                                                                                                                                                                                                                                                                                                                                                                     | Term/<br>Parameter   | Description                                                                                                                                                                                                                                               |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SpO2<br>(%)                             | Measurement of oxygen saturation in the blood.                                                                                                                                                                                                                                                                                                                                  | Vt/kg<br>(ml/kg)     | Tidal volume per kilogram of ideal body weight.                                                                                                                                                                                                           |
| Time<br>before<br>starting SBT<br>(min) | <p>Defines the length of time that patient conditions must stay within the <i>To start SBT</i> limits before an SBT can start.</p> <p>The time is configurable; you can change it in the INTEL-LiVENT-ASV Settings &gt; SBT window.</p> <p>Only applies when automatic SBTs are enabled.</p>                                                                                    | RSB<br>(1 / (l*min)) | <p>Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE).</p> <p>The RSB parameter is only used for patients weighing &gt; 40 kg. For patients weighing less, the PetCO2 parameter is used.</p> |
| Time<br>between 2<br>SBTs<br>(min)      | <p>Defines the minimum length of time that must pass between two SBTs.</p> <p>The time is configurable; you can change it in the INTEL-LiVENT-ASV Settings &gt; SBT window.</p> <p>Only applies when automatic SBTs are enabled.</p>                                                                                                                                            |                      |                                                                                                                                                                                                                                                           |
| Tolerance<br>time<br>(s)                | <p>The length of time a parameter value can be out of range without affecting the countdown to an SBT or an ongoing SBT.</p> <p>For example, with a Tolerance time of 30 seconds, any parameter can be out of range for up to 30 seconds with no effect. If a parameter value remains out of range for 31 or more seconds, the process resets or an ongoing SBT is stopped.</p> |                      |                                                                                                                                                                                                                                                           |

2.2.5 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.



- 1 Quick Wean disabled, default PetCO2 target zone
- 2 Quick Wean enabled, PetCO2 target shifted +5 mmHg to the right

- 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 on the main display.

For details about:

- How the Quick Wean panel indicates progress, see Section 2.4.4
- How the device controls minute volume, see Sections 1.9.2 and 1.9.1

2.3 Enabling/disabling and setting up automatic SBTs

By default, automatic SBTs are disabled.

To enable automatic SBTs, both Quick Wean and Automatic SBTs must be set to On.

For details about enabling/disabling automated SBTs, see Section 1.6.6.

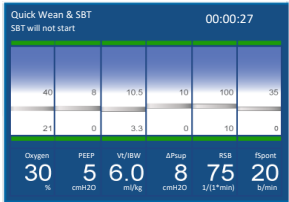
For details about adjusting SBT settings, see Section 1.6.7.



When *To start SBT* criteria are met and ...

Quick Wean/Quick Wean & SBT Status panel

Automatic SBTs are disabled



The device shows the status *Conditions fulfilled, SBT will not start* in the Quick Wean Status panel.

Note that any of the *To start SBT* parameters can be out of range for up to the time specified by the Tolerance time parameter without affecting this status.

### 2.4.1 About %MinVol calculations

When Quick Wean is enabled, once the patient is *active* and the patient's Rate is within the target range as described in Section 1.9.2, the device decreases %MinVol stepwise to 70%.

Note that if %MinVol is already at 70%, no change takes place.

The device adjusts %MinVol as follows:

Table 2-2. %MinVol adjustments

| Patient status                           | Quick Wean status              | The device ...                     |
|------------------------------------------|--------------------------------|------------------------------------|
| <i>Active</i> , Rate within target range | Quick Wean enabled             | Decreases %MinVol to 70%           |
|                                          | Quick Wean disabled            | No %MinVol change                  |
| <i>Active</i> , Rate out of range        | Quick Wean enabled or disabled | INTELLiVENT-ASV %MinVol management |

### 2.4.2 Parameters used to determine weaning readiness (To start SBT group)

#### NOTICE

In the Quick Wean & SBT Status panel, the RSB parameter is shown only for patients with PBW > 40 kg. For patients with PBW ≤ 40 kg, the PetCO<sub>2</sub> parameter is shown instead.

The parameters in Table 2-3 are monitored to determine the patient's readiness for weaning activities. They are monitored regardless of whether automatic SBTs are enabled or disabled.

The default values for most of these parameters are set in Configuration. A few of the parameters can be modified during ventilation in the INTELLiVENT-ASV Settings window (Section 2.4.3).

Some parameters use different thresholds, depending on the patient PBW. Where applicable, these differences are identified in this guide.

For additional details about:

- Parameter definitions, see Section 2.2.4
- Configuring parameters, see Section 2.9
- Parameter specifications, see Section 2.10

Table 2-3. Quick Wean *To start SBT* criteria

| Parameter (unit)                   | Where set/how used                                                                                                   | Default <i>To start SBT</i> setting                                |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| %fSpont                            | Not configurable                                                                                                     | 100% during Time before starting SBT                               |
| Oxygen (%)                         | Configuration > Modes > SBT > To start SBT window<br>For an SBT to start, the value must be ≤ the specified setting. | 40                                                                 |
| PEEP (cmH <sub>2</sub> O)          | Configuration > Modes > SBT > To start SBT window<br>For an SBT to start, the value must be ≤ the specified setting. | Patients > 40 kg: 8<br>Patients ≤ 40 kg: 6                         |
| ΔPsupport max (cmH <sub>2</sub> O) | INTELLiVENT-ASV Settings > SBT window<br>For an SBT to start, the value must be ≤ the specified setting.             | 12                                                                 |
| ΔPsupport min (cmH <sub>2</sub> O) | INTELLiVENT-ASV Settings > SBT window                                                                                | 5                                                                  |
| Rate (b/min)                       | INTELLiVENT-ASV Settings > SBT window<br>For an SBT to start, the value must be ≤ the specified setting.             | Patients > 30 kg: 35<br>Patients ≤ 30 kg: 45                       |
| RSB (1/(l*min))                    | Not configurable<br>For an SBT to start, the value must be ≤ the setting.                                            | 105                                                                |
| SpO <sub>2</sub> (%)               | Not configurable                                                                                                     | In INTELLiVENT-ASV normal/high range (within or above target zone) |
| Vt/kg (ml/kg)                      | Configuration > Modes > SBT > To start SBT window                                                                    | 5                                                                  |

| Parameter (unit)               | Where set/how used                                                                                                                                                                   | Default <i>To start SBT</i> setting           |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Time before starting SBT (min) | INTELLiVENT-ASV Settings > SBT window                                                                                                                                                | 30                                            |
| Time between 2 SBTs (h)        | INTELLiVENT-ASV Settings > SBT window                                                                                                                                                | 0.5                                           |
| SBT time range (hh:mm)         | INTELLiVENT-ASV Settings > SBT window<br>To allow automatic SBTs to start at any time, set both controls to the same time.                                                           | Between 8:00 and 20:00 (8 am to 8 pm)         |
| Tolerance time (s)             | Configuration > Modes > SBT > To start SBT window<br><br>If any one parameter (listed in this table) is out of range for longer than this time period, the countdown timer is reset. | Patients > 40 kg: 180<br>Patients ≤ 40 kg: 60 |

2.4.3 User-modifiable SBT parameters, INTELLiVENT-ASV Settings window

The INTELLiVENT-ASV Settings > SBT window provides access to the SBT-related parameters that you can adjust during ventilation, if needed. You do not have to put the ventilator into Standby to make changes. Changes are implemented immediately, and the system starts making adjustments, if needed.

The time-related parameters (Time before starting SBT, Time between 2 SBTs, and SBT time range) are only enabled when automatic SBTs are turned on. You can adjust the other parameters in this window at any time.

When Quick Wean is set to On, the system monitors the non-time-related parameters to help determine whether to start an SBT, and once an SBT is taking place, whether to stop an ongoing SBT. These values are used in addition to the *To start SBT* parameters and *To stop SBT* parameters specified in Configuration.

To access SBT settings

- ▶ Open the INTELLiVENT-ASV Settings > SBT window, and adjust settings as needed.  
For details, see Section 2.3.

2.4.4 Monitoring progress

When Quick Wean is enabled, two additional monitoring windows are available:

- Quick Wean or Quick Wean & SBT Status panel
- SBT history panel (view 3)

2.4.4.1 Quick Wean/Quick Wean & SBT Status panel

Like the ventilation Vent Status panel, the Quick Wean/Quick Wean & SBT Status panel uses floating indicators moving up and down within the columns to show the values for SBT- and weaning-related parameters. The data is updated every breath.

To help you quickly determine the SBT status (automatic or not), the panel name changes as follows:

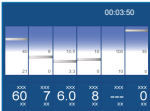
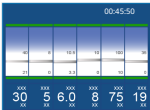
- When automatic SBTs are disabled, the panel is labeled *Quick Wean*.
- When automatic SBTs are enabled, the panel is labeled *Quick Wean & SBT*.

The content of the panel changes depending on which phase the device is in.

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.

Table 2-4. 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 <i>Operator's Manual</i> . |
| Quick Wean is enabled  | INTELLiVENT-ASV displays the Quick Wean panel, showing the monitored weaning parameters (Table 2-9).                                            |

| When ...                                             | Vent Status or Quick Wean panel ...                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------|-------|---|----|----------|---|---|--|---|-----|--|---|---|--|---|----|--|
| One or more parameter values are in the weaning zone | <p>Parameters that are within their target weaning ranges are in their weaning zone, and show a timer indicating the amount of time that parameter has been in the weaning zone.</p>  <table><thead><tr><th>Parameter</th><th>Value</th><th>Timer</th></tr></thead><tbody><tr><td>P</td><td>60</td><td>00:03:50</td></tr><tr><td>R</td><td>7</td><td></td></tr><tr><td>E</td><td>6.0</td><td></td></tr><tr><td>I</td><td>8</td><td></td></tr><tr><td>S</td><td>0</td><td></td></tr></tbody></table>                                              | Parameter | Value | Timer | P | 60 | 00:03:50 | R | 7 |  | E | 6.0 |  | I | 8 |  | S | 0  |  |
| Parameter                                            | Value                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Timer     |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| P                                                    | 60                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 00:03:50  |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| R                                                    | 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| E                                                    | 6.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| I                                                    | 8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| S                                                    | 0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| All of the parameter values are in the weaning zone  | <p>The Quick Wean panel displays:</p> <ul style="list-style-type: none"><li>• A green bar for each of the parameters.</li><li>• A timer (HH:MM:SS) showing how long the patient values have been in the weaning zone.</li></ul>  <table><thead><tr><th>Parameter</th><th>Value</th><th>Timer</th></tr></thead><tbody><tr><td>P</td><td>30</td><td>00:45:50</td></tr><tr><td>R</td><td>5</td><td></td></tr><tr><td>E</td><td>6.0</td><td></td></tr><tr><td>I</td><td>7</td><td></td></tr><tr><td>S</td><td>19</td><td></td></tr></tbody></table> | Parameter | Value | Timer | P | 30 | 00:45:50 | R | 5 |  | E | 6.0 |  | I | 7 |  | S | 19 |  |
| Parameter                                            | Value                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Timer     |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| P                                                    | 30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 00:45:50  |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| R                                                    | 5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| E                                                    | 6.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| I                                                    | 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |
| S                                                    | 19                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |           |       |       |   |    |          |   |   |  |   |     |  |   |   |  |   |    |  |

## 2.4.4.2 SBT history panel

The SBT history panel, available in view 3 of the INTELLiVENT-ASV views, displays an overview of all of the key ventilation parameters.

A green checkmark indicates that the parameter is within acceptable limits. A red up or down arrow indicates a parameter value that is out of the acceptable range.

During an active SBT, the panel displays the start time and date, as well as the status message, *SBT running*.

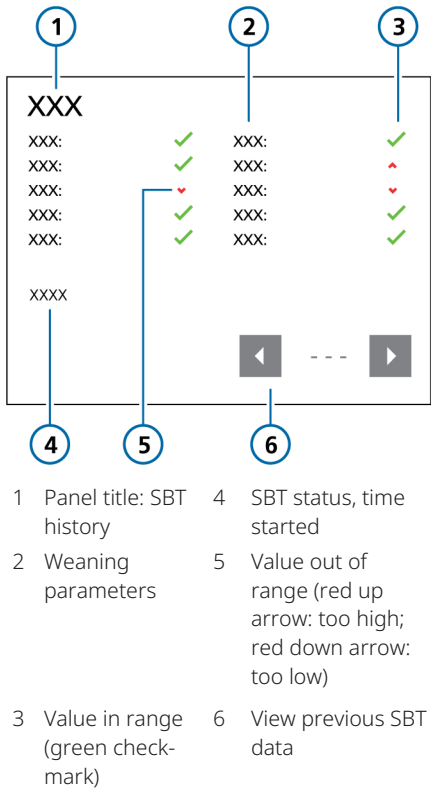
When an SBT is ended, the panel displays information about how the previous SBT ended (successfully completed (*fulfilled*) or stopped prematurely (*stopped*)).

You can swipe left or right in the SBT history panel, or use the arrow buttons at the bottom of the panel to view data for each SBT conducted.

### To display the SBT history panel

- Touch the view buttons until the SBT history panel is displayed.

Figure 2-1. SBT history panel



## 2.5 Conducting an SBT

SBTs can be started manually (Section 2.5.1) or automatically.

To start an automatic SBT, all of the following conditions must be met:

- The patient must be *active*
- Automatic SBTs are enabled (in INTELLiVENT-ASV Settings > Auto window)
- Patient conditions must be within target ranges for all of the *To start SBT* criteria, for the time specified in the Time before starting SBT setting
- Enough time has passed since the last SBT (Time between 2 SBTs setting), if applicable
- The current time is within the allowed range (SBT time range setting)

If all conditions are met, the system starts an SBT.

The following changes occur.

Table 2-5. System changes when conducting an SBT

| System changes                                                                                                                                                                                                                                                                                                   | For details, see ... |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| The Quick Wean & SBT status panel displays pulsing green bars for parameters within the defined thresholds, and starts a timer.                                                                                                                                                                                  | Section 2.4.4.1      |
| The SBT history panel shows the time the SBT started.                                                                                                                                                                                                                                                            | Section 2.4.4.2      |
| Additional parameters are used during the SBT: <ul style="list-style-type: none"> <li>• Rate inc%</li> <li>• PetCO<sub>2</sub> inc (absolute increase in PetCO<sub>2</sub>)</li> </ul> Rate inc% and PetCO <sub>2</sub> inc values are used as <i>To stop SBT</i> criteria. The limits are set in Configuration. | Section 2.5.2        |
| The system changes the settings for %MinVol and PEEP, if needed, to those specified in Configuration (Configuration > Modes > SBT settings window).<br>Note that PEEP settings are changed only if PEEP control is set to Automatic.                                                                             | Section 2.9.1        |

## 2.5.1 Manually starting/stopping an SBT

You can manually start an SBT any time the patient is breathing spontaneously. The **Start SBT** button becomes available in the INTELLiVENT-ASV Settings > SBT window.

### To manually start an SBT

1. Open the INTELLiVENT-ASV Settings > SBT window (Section 1.6.12).
2. Touch **Start SBT**.

The system immediately starts an SBT by reducing %MinVol and PEEP (when control is set to Automatic) to the configured settings. For details on the specific actions, see Table 2-5.

The SBT continues until it successfully completes or is stopped. See Section 2.6.

The SBT history panel displays the start time of the SBT, with the text, *SBT manually started*. It also provides the end time, with a short description of how the SBT ended:

- *SBT successfully fulfilled* (completed in the specified time)
- *SBT stopped* (stopped ahead of time due to parameter value(s) being out of range)
- *SBT manually stopped*

### To manually stop an SBT

- ▶ In the INTELLiVENT-ASV Settings > SBT window, touch **Stop SBT**.

The SBT history panel records the time the SBT was stopped, and shows the text, *SBT manually stopped*.

The system returns to the previous INTELLiVENT-ASV settings and resumes screening the patient readiness-to-wean criteria.

### 2.5.2 PetCO<sub>2</sub> increases

#### NOTICE

PetCO<sub>2</sub> inc is used as part of *To stop SBT* criteria; it is not displayed.

During an SBT, the system uses the PetCO<sub>2</sub> increase as a *To stop SBT* criterion. You set a maximum allowed value in the *To stop SBT* window in Configuration.

The changes in PetCO<sub>2</sub> can give an indication of whether the patient is experiencing increased work of breathing (WOB). The system monitors the PetCO<sub>2</sub> increase, as well as the measured PetCO<sub>2</sub> value against the defined target range. For details about how the controller uses this data, see Section 1.9.2.

### 2.5.3 Monitoring breath rate increases

#### NOTICE

Rate inc % is only monitored during an SBT.

During an SBT, the Rate inc % is monitored and displayed in the SBT history panel.

The changes in this value can provide an indication of whether the patient is experiencing increased work of breathing (WOB) during an SBT. The rate increase is measured every minute by taking the current value and calculating the percent change from an average rate established just prior to the start of the SBT.

## 2.6 Conditions for stopping an SBT

### NOTICE

The maximum length of time a disconnection is allowed is one (1) minute, regardless of the Tolerance time setting.

If an SBT is stopped due to disconnection (whether inadvertent or for suctioning), the ventilator continues with the previous INTELLiVENT-ASV settings.

The SBT history panel displays the message SBT stopped manually.

During an SBT, the device monitors the *To stop SBT* parameters and other settings to determine whether to stop the SBT.

An SBT (automatic or manual) is stopped if any of the following conditions is met:

- If a *To stop SBT* parameter is out of range for longer than the time interval specified in the Tolerance time parameter, the SBT is stopped, and an alarm, SBT aborted, is generated.
- Quick Wean is set to Off in the INTELLiVENT-ASV Settings > Auto window.
- The device is placed into Standby.
- %MinVol is manually changed.
- The ventilation mode is changed.
- A P/V Tool maneuver is performed.
- The patient becomes *passive* (no longer meets the *active* criteria).
- The measured SpO2 value meets the criteria for a rapid therapy escalation.
- A disconnection > one (1) minute occurs.

The following table lists the *To stop SBT* parameters and the default threshold values.

Some of the *To stop SBT* parameters are not explicitly set. Rather, they are either calculated, or you set the *To start/during SBT* value, and a value outside of this setting becomes the *To stop SBT* criterion.

For additional details about:

- Parameter definitions, see Section 2.2.4
- Parameter specifications, see Section 2.10.

Table 2-6. Quick Wean *To stop SBT* criteria

| Parameter (unit)                   | Where set/how used                                                                                                                                                                                                                        | Default <i>To stop SBT</i> setting                                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Oxygen (%)                         | Configuration > Modes > SBT > To start SBT window<br><br>Set in the To start SBT window.<br><br>The Oxygen setting to stop an SBT is always the Oxygen setting in the To start SBT window + 10.                                           | 50                                                                                                                                     |
| PEEP (cmH <sub>2</sub> O)          | Configuration > Modes > SBT > To start SBT window<br><br>Set the upper limit that PEEP cannot exceed during an SBT.                                                                                                                       | Patients > 40 kg: 8<br>Patients ≤ 40 kg: 6                                                                                             |
| PetCO <sub>2</sub> (mmHg)          | Used indirectly together with PetCO <sub>2</sub> inc as <i>To stop SBT</i> criteria.<br><br>For additional details, see Section 1.9.2.                                                                                                    | If PetCO <sub>2</sub> > (upper limit INTELLiVENT-ASV PetCO <sub>2</sub> target range + 3 mmHg), an ongoing SBT is stopped immediately. |
| PetCO <sub>2</sub> inc (mmHg)      | Configuration > Modes > SBT > To stop SBT window<br><br>End-tidal CO <sub>2</sub> pressure increase compared to the values before the SBT. Only applies during an SBT. If the increase is more than the this setting, the SBT is stopped. | 8                                                                                                                                      |
| ΔPsupport max (cmH <sub>2</sub> O) | INTELLiVENT-ASV Settings > SBT window<br><br>Set the upper limit that ΔPsupport cannot exceed during the SBT.                                                                                                                             | 8                                                                                                                                      |
| ΔPsupport min (cmH <sub>2</sub> O) | INTELLiVENT-ASV Settings > SBT window<br><br>Set the lower limit that ΔPsupport cannot go below during the SBT.                                                                                                                           | 5                                                                                                                                      |
| Rate (b/min)                       | INTELLiVENT-ASV Settings > SBT window<br><br>Set the upper limit that Rate cannot exceed during SBT.                                                                                                                                      | Patients > 30 kg: 35<br>Patients ≤ 30 kg: 45                                                                                           |

| Parameter (unit)       | Where set/how used                                                                                                                                                                                                 | Default <i>To stop SBT</i> setting                                   |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Rate inc               | Configuration > Modes > SBT > To stop SBT window<br>Percentage increase in respiratory rate as a result of the SBT. Only applies during an SBT. If the increase is more than the this setting, the SBT is stopped. | 50% increase over the average rate established just prior to the SBT |
| RSB<br>(1/(l*min))     | Not configurable.                                                                                                                                                                                                  | > 105                                                                |
| SpO2<br>(%)            | Not configurable.                                                                                                                                                                                                  | < (INTELLiVENT-ASV-set SpO2 target range)                            |
| Vt/kg<br>(ml/kg)       | Configuration > Modes > SBT > To start SBT window<br>Specify the minimum Vt/kg setting allowed during an SBT.                                                                                                      | 5                                                                    |
| Tolerance time<br>(s)  | Configuration > Modes > SBT > To stop SBT window                                                                                                                                                                   | Patients > 40 kg: 180<br>Patients ≤ 40 kg: 30                        |
| Max. duration<br>(min) | Configuration > Modes > SBT > To stop SBT window                                                                                                                                                                   | 30                                                                   |

## 2.7 Conditions for successfully completing an SBT

During an SBT, the device monitors parameters against the *To stop SBT* threshold values. If parameters remain in range for the duration set for the SBT (specified by the Max. duration parameter), the SBT is ended and marked as SBT successfully fulfilled. An SBT fulfilled alarm is generated.

When an SBT is fulfilled (completed), the device:

- Returns to the previous INTELLiVENT-ASV settings.
- Returns %MinVol and PEEP (when set to Automatic) to the value prior to the start of the SBT.
- Starts monitoring patient conditions against the *To start SBT* thresholds (Section 2.4), and the Time between 2 SBTs time.

## 2.8 About Quick Wean alarms and messages

Quick Wean provides a set of alarms and messages related to weaning activities, including SBTs. Messages are written to the Event log. Alarms and messages are displayed in the following locations:

- Alarm message bar
- Event log
- SBT history panel

### To review and dismiss an alarm

- ▶ Do any of the following:
  - Touch the message to open the Alarms > Buffer window. Review the message, then close the window.
  - Touch the red i-icon and view the alarm log.
  - Touch **Alarms** > **Buffer** to open the window and review the alarm message, then close the window.

To review help information for the alarm, touch the alarm entry in the buffer. A short description is displayed.

The following table provides an overview of the Quick Wean-related alarms and messages.

For detailed information about system alarms, see your ventilator *Operator's Manual*.

Table 2-7. Quick Wean alarms and messages

| Alarm message                                                      | Description                                                                                                                                                                                                               |
|--------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SBT canceled<br><i>Medium priority.</i>                            | The SBT was stopped. For possible reasons, see Section 2.6.<br>Dismiss the alarm as described in Section 2.8.                                                                                                             |
| SBT successfully fulfilled<br><i>Medium priority.</i>              | The SBT was ended because <b>Max. duration</b> was reached.<br>Dismiss the alarm as described in Section 2.8.                                                                                                             |
| SBT stopped after HHH hours<br>MM minutes                          | Indicates how long the SBT ran before being stopped.<br>Shown in SBT history panel and Event log.                                                                                                                         |
| SBT started at YYYY-MM-DD<br>HHH hours MM minutes                  | When an SBT starts automatically, this message records the time.<br>Shown in SBT history panel and Event log.                                                                                                             |
| SBT fulfilled after HHH hours<br>MM minutes                        | When an SBT ends successfully, this message records the time. The time is equal to the <b>Max. duration</b> value.<br>Shown in SBT history panel.                                                                         |
| SBT manually started at<br>YYYY-MM-DD HHH hours<br>MM minutes      | When an SBT is manually started by selecting the <b>Start SBT</b> button, this message records the time.<br>Shown in SBT history panel.                                                                                   |
| SBT manually stopped after<br>HHH hours MM minutes                 | When an SBT is manually ended by selecting the <b>Stop SBT</b> button, this message records for how long the SBT ran.<br>Shown in SBT history panel and Event log.                                                        |
| Too high (red up arrow) and<br>Too low (red down arrow) indicators | When a parameter's value goes above the allowed range, a red up arrow is displayed next to the parameter in the SBT history panel.<br>When a parameter's value is below the allowed range, a red down arrow is displayed. |
| Within range (green checkmark)<br>indicator                        | When a parameter's value is within the specified range, a green checkmark is displayed.                                                                                                                                   |

2.9 Configuring Quick Wean and SBTs

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

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, what adjustments to make when an SBT begins, and whether to stop the weaning activities.

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

Some settings are based on the patient's PBW: patients with PBW > 40 kg and those with PBW ≤ 40 kg.

For the list of default values, see Table 2-9.

2.9.1 Adjusting default SBT values in Configuration

The default SBT control settings are defined in the following locations:

- In Configuration mode, in the Modes > SBT windows: To start SBT, SBT settings, and To stop SBT
- In the INTELLiVENT-ASV Settings > SBT window (Section 2.3)

The SBT configuration windows provide access to the following controls:

Table 2-8. SBT default settings configuration windows

| Configura-<br>tion window | Controls                                                                                                                                                                                            |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| To start SBT              | Patient conditions are monitored against the limits defined here for the listed parameters to determine when they are ready for an SBT: PEEP, Oxygen, Vt/kg, Tolerance time                         |
| SBT settings              | When an SBT begins, the device adjusts PEEP (when control is set to Automatic) and %MinVol to the values specified here.                                                                            |
| To stop SBT               | During an SBT, patient conditions are monitored against the limits defined here for the listed parameters to determine whether to stop the SBT: Rate inc, PetCO2 inc, Tolerance time, Max. duration |

Each of these windows is divided into two groups: the controls on the top half apply to patients with PBW > 40 kg; the controls on the bottom half apply to patients with PBW ≤ 40 kg.

You can change the default settings to match your institution's protocol, if needed.

### To change the default *To start SBT*, *SBT*, and/or *To stop SBT* settings in Configuration

1. Without a patient connected, put the ventilator into Standby.
2. Access the Configuration windows, and on the left side, touch **Modes**, then touch **SBT**.  
The **SBT** tabs appear, with the *To start SBT* parameters displayed by default.
3. In the *To start SBT* window, review and adjust the threshold values for starting an SBT for the following parameters: PEEP, Oxygen, Vt/kg, and Tolerance time.  
For details about the parameters, see Table 2-3.
4. Touch the **SBT settings** tab to review and adjust the starting PEEP and %MinVol values for an SBT.  
When conditions to start an SBT are met, the device adjusts these parameters to the values set here for the duration of the SBT.
5. Touch the **To stop SBT** tab to review and adjust the threshold values for stopping an SBT for the following parameters: Rate inc, PetCO<sub>2</sub> inc, Tolerance time, and Max. duration.  
For details about the parameters, see Table 2-6.
6. To reset the values to the factory defaults, touch the **Use factory settings** button, and when prompted to confirm, touch **Yes**.  
Touch **No** to cancel the reset.  
All of the controls on all three SBT windows are reset to the factory default settings.

7. Touch the **Back** button to return to the main Configuration window.
8. When finished, exit Configuration mode.

### 2.9.2 Adjusting default SBT values in the INTELLiVENT-ASV Settings window

The SBT controls provided in the INTELLiVENT-ASV Settings window are *not* available in the Configuration window; however, you can change the default settings, if desired. You can also set separate values for patients with PBW > 40 kg and ≤ 40 kg.

The default values for these controls, ΔP<sub>support</sub> max, ΔP<sub>support</sub> min, Rate, Time before starting SBT, and Time between 2 SBTs, are stored with individual Quick Setups.

#### To change default SBT values in the INTELLiVENT-ASV Settings window

1. Set all ventilator parameters, alarm limits, graphics layout, and SBT values (in the INTELLiVENT-ASV Settings > SBT window) to the desired settings for the target patient group (adult or pediatric).
2. Put the ventilator into Standby and access the Configuration > Setups window.
3. Select the Quick Setup option to configure, make any further changes to settings, and save the settings as described in your ventilator *Operator's Manual*.

The SBT parameter values that you saved in the INTELLiVENT-ASV Settings window are now saved as the default values for the selected Quick Setup.

2.9.3 Restoring factory default settings

To return the SBT parameter values to factory defaults

- 1. Open the Configuration > Modes > SBT window.
- 2. Touch the **Use factory settings** button.

All of the controls on all three SBT windows are reset to the factory default settings.

Note that this does not affect the SBT parameters that are set in the INTELLiVENT-ASV Settings window. Those parameter defaults are configured in individual Quick Setups.

2.10 Quick Wean parameter specifications

The following table is a comprehensive list of all of the Quick Wean-related parameters.

Table 2-9. Quick Wean parameters

| Parameter           | Default values                                                                                  | Where displayed/Where set                                                                                                                                                         | Range                        |
|---------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| %fSpont (%)         | To start SBT: 100%                                                                              | <b>Displayed in:</b><br>SBT history panel<br><b>Set in:</b> N/A (calculated value)                                                                                                | --                           |
| %MinVol (%)         | Quick Wean enabled: 70<br>During SBT: 25                                                        | <b>Displayed in:</b><br>INTELLiVENT-ASV main display in the %MinVol control<br><b>Set in:</b> Configuration > Modes > SBT > SBT settings                                          | %MinVol during SBT: 25 to 70 |
| fSpont              | --                                                                                              | <b>Displayed in:</b> <ul style="list-style-type: none"> <li>Quick Wean &amp; SBT status panel</li> <li>SBT history panel</li> <li>Monitoring window</li> </ul> <b>Set in:</b> N/A | --                           |
| Max. Duration (min) | By default, set to 30 minutes.<br>Off means that there is no limit to how long the SBT can run. | <b>Displayed and set in:</b><br>Configuration > Modes > SBT > To stop SBT                                                                                                         | Off, 20 to 240               |

Note that references to the Quick Wean status panel apply to both Quick Wean and Quick Wean & SBT.

For parameter definitions, see Section 2.2.4.

|            |                                                                                                                                                                   |                                                                                                                                                                                                                                                                                      |                                                 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Oxygen (%) | To start SBT: ≤ 40<br>To stop SBT: > 50<br><br>The buttons are interdependent: The <i>To start SBT</i> setting is always 10 below the <i>To stop SBT</i> setting. | <b>Displayed in:</b> <ul style="list-style-type: none"> <li>INTELLiVENT-ASV main display in the Oxygen control</li> <li>Quick Wean &amp; SBT status panel</li> <li>SBT history panel</li> <li>Monitoring window</li> </ul> <b>Set in:</b> Configuration > Modes > SBT > To start SBT | To start SBT: 30 to 50<br>To stop SBT: 40 to 60 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|

| Parameter                     | Default values                                                                                                                                                                                                               | Where displayed/Where set                                                                                                                                                                                                                                                                                                                                                                                                        | Range                                                               |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| PEEP (cmH <sub>2</sub> O)     | <p>To start SBT:<br/>Patient PBW &gt; 40 kg: ≤ 8<br/>Patient PBW ≤ 40 kg: ≤ 6</p> <p>To stop SBT:<br/>Patient PBW &gt; 40 kg: &gt; 8<br/>Patient PBW ≤ 40 kg: &gt; 6</p> <p>During SBT:<br/>PEEP is set to 5 by default.</p> | <p><b>Displayed in:</b></p> <ul style="list-style-type: none"> <li>• INTELLiVENT-ASV main display in PEEP control</li> <li>• Quick Wean &amp; SBT status panel</li> <li>• SBT history panel</li> <li>• Monitoring window</li> </ul> <p><b>Set in:</b></p> <ul style="list-style-type: none"> <li>• Configuration &gt; Modes &gt; SBT &gt; To start SBT</li> <li>• Configuration &gt; Modes &gt; SBT &gt; SBT settings</li> </ul> | <p>To start SBT:<br/>5 to 10</p> <p>PEEP during SBT:<br/>0 to 5</p> |
| PetCO <sub>2</sub> (mmHg)     | <p>To stop SBT:<br/>PetCO<sub>2</sub> &gt; (upper limit INTELLiVENT-ASV PetCO<sub>2</sub> target range + 3 mmHg)</p>                                                                                                         | <p><b>Displayed in:</b></p> <ul style="list-style-type: none"> <li>• Patient PBW ≤ 40 kg: Quick Wean status panel</li> <li>• SBT history panel</li> <li>• CO<sub>2</sub> elimination horizon and map</li> <li>• Monitoring &gt; CO<sub>2</sub> window</li> <li>• Dynamic Lung panel</li> </ul> <p>This value is not configured. You can adjust the target range, if needed. See Section 1.6.13.2.</p>                            | <p>Depends on PetCO<sub>2</sub> target range</p>                    |
| PetCO <sub>2</sub> inc (mmHg) | <p>To stop SBT:<br/>&gt; 8 increase</p>                                                                                                                                                                                      | <p>Not displayed.</p> <p><b>Set in:</b> Configuration &gt; Modes &gt; SBT &gt; To stop SBT</p>                                                                                                                                                                                                                                                                                                                                   | <p>4 to 20</p>                                                      |

| Parameter            | Default values                                                                                                                                                                               | Where displayed/Where set                                                                                                                                                                                                                                                           | Range     |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Rate<br>(b/min)      | <p>To start SBT:<br/>Patient PBW &gt; 30 kg:<br/>≤ 35<br/>Patient PBW ≤ 30 kg:<br/>≤ 45</p> <p>To stop SBT:<br/>Patient PBW &gt; 30 kg:<br/>&gt; 35<br/>Patient PBW ≤ 30 kg:<br/>&gt; 45</p> | <p><b>Displayed in:</b></p> <ul style="list-style-type: none"> <li>Quick Wean &amp; SBT status panel (as fSpont)</li> <li>SBT history panel (as fSpont)</li> <li>INTELLiVENT-ASV Settings &gt; SBT window</li> </ul> <p><b>Set in:</b> INTELLiVENT-ASV Settings &gt; SBT window</p> | 25 to 65  |
| Rate inc<br>(%)      | <p>To stop SBT:<br/>&gt; 50% increase over the average rate established just prior to the start of the SBT</p>                                                                               | <p><b>Displayed in:</b><br/>SBT history panel</p> <p><b>Set in:</b> Configuration &gt; Modes &gt; SBT &gt; To stop SBT</p>                                                                                                                                                          | 20 to 100 |
| RSB<br>(1 / (l*min)) | <p>To start SBT:<br/>≤ 105</p> <p>To stop SBT:<br/>&gt; 105</p>                                                                                                                              | <p><b>Displayed in:</b></p> <ul style="list-style-type: none"> <li>Patient PBW &gt; 40 kg: Quick Wean &amp; SBT status panel</li> <li>SBT history panel</li> </ul> <p>The RSB parameter is only used for patients with PBW &gt; 40 kg.</p> <p>This value is not configured.</p>     | 105       |
| SBT time range       | <p>To allow SBTs at any time, set both controls to the same time.</p> <p><b>Default:</b> Between 8:00 and 20:00</p>                                                                          | <p><b>Displayed and set in:</b><br/>INTELLiVENT-ASV Settings &gt; SBT window</p>                                                                                                                                                                                                    | HH:MM     |

| Parameter                      | Default values                                                                                                                                                                                                                                                                                                                 | Where displayed/Where set                                                                                                                                                                                                                                                                                                                     | Range                                                                                                                                     |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| SpO2 (%)                       | <p>To start SBT:<br/>Within or above the INTELLiVENT-ASV SpO2 target range</p> <p>To stop SBT:<br/>Below the INTEL-LiVENT-ASV SpO2 target range minus 2%</p>                                                                                                                                                                   | <p><b>Displayed in:</b></p> <ul style="list-style-type: none"> <li>• Oxygenation horizon and map (views 1, 2, 3)</li> <li>• Monitoring &gt; SpO2 window</li> <li>• SBT history panel</li> <li>• Main display under MMP list</li> </ul> <p>This value is not configured. You can adjust the target range, if needed. See Section 1.6.13.2.</p> | Depends on the SpO2 target range                                                                                                          |
| Time before starting SBT (min) | By default, set to 30 minutes                                                                                                                                                                                                                                                                                                  | <b>Displayed and set in:</b><br>INTELLiVENT-ASV Settings > SBT window                                                                                                                                                                                                                                                                         | 10 to 120                                                                                                                                 |
| Time between 2 SBTs (h)        | <p>To start next SBT:<br/>By default, 30 minutes</p>                                                                                                                                                                                                                                                                           | <b>Displayed and set in:</b><br>INTELLiVENT-ASV Settings > SBT window                                                                                                                                                                                                                                                                         | <ul style="list-style-type: none"> <li>• 0.5 to 4 hour (in 0.5 hour increments)</li> <li>• 4 to 24 hour (in 1 hour increments)</li> </ul> |
| Tolerance time (s)             | <p>For the following parameters, the Tolerance time setting is predefined (regardless of the Configuration settings):</p> <ul style="list-style-type: none"> <li>• %fSpont: must be 100% for a minimum of 60 seconds</li> <li>• For patients with PBW ≤ 40 kg, the Tolerance Time for Rate and Vt/kg is 180 seconds</li> </ul> |                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                           |
| Tolerance time (s)             | <p>To start SBT:<br/>Patient PBW &gt; 40 kg: 180 seconds<br/>Patient PBW ≤ 40 kg: 60 seconds</p> <p>To stop SBT:<br/>Patient PBW &gt; 40 kg: 180 seconds<br/>Patient PBW ≤ 40 kg: 30 seconds</p>                                                                                                                               | <p><b>Displayed and configured in:</b></p> <ul style="list-style-type: none"> <li>• Configuration &gt; Modes &gt; SBT &gt; To start SBT</li> <li>• Configuration &gt; Modes &gt; SBT &gt; To stop SBT</li> </ul>                                                                                                                              | 10 to 300                                                                                                                                 |

| Parameter                                | Default values                                          | Where displayed/Where set                                                                                                                                                                                                      | Range   |
|------------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Vt/kg<br>(ml/kg)                         | To start SBT:<br>≥ 5 ml/kg<br>To stop SBT:<br>< 5 ml/kg | <b>Displayed in:</b> <ul style="list-style-type: none"> <li>• Quick Wean &amp; SBT status panel</li> <li>• SBT history panel</li> <li>• Monitoring window</li> </ul> <b>Set in:</b> Configuration > Modes > SBT > To start SBT | 3 to 6  |
| ΔPsupport<br>max<br>(cmH <sub>2</sub> O) | To start SBT:<br>≤ 12<br>To stop SBT:<br>> 8            | <b>Displayed in:</b> <ul style="list-style-type: none"> <li>• INTELLiVENT-ASV Settings &gt; SBT window</li> <li>• SBT history panel</li> </ul> <b>Set in:</b> INTELLiVENT-ASV Settings > SBT window                            | 6 to 25 |
| ΔPsupport<br>min<br>(cmH <sub>2</sub> O) | To start SBT:<br>≥ 5<br>To stop SBT:<br>< 5             | <b>Displayed in:</b> <ul style="list-style-type: none"> <li>• INTELLiVENT-ASV Settings &gt; SBT window</li> <li>• SBT history panel</li> </ul> <b>Set in:</b> INTELLiVENT-ASV Settings > SBT window                            | 0 to 10 |



# 3

## Specifications

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3.1 Potential complications and residual risks

Using pulse oximetry and capnometry sensors integrated with the ventilator, the INTELLiVENT-ASV mode implements algorithms to adjust minute ventilation, level of PEEP, and Oxygen based on end-tidal CO2 pressure (PetCO2) and oxygen pulse saturation (SpO2) monitoring. This allows INTELLiVENT-ASV to automatically control gas exchange at the lowest work of breathing within protective limits defined by the clinician.

Residual risks related to the automatic control of breathing are analyzed and assessed in the following sections.

| For details about ...                           | See ...       |
|-------------------------------------------------|---------------|
| Risks related to user misin-formation           | Section 3.1.1 |
| Risks related to inade-quate minute ventilation | Section 3.1.2 |
| Risks related to inade-quate oxygenation        | Section 3.1.3 |

For the intended use, indications for use, and contraindications, see Sections 1.2 and 1.3.

3.1.1 Risks related to user misinforma-tion

The following risks are related to oper-ator-device interaction where the oper-ator can be in any of the following situa-tions:

- Operator thinks controllers are set to Automatic but they are not
- Operator not notified about a neces-sary treatment

The operator thinks controllers are set to Automatic but they are not

The operator may have selected Auto-matic mode, but did not confirm the selection. As a result, the operator may think that the controllers are in Auto-matic mode despite them remaining in Manual mode.

Delaying settings-related decisions with an intensive care ventilator could be the result, leading to critical consequences. The probability of such harm is low (1 in 1,000,000 patients).

To mitigate this risk, indicators on the display, as well as alarms are imple-mented:

- The shape and color of the controls, together with animation when set to Automatic, indicate what mode a controller is set to, and what state the controller is in
- Low and high SpO2 alarms
- Low and high ExpMinVol alarms

The operator is not notified about neces-sary treatment, such as airway suctioning during INTELLiVENT-ASV ventilation

This hazardous situation might lead to an incorrect SpO2 measurement even when the quality index is good (for example, due to a defect or program error) and an inappropriately high or low inspired Oxygen setting, resulting in various clinical consequences.

Several mitigations have been implemented to address these risks:

- The maximum PEEP is set by default to 15 cmH<sub>2</sub>O.
- The minimum PEEP is set by default to 5 cmH<sub>2</sub>O.
- The Plimit setting (P ASV limit on HAMILTON-G5/S1) also limits PEEP and airway pressure to the recommended protective values.
- The operator can set the PEEP controller to Manual mode at any time.
- The operator can set the Oxygen controller to Manual mode at any time.
- As stated in the *Operator's Manual*, additional ventilator-independent patient monitoring (for example, bedside vital monitoring or a blood gas analyzer) must be used during INTELLiVENT-ASV ventilation. Check PaCO<sub>2</sub> against displayed PetCO<sub>2</sub>, and SaO<sub>2</sub> against SpO<sub>2</sub>.
- As stated in the *Operator's Manual*, Periodically verify the SpO<sub>2</sub> value by checking the plethysmographic waveform and the quality index of the measured SpO<sub>2</sub> value.

### 3.1.2 Risks related to inadequate minute ventilation

With the INTELLiVENT-ASV ventilation strategy, the Ventilation controller constantly adjusts minute volume (%MinVol) based on continuous PetCO<sub>2</sub> readings. The target ranges for PetCO<sub>2</sub> and SpO<sub>2</sub> are set by the operator.<sup>1, 2, 3</sup> INTELLiVENT-ASV provides ventilation based on an operator-set minute volume if a patient is passive, or according to the patient's demands when a patient is or becomes *active*.

The main risks related to the Ventilation controller are providing inappropriately high or low minute volume, which might result, in the worst case, in respiratory alkalosis or acidosis, respectively. In patients with acute brain injury, respiratory acidosis might also lead to increased intracranial pressure contributing to further brain injury.

Each of these risks are briefly assessed in this section.

<sup>1</sup> Bialais E, Wittebole X, Vignaux L, *et al.* Closed-loop ventilation mode (IntelliVent®-ASV) in intensive care unit: a randomized trial. *Minerva Anestesiol* 2016; 82: 657–68.

<sup>2</sup> Buiteman-Kruizinga LA, Mkadmi HE, Neto AS, *et al.* Effect of INTELLiVENT-ASV versus Conventional Ventilation on Ventilation Intensity in Patients with COVID-19 ARDS—An Observational Study. *J Clin Medicine* 2021; 10: 5409.

<sup>3</sup> Botta M, Wenstedt EFE, Tsonas AM, *et al.* Effectiveness, Safety and Efficacy of INTELLiVENT-Adaptive Support Ventilation, a Closed-loop Ventilation Mode for use in ICU Patients—a systematic review. *Expert Rev Res Med* 2021. DOI:10.1080/17476348.2021.1933450.

### High minute volume

Here we assess the risk of the patient developing a compensated respiratory alkalosis during ventilation using INTELLiVENT-ASV.

Several conditions precede such harm, including:

- The patient's PetCO<sub>2</sub> is too high.
- The operator sets the %MinVol limit inappropriately high for patient (> 200%), leading the Ventilation controller to increase the %MinVol setting.
- The patient's gas exchange reacts slowly to the %MinVol increase, and PetCO<sub>2</sub> does not improve immediately.
- The Ventilation controller overshoots by the time the patient recovers.

If these situations persist for a long enough time, a compensated respiratory alkalosis (PaCO<sub>2</sub> as low as 25 – 35 mmHg with a pH < 7.45) might take place.<sup>1</sup>

The risk of severe respiratory alkalosis during ventilation with INTELLiVENT-ASV can also exist if the CO<sub>2</sub> sensor is incorrectly measuring PetCO<sub>2</sub> and reporting values that are too high. This might lead to excessive minute ventilation and, if

this situation persists for an extended period of time, a severe respiratory alkalosis (PaCO<sub>2</sub> < 25 mmHg) might develop.<sup>2</sup>

However, and especially with critically ill patients under mechanical ventilation, the values of PaCO<sub>2</sub> are most likely routinely checked using arterial blood gas analysis.<sup>3</sup> Moreover, based on bench testing, the probability of occurrence of such harm is low (1 in 1,000,000 patients).

Thus, Hamilton Medical considers this harm to be quite unlikely. The detection of such an error can be helped by routine arterial blood gas analysis and the high PetCO<sub>2</sub> alarm on the ventilator.

### Low minute volume

Here we assess the risks related to an incorrect and systematically low PetCO<sub>2</sub> measurement or to an error due to low barometric pressure, leading to under-reported PetCO<sub>2</sub> values.

This situation might result in any of the following conditions:

- Low minute ventilation and severe pulmonary acidosis, especially when minute ventilation is reduced to below 50% of the desirable value.
- Mild organ dysfunction if PaCO<sub>2</sub> is higher than 60 mmHg with a pH ranging from 7.1 to 7.35.<sup>1, 4, 5, 6</sup>

<sup>1</sup> Feihl F, Perret C. Permissive hypercapnia. How permissive should we be? *Am J Resp Crit Care* 1994; 150: 1722–37.

<sup>2</sup> Foray N, Stone T, Johnson A, et al. Severe metabolic alkalosis—a diagnostic dilemma. *Respir Medicine Case Reports* 2018; 25: 177–80.

<sup>3</sup> Fan E, Sorbo LD, Goligher EC, et al. An Official American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. *Am J Resp Crit Care* 2017; 195: 1253–63.

<sup>4</sup> Contreras M, Masterson C, Laffey JG. Permissive hypercapnia. *Curr Opin Anaesthesiol* 2015; 28: 26–37.

<sup>5</sup> Ryu J, Haddad G, Carlo WA. Clinical Effectiveness and Safety of Permissive Hypercapnia. *Clin Perinatol* 2012; 39: 603–12.

<sup>6</sup> Barnes T, Zochios V, Parhar K. Re-examining Permissive Hypercapnia in ARDS A Narrative Review. *Chest* 2018; 154: 185–95.

- In patients with acute brain injury, this error might further increase PaCO<sub>2</sub> (> 45 mmHg), leading to cerebral vasodilation, which further increases intracranial pressure, aggravating the brain injury.<sup>1, 2, 3</sup>

However, and especially with patients with neurologic diseases under mechanical ventilation, the values of PaCO<sub>2</sub> and PaO<sub>2</sub> are most likely routinely checked with arterial blood gas analysis.

Some mitigations are implemented:

- The PetCO<sub>2</sub> quality index, which displays the continuously monitored CO<sub>2</sub> sensor signal quality.
- The ability to select Brain injury as a specific condition.
- With an *active* patient, the PaCO<sub>2</sub>-PetCO<sub>2</sub> gradient increase is limited, as the Ventilation controller switches to PetCO<sub>2</sub>-based control if the upper PetCO<sub>2</sub> limit + 3 mmHg is reached.

### 3.1.3 Risks related to inadequate oxygenation

The following section assesses the risk of the patient developing hyperoxia or hypoxemia during ventilation with INTELLiVENT-ASV.

#### Hyperoxia

This harm might occur in the following situation:

- The patient presents a low SpO<sub>2</sub> value and the Oxygen controller increases the inspired Oxygen setting, but the SpO<sub>2</sub> does not improve immediately.
- The Oxygen controller overshoots the desired SpO<sub>2</sub>, resulting in the patient being ventilated with a high level of oxygen over a certain period (usually not longer than 2 minutes).

However, and especially with critical ill patients under mechanical ventilation, the PaO<sub>2</sub> values are most likely routinely checked with arterial blood gas analysis.<sup>4</sup>

<sup>1</sup> Bassi TG, Rohrs EC, Fernandez KC, *et al.* Brain injury after 50 h of lung-protective mechanical ventilation in a preclinical model. *Sci Rep-uk* 2021; 11: 5105.

<sup>2</sup> Mazzeo AT, Fanelli V, Mascia L. Brain-lung crosstalk in critical care: how protective mechanical ventilation can affect the brain homeostasis. *Minerva Anestesiol* 2012; 79: 299–309.

<sup>3</sup> Ziaka M, Exadaktylos A. Brain-lung interactions and mechanical ventilation in patients with isolated brain injury. *Crit Care* 2021; 25: 358.

<sup>4</sup> Fan E, Sorbo LD, Goligher EC, *et al.* An Official American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. *Am J Resp Crit Care* 2017; 195: 1253–63.

The risk of a transient hyperoxia is still not well addressed in the literature<sup>1,2,3,4</sup>; the overshoot period is not expected to be as long as two (2) minutes.

### Hypoxemia

This harm might occur in the following situation:

- The patient presents a high SpO<sub>2</sub> value and the Oxygen controller decreases the inspired Oxygen setting, but the SpO<sub>2</sub> does not decrease immediately.
- The Oxygen controller overshoots the desired SpO<sub>2</sub>, resulting in the patient being ventilated with a low level of oxygen over a certain period (usually not longer than 2 minutes).

The risk of a transient desaturation, which can result in several critical consequences, is highly dependent on both the severity of desaturation (SpO<sub>2</sub> < 80%) and the time spent in this condition.<sup>3</sup> With unstable patients, the continuous monitoring of the SpO<sub>2</sub> would generate an alarm under these conditions, informing the clinician of the issue.

Severe desaturation might also be related to the need to restart the ventilator due to an internal error, leading to a short time interruption in ventilation/therapy during the reboot time. This

interruption might lead to patient desaturation (SpO<sub>2</sub> 80% – 87%) depending on underlying patient conditions.<sup>5</sup>

### 3.1.4 Conclusion of risks and potential complications

A critically ill patient under mechanical ventilation in an intensive care unit is continuously monitored using both noninvasive and invasive monitoring systems. The clinician, nurses, and respiratory therapists are also closely and regularly assisting the patient. A qualified health professional is always available to intervene at the bedside, and would be able to easily recognize the risks associated with inadequate ventilation and oxygenation, and provide an alternative ventilation strategy.

With the measures taken as described, the identified risks of INTELLiVENT-ASV have been reduced as far as possible without having negative impact on the benefit-risk ratio. Therefore, the residual risk associated with each hazard, as well as the overall residual risks, are judged acceptable for INTELLiVENT-ASV.

<sup>1</sup> Kilgannon JH, Jones AE, Shapiro NI, *et al.* Association Between Arterial Hyperoxia Following Resuscitation From Cardiac Arrest and In-Hospital Mortality. *Jama* 2010; 303: 2165–71.

<sup>2</sup> Poder TG, Kouakou CRC, Bouchard P-A, *et al.* Cost-effectiveness of FreeO<sub>2</sub> in patients with chronic obstructive pulmonary disease hospitalised for acute exacerbations: analysis of a pilot study in Quebec. *Bmj Open* 2018; 8: e018835.

<sup>3</sup> Barbateskovic M, Schjørring OL, Krauss SR, *et al.* Higher versus lower fraction of inspired oxygen or targets of arterial oxygenation for adults admitted to the intensive care unit. *Cochrane Db Syst Rev* 2019; 2019. DOI:10.1002/14651858.cd012631.pub2.

<sup>4</sup> Sjöberg F, Singer M. The medical use of oxygen: a time for critical reappraisal. *J Intern Med* 2013; 274: 505–28.

<sup>5</sup> Neumann P, Berglund JE, Fernandez-Mondéjar E, Magnusson A, HEDENSTIERNA G. Dynamics of lung collapse and recruitment during prolonged breathing in porcine lung injury. *Journal of Applied Physiology* 1998; 85: 1533–43.

## 3.2 Technical data

Table 3-1. INTELLiVENT-ASV technical data

| Parameter                           | Specification                                                                                                                                                                                                                                                             |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Operator settings</b>            |                                                                                                                                                                                                                                                                           |
| Patient height (cm)                 | 50 to 250 (adult, pediatric)                                                                                                                                                                                                                                              |
| %MinVol (%)                         | 25 to 350 (manual)<br>70 to 200 (automatic)                                                                                                                                                                                                                               |
| Oxygen (%)                          | 21 to 100 (manual and automatic)                                                                                                                                                                                                                                          |
| PEEP (cmH <sub>2</sub> O)           | 0 to 50 (manual)<br>5 to 24 (automatic)                                                                                                                                                                                                                                   |
| <b>Internal calculations</b>        |                                                                                                                                                                                                                                                                           |
| Predicted body weight, PBW (kg)     | Calculation based on patient height and sex. For details, see your ventilator <i>Operator's Manual</i> .<br>INTELLiVENT-ASV can only be used for patients weighing more than 7 kg.                                                                                        |
| MinVol (target) (l/min)             | Target MinVol is calculated as:<br>$PBW \times \text{NormMinVent} \times \% \text{MinVol} / 100$<br>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 1.9.2.                                                                                                                                                                                                                                 |
| V <sub>daw</sub> (ml/kg)            | Calculation of the dead space: $PBW \times 2.2$                                                                                                                                                                                                                           |
| V <sub>t</sub> (target)             | MinVol/f (target)                                                                                                                                                                                                                                                         |
| <b>Monitoring</b>                   |                                                                                                                                                                                                                                                                           |
| Values (numerical)                  | PetCO <sub>2</sub> target range, depending on patient condition and treatment (P <sub>peak</sub> ); SpO <sub>2</sub> target range, depending on patient condition and treatment (PEEP)                                                                                    |
| Current ventilation settings        | ExpMinVol, f <sub>Total</sub> , f <sub>Control</sub> , P <sub>peak</sub> (P <sub>insp</sub> + PEEP), Oxygen, PEEP                                                                                                                                                         |
| Patient status                      | f <sub>Spont</sub> , PetCO <sub>2</sub> , SpO <sub>2</sub>                                                                                                                                                                                                                |
| Graphics                            | f (target)/V <sub>t</sub> , PetCO <sub>2</sub> /target, PEEP/O <sub>2</sub> , PEEP/SpO <sub>2</sub>                                                                                                                                                                       |

| Parameter                                                 | Specification                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trend parameters                                          | Ventilation control, Oxygenation control                                                                                                                                                                                                                                                                                             |
| Oxygen level notification                                 | Oxygen alert: 40% to 100%/Off (in the INTELLiVENT-ASV Settings > More window)                                                                                                                                                                                                                                                        |
| <b>Performance specifications, Ventilation controller</b> |                                                                                                                                                                                                                                                                                                                                      |
| 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%                                                                                                                                                                                                                                                                                                                                   |
| <b>Performance specifications, Oxygenation controller</b> |                                                                                                                                                                                                                                                                                                                                      |
| Settling time                                             | <p><i>Oxygen:</i> The settling time depends on the patient condition relative to the SpO2 target, as defined by the appropriate approach (<i>ARDSnet</i> or Open Lung concept) for the current treatment. Note that if SpO2 enters the emergency zone, the system immediately sets Oxygen to 100%.</p> <p><i>PEEP:</i> 6 minutes</p> |
| Response time (90% of steady state)                       | <p><i>Oxygen:</i> N/A; only the target range for SpO2 is specified</p> <p><i>PEEP:</i> 6 minutes</p>                                                                                                                                                                                                                                 |
| Rel/Command overshoot                                     | <p><i>Oxygen:</i> none</p> <p><i>PEEP:</i> N/A; the SpO2 of some patients does not respond at all to PEEP changes. In this case, Oxygen is also changed if control is set to Automatic.</p>                                                                                                                                          |
| Command overshoot                                         | <p><i>Oxygen:</i> none</p> <p><i>PEEP:</i> N/A; the SpO2 of some patients does not respond at all to PEEP changes.</p> <p><i>Upper PEEP limit:</i> 24 cmH2O</p> <p>The user can set a lower limit.</p>                                                                                                                               |
| Steady state deviation                                    | <p><i>Oxygen:</i> N/A; only the target range for SpO2 is specified</p> <p><i>PEEP:</i> N/A; only the target range for SpO2 is specified</p>                                                                                                                                                                                          |

| Parameter                                                  | Specification                                                                                                                                                                               |
|------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking error                                             | <i>Oxygen:</i> N/A<br><i>PEEP:</i> N/A; only the target range for SpO2 is specified                                                                                                         |
| Maximum change                                             | <i>Oxygen:</i><br><i>Decrease:</i> 5% of current Oxygen setting every 60 seconds<br><i>Increase:</i> 10% of current Oxygen setting every 30 seconds<br><i>PEEP:</i> 1 cmH2O every 6 minutes |
| <b>Lung-protective ventilation, Ventilation controller</b> |                                                                                                                                                                                             |
| Minimum %MinVol                                            | 70% (100% if no PetCO2 is available)                                                                                                                                                        |
| Maximum %MinVol                                            | 200%                                                                                                                                                                                        |
| <b>Lung-protective ventilation, Oxygenation controller</b> |                                                                                                                                                                                             |
| Minimum Oxygen (%)                                         | 21% or 30%, depending on what is selected in the Oxygen limit control in the INTELLiVENT-ASV Settings > More window.<br><i>Default:</i> 21%                                                 |
| Maximum Oxygen (%)                                         | 100%                                                                                                                                                                                        |
| PEEP limits (cmH2O)                                        | <i>Low:</i> 5 to 22 (Default: 5)<br><i>High:</i> 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's processor.

Table 3-2. Data log inputs

| Saved parameters       | Unit            |
|------------------------|-----------------|
| Date                   | N/A             |
| Time                   | N/A             |
| ARDS                   | N/A             |
| Chronic hypercapnia    | N/A             |
| Brain injury           | N/A             |
| Quick Wean             | N/A             |
| Controller ventilation | N/A             |
| Controller oxygenation | N/A             |
| Controller PEEP        | N/A             |
| fSpont                 | N/A             |
| PEEP limit             | cmH2O           |
| %MinVol                | %               |
| ExpMinVol              | l/min           |
| RRIMV                  | breaths per min |
| RRtot                  | breaths per min |
| RRtarget               | breaths per min |

| Saved parameters | Unit                   |
|------------------|------------------------|
| fSpont           | breaths per min        |
| Ti               | s                      |
| ΔPinsp           | cmH2O                  |
| 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-by-breath, but at most once per second.

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

### 3.4 Symbols

| Symbol                                                                             | Definition                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Catalog number                                                                                                                                                                                                                                                       |
|   | Medical Device                                                                                                                                                                                                                                                       |
|   | Manufacturer                                                                                                                                                                                                                                                         |
|   | Follow the Instructions for use.<br>To download the latest version of this manual or other documents, visit the Hamilton Medical Resource Center:<br><a href="https://www.hamilton-medical.com/Resource-center">https://www.hamilton-medical.com/Resource-center</a> |
|   | CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Medical Device Regulation (EU) 2017/745 concerning medical devices                                                                                                |
|   | Authorized representative in the European Community/ European Union                                                                                                                                                                                                  |
|  | Unique device identification - device identifier<br>HAMILTON-C6 INTELLiVENT-ASV: 07630002814973                                                                                                                                                                      |

### 3.5 References

References are available on the Hamilton Medical website, [www.hamilton-medical.com](http://www.hamilton-medical.com).

#### Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance for INTELLiVENT-ASV will be made available on the Eudamed public website, where it is linked to the Basic UDI-DI (76300028PN1607583T): <https://ec.europa.eu/tools/eudamed>

On the ventilator, the UDI-DI is shown in the  > Info > Info 3 window.



**%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 CO<sub>2</sub> 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 CO<sub>2</sub> values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both

**CO<sub>2</sub> elimination horizon**

For a passive patient, shows a zoom into the CO<sub>2</sub> elimination map at the current PetCO<sub>2</sub> value and target range. For an active patient, shows the spontaneous breathing rate (fSpont). Displayed during active ventilation in INTELLiVENT-ASV. Also called the Ventilation horizon.

**CO<sub>2</sub> elimination map**

Shows the current patient PetCO<sub>2</sub> value and target range in relation to Ppeak, together with the set limits. Displayed during active ventilation in INTELLiVENT-ASV. Also called the Ventilation map.

**fSpont**

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

**Max. duration**

Defines the length of time the SBT can run. If the patient conditions continue to stay within defined thresholds, the SBT ends after the time specified by this parameter. Only applies during an SBT.

**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 SpO<sub>2</sub> value and target range. Displayed during active ventilation in INTELLiVENT-ASV

### **Oxygenation map**

The PEEP/SpO<sub>2</sub> view shows the current patient SpO<sub>2</sub> value and target range in relation to PEEP, together with the set limits. The FiO<sub>2</sub>/PEEP map shows the patient's current combination of Oxygen/PEEP values.

### **PaCO<sub>2</sub>-PetCO<sub>2</sub> gradient**

The difference between the PaCO<sub>2</sub> measured in the blood (using blood gas analysis) and the PetCO<sub>2</sub> measured using a noninvasive CO<sub>2</sub> sensor. Under normal conditions, PaCO<sub>2</sub> is approximately 2-5 mmHg higher than PetCO<sub>2</sub>.

### **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.

### **PBW**

Predicted body weight, used for pediatric patients. The commonly accepted calculation is to use the median (50th percentile) of population-based body height and weight data according to age, without consideration of gender (no significant differences); used as the basis for initial settings of various parameters.

### **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.

### **PetCO<sub>2</sub>**

Measured end-tidal CO<sub>2</sub> partial pressure.

### **PetCO<sub>2</sub> inc**

The absolute increase in PetCO<sub>2</sub> (relative to an average calculated prior to the start of the SBT) that is permitted during an SBT. The PetCO<sub>2</sub> inc value is monitored and used as a criterion to determine whether to stop the SBT.

### **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.

**Rate inc**

Percentage increase in respiratory rate as a result of an SBT. Only applies during an SBT, when the Rate inc value is monitored and used as a criterion to determine whether to stop the SBT.

**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 PetCO<sub>2</sub> parameter is used.

**SBT (spontaneous breathing trial)**

Diagnostic test to help determine whether patients are ready to be removed from ventilator support and can breathe on their own.

**SBT time range**

Defines the hours between which an SBT can be started. Even if the To start SBT criteria are met, the SBT will not take place until the current time of day is inside the specified range, if criteria are still met. If an SBT is in progress when the time is out of range, the SBT continues until it is completed.

**SpO<sub>2</sub>**

Measurement of oxygen saturation in the blood.

**Time before starting SBT**

Defines the length of time that patient conditions must stay within the To start SBT limits before an SBT can start. Only applies when automatic SBTs are enabled.

**Time between 2 SBTs**

Defines the minimum length of time that must pass between two SBTs. Only applies when automatic SBTs are enabled.

**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.

**Vt/kg**

Tidal volume is calculated according to predicted body weight (PBW) for adult/pediatric patients and according to the actual body weight for neonatal patients.

 **$\Delta$ Psupport max**

The maximum pressure support allowed for an SBT. If this value is exceeded, the SBT is aborted.

 **$\Delta$ Psupport min**

The minimum pressure support that will be applied during an SBT. Shown as the lower  $\Delta$ Psup limit in the Quick Wean & SBT Status panel.



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