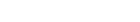


### **INTELLIVENT-ASV**

## Operator's Manual HAMILTON-C6



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# Operator's Manual INTELLIVENT-ASV

2022-06-15

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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
- Pulse oximetry Instructions for use for your ventilator

### Conventions used in this guide

In this manual:

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

- A green check mark or button
   xxx indicates a selected item or feature.
- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
  - 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.
  - These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- PI and PVI<sup>1</sup> are only available with a Masimo SET<sup>§</sup> pulse oximeter.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

<sup>&</sup>lt;sup>1</sup> Available as an option.

Safety messages are displayed as follows:



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!

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

• An *active* patient is one who is making inspiratory efforts.

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

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

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

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

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

# INTELLIVENT-ASV

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### 1.1 Overview

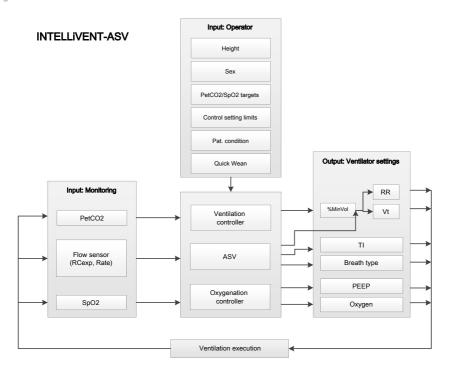
INTELLIVENT®-ASV® is an advanced ventilation mode, based on the proven Adaptive Support Ventilation (ASV) mode, to automatically regulate CO2 elimination and oxygenation for both *passive* and *active* patients, using both physiologic data from the patient and clinician-set targets and limits.

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

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

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

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

### 1.2 Indications and contraindications for use

#### Indications for use

### NOTICE

- Use INTELLIVENT-ASV for adult and pediatric patients only.
- Use INTELLIVENT-ASV for intubated patients only.
- Be sure you are familiar with the use of the CO2 and SpO2 sensors. See your ventilator Operator's Manual, the Pulse Oximetry Instructions for Use, and documentation provided with the sensors.

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

#### Contraindications for use

### **MARNING**

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

### **CAUTION**

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

#### Do NOT use INTELLIVENT-ASV if:

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

### 1.3 Preparing for ventilation with INTELLiVENT-ASV

### **MARNING**

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

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

- 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.

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

То	See
Set up and enable the CO2 and SpO2	• Ventilator Opera- tor's Manual
sensors	<ul> <li>Pulse oximetry documentation</li> </ul>
	• CO2 documenta- tion
Prepare the ventilator for operation, includ-	• Ventilator Opera- tor's Manual
ing performing the preoperational check	<ul> <li>Preoperational Check Quick Reference</li> </ul>

То	See
Set up and connect the patient	Ventilator <i>Operator's</i> <i>Manual</i>
Specify and confirm INTELLIVENT-ASV settings	Section 1.4
Start ventilation and monitor the patient	Ventilator <i>Operator</i> 's <i>Manual</i>

### 1.4 Specifying INTELLiVENT-ASV settings

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

The INTELLIVENT-ASV Settings window allows you to:

- Set the control management strategy (Automatic or Manual)
- If applicable, select one or more conditions that apply to the patient (for example, ARDS)
- Review SpO2 and PetCO2 target ranges, and adjust if needed
- Enable or disable Quick Wean and SBTs
- Set Oxygen and PEEP limits for the Oxygenation controller (if set to Automatic)
- Enable auto-recruitment<sup>3</sup>
- Fine-tune %MinVol, PEEP, and Oxygen settings

<sup>3</sup> Not available in all markets.

#### **Navigating the INTELLIVENT-ASV Settings** window

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

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

#### **Specifying INTELLIVENT-ASV settings**

Specifying settings comprises the following steps.

Table 1-2. Specifying INTELLIVENT-ASV settings

See
Section 1.4.1
Section 1.4.2
Section 1.4.3
Section 1.4.4
Section 1.4.5
Section 1.4.6
Section 1.4.7
Section 1.4.8
Section 1.4.9
Section 1.4.10
Section 1.4.11

<sup>4</sup> Not available in all markets.

### 1.4.1 Specifying patient data

#### NOTICE

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

### To specify patient data

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

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

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

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

### 1.4.1.1 Notes about exiting Standby

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

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

### 1.4.2 Selecting the INTELLiVENT-ASV mode

INTELLIVENT-ASV is an option in the ventilator Modes window.

#### To select the INTELLiVENT-ASV mode

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

The INTELLIVENT-ASV Settings window (Figure 1-2) opens, displaying the **Auto** tab.

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

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

#### NOTICE

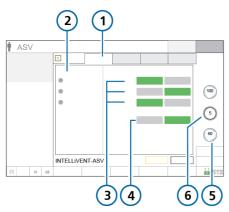
- Only Manual mode is available for all controls when the patient IBW is below 7 kg. (INTELLIVENT-ASV is designed for use *only* with adult and pediatric patients with an IBW of 7 kg or more.)
- Only Manual mode is available for %MinVol when the CO2 sensor hardware option is deactivated in Configuration.<sup>5</sup>
- Only Manual mode is available for PEEP when:
  - Either the Chronic Hypercapnia or Brain Injury condition is selected.
  - The SpO2 sensor hardware option is deactivated in Configuration.<sup>5</sup>
  - However, if Chronic Hypercapnia and ARDS are both selected, PEEP management can be set to Automatic.
- Only Manual mode is available for Oxygen when the SpO2 sensor hardware option is deactivated in Configuration 5

### Use the INTELLIVENT-ASV Settings > Auto window to:

- Specify whether adjustments of one or more of the following controls should be performed automatically by the device or manually by the clinician: %MinVol, PEEP, and Oxygen
   Sections 1.7 and 1.8 in this guide provide detailed information about how INTELLIVENT-ASV regulates these controls automatically.
- Select one or more conditions (ARDS, Chronic Hypercapnia, or Brain injury), if appropriate.
- Enable or disable Quick Wean

<sup>&</sup>lt;sup>5</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 System > Sensors window. If a sensor is not connected, a medium-priority sensor-related alarm is generated.

Figure 1-2. INTELLiVENT-ASV Settings window, Auto tab



- 1 Auto
- 4 Quick Wean settings: Automatic. Disabled
- 2 Specific condition options
- 5 Automated management indicator, parameter value
- 3 Controller settings: Automatic, Manual buttons for %MinVol, PEEP, Oxygen
- 6 Manual management indicator, parameter value

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

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.11).
- 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** <sup>6</sup> to have **INTELLi-VENT-ASV** automatically regulate the control setting to keep the patient within the target range.
  - If needed, touch **Manual** to manually adjust the control setting as appropriate. The ventilator does **not** make any adjustments to control settings in response to changes in the patient condition; settings are changed by the ventilator operator.
  - In all cases, the selected button turns green.
- Select a specific condition (such as ARDS), if needed. See Section 1.4.4.
   Otherwise, continue to step 4.
- Enable (or disable) Quick Wean, if desired. See Section 1.4.5.
   Otherwise, continue to step 5.
- Review the control settings on the right (%MinVol, PEEP/CPAP, Oxygen) and, if desired, make any adjustments.
- If displayed, touch **Continue** to accept the settings and proceed to the next step.

<sup>&</sup>lt;sup>6</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 System > Sensors window.

<sup>&</sup>lt;sup>6</sup> If a sensor is *not* connected, a medium-priority sensor-related alarm is generated.

### 1.4.4 Adjusting for specific conditions

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

Selecting a condition may affect ventilation and oxygenation control setting startup values and PetCO2 and SpO2 target ranges, as well as the upper and lower target shift limits. For details on the use of specific conditions, see Section 1.4.12.1.

When selecting a condition, control settings are automatically updated in realtime. 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 CO2 elimination and Oxygenation maps.

Figure 1-3. Specific conditions



### To select a specific condition

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.11).
- 2. Before proceeding, be sure to read the safety information related to selecting specific conditions, in Section 1.4.12.1.
- 3. Only if the patient has any special conditions, select one or more of the following entries: ARDS, Chronic Hypercapnia, or Brain injury. See Figure 1-3. Selecting a condition may change the startup settings and targets for CO2 elimination and/or oxygenation, and can affect whether regulation of PEEP can be set to Automatic. It may also affect whether Quick Wean can be enabled. See Table 1-5 in Section. 1 4 12 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.

### 1.4.5 Enabling or 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 1-4. INTELLIVENT-ASV Settings > Auto window, Quick Wean



#### To enable or disable Quick Wean

- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 2.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.11).
- 2. To enable Quick Wean, touch Automatic

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

The **Quick Wean** tab is now enabled. To disable **Quick Wean**, touch **Disabled**. The button turns green. The **Quick Wean** tab is disabled.

If displayed, touch Continue to accept the settings and proceed to the next step.

### 1.4.6 Enabling/disabling automated SBTs

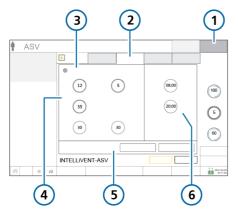
Use the INTELLIVENT-ASV Settings > Quick Wean window to enable/disable automated spontaneous breathing trials (SBT) and specify SBT settings, when needed.

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

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

For details about working with SBTs, see Section 2.3.

Figure 1-5. INTELLIVENT-ASV Settings window, Ouick Wean tab



- 1 Modes
- 4 SBT controls
- 2 Quick Wean
- 5 Manually start/ stop SBT
- 3 Automatic SBT checkbox
- 5 SBT time range settings

#### To enable/disable automated SBTs

To enable SBTs, Quick Wean must be set to Automatic in the INTELLIVENT-ASV Settings > Auto window.

- If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 3.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.11).
- 2. To display SBT options, touch the **Quick Wean** tab (Figure 1-5).
- 3. To enable automated SBTs, select the Automatic SBT checkbox.<sup>7</sup>

The checkbox turns green.

To disable automated SBTs, ensure the Automatic SBT checkbox is gray.

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

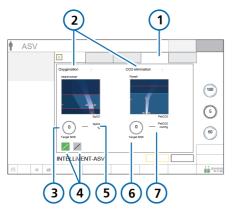
<sup>&</sup>lt;sup>7</sup> If the checkbox cannot be selected, Quick Wean is set to Disabled. Open the INTELLIVENT-ASV Settings > Auto window, and set Quick Wean to Automatic.

### 1.4.7 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 1-6. INTELLIVENT-ASV Settings window, Target tab



- 1 Target
- 5 Current SpO2 value, quality index
- 2 Oxygenation and CO2 elimination maps
- 6 Target Shift control (PetCO2)
- 3 Target Shift control (SpO2)
- 7 Current PetCO2 value, quality index
- 4 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 1.4.11).
- To display the SpO2 and PetCO2 target ranges, touch the Target tab (Figure 1-6).
- 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.

- If needed, make adjustments using the appropriate Target Shift control, as described next.
- 5. When finished, if displayed, touch **Continue** to accept the settings, and proceed to the next step.

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#### To adjust the SpO2 target range

For details on target shift limits associated with specific conditions, see Tables 1-8 and 1-7 in Section 1 4 12 3

- 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 1-7.
- 2 Turn the P&T knob clockwise or counterclockwise to move the target range as described next, then press the P&T knob to accept the setting. The control turns gray again.
  - Setting the value to a positive number moves the target range to the right, targeting a higher SpO2.
  - Setting the value to a negative number moves the target range to the left, targeting a lower SpO2.

Figure 1-7. Target shift active: SpO2



#### To adjust the PetCO2 target range

- 1. Under the CO2 elimination map, touch Target Shift next to the PetCO2 value. The button turns orange, and the limits appear on either side of the control. See Figure 1-8.
- 2. Turn the P&T knob clockwise or counterclockwise to move the target range as described below, then press the P&T knob to accept the setting. The control turns gray again.
  - Setting the value to a positive number moves the target range to the right, targeting a higher PetCO2.
  - Setting the value to a negative number moves the target range to the left, targeting a lower PetCO2.
- 3. To shift the PetCO2 target range to a value beyond ±5 mmHg:
  - a. Set the value now to +5 or -5, as needed, and press the P&T knob to accept the value.
  - b. Touch the **Target Shift** control again and set the value beyond ±5, as needed, and press the P&T knob to accept the value.

Figure 1-8. Target shift active: PetCO2



### 1.4.8 Specifying additional settings

The INTELLiVENT-ASV Settings > More window<sup>8</sup> provides access to additional INTELLi-VENT-ASV options:

- Set the minimum Oxygen level (between 21% and 30%)
- Set an upper and/or lower PEEP limit
- Enable/disable auto-recruitment<sup>9</sup>

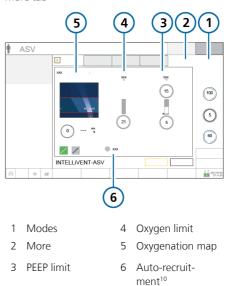
The Oxygenation map is also displayed in the window.

Table 1-3. More window settings

Setting	Description
Oxygen limit	When the Oxygen control is set to Automatic, you can set an absolute lower limit that the Oxygen controller cannot fall below.  The limit can be set between 21% (the default) and 30%.  See Section 1.4.12.4.
PEEP limit	When the PEEP control is set to Automatic, you can set an absolute upper limit that the PEEP controller cannot exceed, as well as an absolute lower limit that it cannot fall below. The minimum difference allowed between the low and high limit is 2 cmH2O.  See Section 1.4.12.5.

Setting	Description
Auto- recruit- ment <sup>10</sup>	When the PEEP control is set to Automatic, you can enable automatic recruitment.
	To enable auto-recruitment, touch the checkbox to select it.
	When auto-recruitment is enabled, the text auto-recruitment is displayed on the Oxygenation map and horizon (views 1 and 2).
	By default, auto-recruitment is disabled. See Section 1.4.12.2.

Figure 1-9. INTELLIVENT-ASV Settings window, More tab



 $<sup>^{8}</sup>$  When PEEP and Oxygen are both set to Manual, the More tab is grayed out and unavailable.

<sup>9</sup> Not available in all markets.

<sup>&</sup>lt;sup>10</sup> Not available in all markets.

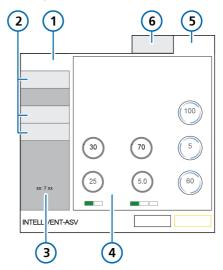
### To set minimum oxygen limit, PEEP limit, and auto-recruitment options

- ✓ If you just selected the INTELLIVENT-ASV mode and are going through the initial setup process, start with step 3.
- 1. Open the INTELLIVENT-ASV Settings window (Section 1.4.11).
- 2. Touch the **More** tab (Figure 1-9).
- 3. Set options, described in Table 1-3, if needed
- 4. If displayed, touch **Confirm** to accept the settings and proceed to the next step, reviewing and adjusting control settings.

### 1.4.9 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 1-10. INTELLIVENT-ASV Controls window, Basic tab



- 1 Basic
- Control settings
- 2 More, TRC, Patient tabs
- 5 Modes
- 3 Current minute volume
- 6 Target

#### 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.
- 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 as 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 **IBW** is calculated.
  - You can also access the Patient window by touching the Patient icon at the top left of the display.
- If displayed, touch Confirm to accept the settings and proceed to the next step, reviewing and adjusting alarm limits.

### 1.4.10 Adjusting alarm limits

### ♠ WARNING

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

### NOTICE

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

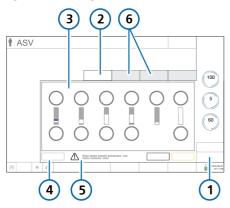
For details, see the chapter, *Responding* to alarms, in your ventilator *Operator's* Manual.

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

For additional information:

- For details about Oxygen level notification, see Section 1.4.12.6.
- For troubleshooting, see Section 1.6.
- For detailed information about alarms, including default settings and ranges, see your ventilator Operator's Manual and the Pulse Oximetry Instructions for Use.

Figure 1-11. Setting alarm limits



- 1 Alarms
- 4 Auto
- 2 Limits 1
- 5 Safety notice
- 3 Alarm limit controls
- 6 Limits 2, Limits 3<sup>11</sup>

### To adjust INTELLiVENT-ASV alarm limits

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

The contents of the **Limits 1** tab are displayed by default.

- 2. Adjust any limits as needed.
- Touch the Limits 2 and Limits 3 (if displayed) tabs to review and adjust additional alarm limits.

- 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.

### 1.4.11 Adjusting settings during active ventilation

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

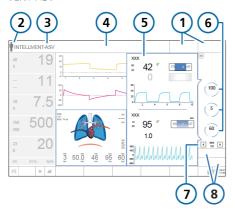
You can also review patient information in multiple scrollable views. For details, see Section 1.5.1.

During active ventilation, all of the tabs in the INTELLIVENT-ASV Settings window are available and function the same way as during initial setup, except that there are no Cancel/Back, Continue/Confirm buttons. Changes are applied at the end of the current breath cycle.

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

<sup>11</sup> When Masimo rainbow SET SpO2 parameters are enabled, additional alarm limit settings are available in the Limits 3 window.

Figure 1-12. Active ventilation with INTELLi-VENT-ASV



- 1 Target, Modes
- 2 Touch patient icon to open the Patient window
- 6 Controls managed by INTELLi-VENT-ASV shown with rotating blue comets

5 Selected INTELLi-

VFNT-ASV view

- 3 Touch mode name to open the INTELLIVENT-ASV Settings window
- 7 View number and navigation arrows
- 4 Alarm message
- 8 Alarms, Controls

### To display the INTELLiVENT-ASV Settings window

- At any time during ventilation with INTELLIVENT-ASV, do any of the following:
  - Touch the INTELLIVENT-ASV mode name at the top left of the display.
  - Touch an automated controller on the right of the display, if available.
  - 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.
- 4. To review or change alarm settings, touch **Alarms** and make changes, as needed

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### 1.4.12 About INTELLIVENT-ASV settings

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

Settings	See
Specific conditions	Section 1.4.12.1
Auto-recruitment maneuvers <sup>12</sup>	Section 1.4.12.2
Target shift	Section 1.4.12.3
Oxygen limit	Section 1.4.12.4
PEEP limit	Section 1.4.12.5
Oxygen level notification (Oxygen msg %)	Section 1.4.12.6

### 1.4.12.1 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 CO2 levels and high cranial pressure might result. Carefully monitor intracranial pressure when available.

### NOTICE

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

<sup>12</sup> Not available in all markets.

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
- SpO2 and PetCO2 target ranges, and upper and lower target shift limits
- %MinVol for active patients based on fSpont, or, based on PetCO2 for passive patients when the Brain injury condition is selected
- Whether or not Quick Wean can be activated

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

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

Table 1-4. 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	Passive patients with brain injuries for whom it is critical to maintain CO2 under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range. The Brain injury condition is only to be used for passive patients. When selected, Quick Wean remains disabled.
Chronic Hypercapnia	For patients with chronically high arterial CO2 values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both.
Mixed (ARDS and Chronic Hypercapnia)	For patients with both listed conditions. In this case, select both entries.

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

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

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 them at any time, as appropriate.

You can change these values at any time.

For details about changing the SpO2 or PetCO2 target ranges, see Section 1.4.12.3.

In all cases, Quick Wean, auto-recruitment, and PEEP limitation by HLI are disabled at startup.

When PEEP must be manually set, PEEP limitation by HLI is inactive.

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

	Ventilation		Oxygenation	
Condition	%MinVol (%)	Plimit (cmH2O) <sup>13</sup>	Oxygen (%)	PEEP (cmH2O) <sup>14</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>15</sup>	100	30	60	Manual

<sup>&</sup>lt;sup>13</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>&</sup>lt;sup>14</sup> The control of settings not explicitly marked as Manual can be set to Automatic.

<sup>&</sup>lt;sup>15</sup> Any combination of conditions that includes Brain injury uses the Brain injury settings for Plimit.

Condition	Plimit (cmH2 O)	ExpMinVol High/Low (I/min)	Rate (1/min)	Vt High/ Low (ml/kg)	PetCO2 High/ Low (mmHg)	SpO2 Low (%)
Normal	40	25/4	35	10/4	50/30	90
ARDS	45	25/4	35	10/4	50/30	90
Chronic Hypercapnia	45	25/4	35	12/4	60/25	88
ARDS + Chronic Hypercapnia	45	25/4	35	10/4	60/25	88
Brain Injury	40	25/4	35	10/4	40/30	92

Table 1-6. Specific conditions and associated startup alarm limits

### 1.4.12.2 Automatic recruitment maneuvers

### **↑** CAUTION

Check for pneumothorax and potential susceptibility to pneumothorax before ventilating the patient. Automatic PEEP adjustment during recruitment maneuvers can lead to an increase in ventilation pressure levels.

Automatic recruitment is a strategy for reexpanding collapsed lung tissue, and then maintaining higher PEEP to prevent subsequent "de-recruitment". <sup>16</sup> To recruit collapsed lung tissue, sufficient pressure must be imposed to exceed the critical opening pressure of the affected lung.

Automatic recruitment in INTELLIVENT-ASV, called *auto-recruitment*, is an optional function designed to reopen collapsed lung units in severely hypoxemic patients, such as those with ARDS.

The ventilator automatically performs a recruitment maneuver when a second consecutive PEEP increase is required and the following conditions are met:

- PEEP controller is set to Automatic
- Auto-recruitment is enabled.
- The patient is *not* breathing spontaneously; that is, the patient is passive
- Monitored SpO2 is below the target range (that is, the patient is hypoxemic)
- The ventilator has made two consecutive PEEP increases, according to the automated PEEP regulation rules
- The set maximum PEEP has not been reached

<sup>16</sup> Automatic recruitment is not available in all markets.

When these conditions are met, the ventilator performs a recruitment maneuver. PEEP is increased to 40 cmH2O and held for 20 seconds; PEEP is then decreased to the appropriate setting according to the automated PEEP regulation rules.

Auto-recruitment maneuvers occur after two consecutive automatic increases of PEEP of 1 cmH2O. This means the recruitment maneuver cycle occurs no more often than once every 12 minutes. As soon as a recruitment maneuver is performed, the device generates a Recruitment maneuver in progress message.

Note that use of the P/V Tool also counts as a recruitment maneuver.

By default, auto-recruitment is disabled, and must be manually enabled for use. Before enabling auto-recruitment, check the patient's recruitability.

#### To enable or disable auto-recruitment

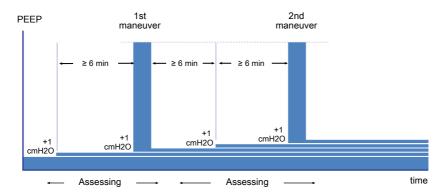
 In the INTELLIVENT-ASV Settings > More window, touch the Auto-recruitment checkbox, if displayed. See Figure 1-9.

When auto-recruitment is enabled, the text **Auto-recruitment** is displayed on the **Oxygenation** maps and horizon.

#### Important:

- After the recruitment maneuver, be sure to check the PEEP setting to ensure it is sufficient to maintain adequate recruitment during ventilation.
- During the recruitment maneuver, all patient alarms are suppressed.
- The maneuver is canceled if a flow sensor failure or any pneumatic disconnection is detected.
- No recruitment maneuver takes place if any of the following occurs:
  - PEEP is manually changed
  - The patient is active





### 1.4.12.3 Adjusting the SpO2/PetCO2 target range (Target Shift)

### **↑** CAUTION

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

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

These target ranges are shown in the Oxygenation and CO2 elimination maps and horizons. INTELLIVENT-ASV adjusts the associated controls to bring the patient to the middle of the set range.

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

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

The **Target Shift** control allows you to move the **SpO2** and **PetCO2** target ranges to the left (lower values) or to the right (higher values), within the limits defined in Tables 1-8 and 1-7.

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

### Considerations for evaluating the PetCO2 target range

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

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

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

Check whether one of the specific conditions 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

- Measure the difference between current PaCO2 and the desired PaCO2.
- Adjust the PetCO2 target range by the same value as the difference between the current and the desired PaCO2.
- If the desired PaCO2 in 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>17</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 217

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 1-7. PetCO2 target shift limits

PetCO2 target shift limits	
All conditions	-20 mmHg to 20 mmHg <sup>18</sup>

Table 1-8. SpO2 target shift limits

SpO2 target shift limits <sup>19</sup>	
Normal (no condition selected)	-5% to +4%
ARDS	-5% to +4% <sup>20</sup>
Chronic Hypercapnia	-2% to +5%
Mixed (Chronic Hyper- capnia + ARDS)	-2% to +5%
Brain Injury	-5% to +2% <sup>21</sup>

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

<sup>&</sup>lt;sup>17</sup> The example situations and values provided here are for illustration purposes only; they are *not* intended to be used as clinical recommendations or quidelines.

<sup>&</sup>lt;sup>18</sup> In some markets, the upper target shift limit is 10 mmHg.

<sup>&</sup>lt;sup>19</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>&</sup>lt;sup>20</sup> In some markets, the lower target shift limit is -2% when the ARDS condition is selected.

<sup>&</sup>lt;sup>21</sup> In some markets, the lower target shift limit is -2% when the Brain Injury condition is selected.

Table 1-9. Target shift display

Target Shift control	Text color and description
0	Black text.  Target shift is 0; there is no change to the target range values.
2	Yellow text.  Target shift is between ±1 and ±5.
7	Orange text.  Target shift is greater than ±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 1.4.7.

### 1.4.12.3.1 About the Target Shift display on the horizons

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

Table 1-10. Target Shift setting in Oxygenation and CO2 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.  Target Shift: 0  93 • • • 97
Target Shift: n > indicates the range is shifted to the right.	In this example, the setting is +2.  Target Shift: 2 > 95  99
Target Shift: < n indicates the range is shifted to the left.	In this example, the setting is -2.  Target Shift: < 2

### 1.4.12.4 Minimum Oxygen limit

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

### To set the minimum Oxygen limit

In the INTELLIVENT-ASV Settings > More window, set the limit to any value between 21% and 30%. The default setting is 21%.

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#### 1 4 12 5 PFFP limit

When the PEEP controller is set to Automatic, the PEEP limit control allows you to define an absolute high limit that the PEEP controller cannot exceed. If enabled, you can also specify an absolute low limit for PEEP; the PEEP controller cannot fall below this limit, listed in Table 1-11.

Note that the minimum difference between the low and high limit is 2 cmH20

Table 1-11. PEEP limit settings

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

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

#### To set PEEP limits

In the INTELLIVENT-ASV Settings > More window, set the desired high and/or low PEEP limits. See Figure 1-9.

#### 1.4.12.6 Oxygen level notification

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

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

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

For alarm details, see Section 1.4.10.

## 1.5 Monitoring INTELLiVENT-ASV

## **↑** CAUTION

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

#### **NOTICE**

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

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

Data is shown on the main display in the Monitoring window, in the various graphic panels, as MMPs/SMPs, and in the INTELLi-VENT-ASV windows, called views.

These views present the following information:

- CO2 elimination and Oxygenation horizons
- Capnogram and plethysmogram
- Intelligent panels (Dynamic Lung, Vent Status, QuickWean (when enabled), and ASV Graph)
- Waveforms
- Trends

Trend graphs for PetCO2- and SpO2- related parameters, as well as for the CO2 elimination and Oxygenation controller settings, are also available. For details, see Section 1.5.7.1.

The following sections provide details about the views.

# 1.5.1 About the INTELLiVENT-ASV windows and views

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

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

#### To display view windows

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

The view number is displayed between the buttons.



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

Table 1-12. INTELLIVENT-ASV views, overview

View Description  CO2 elimination map Shows the current patient PetCO2 value at target range in relation to Ppeak, together the set limits.  The map is shown:  In the INTELLIVENT-ASV Settings > Target window  During active ventilation in view 2  CO2 elimination horizon For a passive patient, shows a zoom into map at the current PetCO2 value and target range in relation to Ppeak, together the set limits.  The map is shown:  In the INTELLIVENT-ASV Settings > Target window  To a passive patient, shows a zoom into map at the current PetCO2 value and target range in relation to Ppeak, together the set limits.	For details about the rules used to regulate CO2 elimination, see Section 1.7.  the Section 1.5.3
target range in relation to Ppeak, together the set limits.  The map is shown:  In the INTELLIVENT-ASV Settings > Target window  During active ventilation in view 2  CO2 elimination  For a passive patient, shows a zoom into	For details about the rules used to regulate CO2 elimination, see Section 1.7.  the Section 1.5.3
CO2 elimination For a <i>passive</i> patient, shows a zoom into	
range.	gei
For an <i>active</i> patient, shows the spontan breathing rate (fSpont).	eous
The horizon is shown during active ventil in view 1.	lation
Oxygenation maps  Two maps are available:	Section 1.5.4
<ul> <li>The PEEP/SpO2 view shows the curren patient SpO2 value and the target ranger relation to PEEP, together with the set</li> <li>The FiO2/PEEP view shows the patient current combination of Oxygen/PEEP v together with the set limits.</li> </ul>	ge in rules used to regulate limits. oxygenation, see Section 1.8.
The selected map is shown:	
<ul> <li>In the INTELLIVENT-ASV Settings &gt; Target window</li> </ul>	et
<ul> <li>During active ventilation in view 2</li> </ul>	
Oxygenation horizon Shows a zoom into the map at the curre SpO2 value and target range.	nt Section 1.5.5
The horizon is shown during active ventil in view 1.	lation
Plethysmogram Provides a real-time waveform that repretente the pulsating blood volume.	sents Section 1.5.6
A plethysmogram is shown:	
<ul> <li>During active ventilation in views 1 and</li> </ul>	d 3
<ul> <li>As a waveform on the main display, if selected</li> </ul>	

View	Description	See	
Capnogram	Provides a real-time CO2 waveform.	Section 1.5.6	
	A capnogram is shown:		
	• During active ventilation in views 1 and 3		
	<ul> <li>As a waveform on the main display, if selected</li> </ul>		
Quick Wean related			
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	

#### 1.5.2 About the CO2 elimination map

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

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

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

# 1.5.2.1 Reviewing the CO2 elimination map

#### NOTICE

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

The CO2 elimination map is available in two locations:

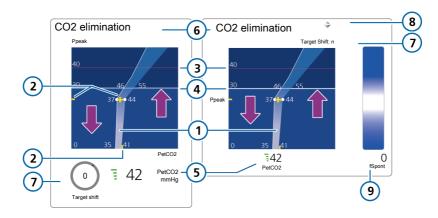
- INTELLIVENT-ASV Settings > Target window
- During active ventilation with INTELLi-VENT-ASV, in view 2

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

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

Figure 1-14. CO2 elimination map, INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)



- 1 Target zone
- 2 Patient symbol, patient values
- 3 High Pressure alarm limit
- Pressure limitation: Plimit
- 5 Current PetCO2 value, quality index

- 6 Map title
- 7 Target Shift control and setting
- 8 When %MinVol is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, %MinVol is in target zone.
- 9 For *active* patient: target range and current **fSpont** value

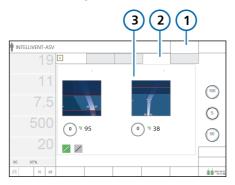
# To display the CO2 elimination map in the INTELLiVENT-ASV Settings window

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 1-15. CO2 elimination map, INTELLi-VENT-ASV Settings window



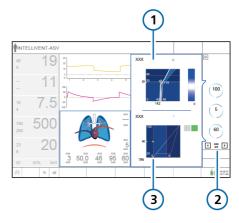
- 1 Target
- 3 CO2 elimination map
- 2 Target

# 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.

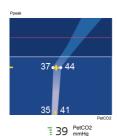
Figure 1-16. CO2 elimination map, in main display during active ventilation



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

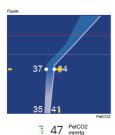
#### 1.5.2.2 About the PetCO2 target zone

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



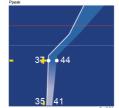
## Patient symbol within the PetCO2 target zone

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



#### Patient symbol above the PetCO2 target zone

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



#### Patient symbol below the PetCO2 target zone

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

# 1.5.3 About the CO2 elimination horizon

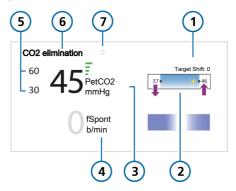
For a passive patient, the CO2 elimination horizon shows a simplified view of the same data as the CO2 elimination map, together with the upper and lower PetCO2 alarm limits

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

Notes for the following two figures:

- When %MinVol is increasing (^) or decreasing (v), the appropriate indicator is highlighted. When the arrows are the same size, %MinVol is in the target zone.
- The purple arrows are for clarification purposes only; they do not appear on the display.
  - Up arrow: Increase zone (PetCO2 too high, increase %MinVol)
  - Down arrow: Decrease zone (PetCO2 too low, decrease %MinVol)
- When the PetCO2 target range is changed (using the Target Shift control), the setting is shown above the horizon. For details, see Section 1.4.12.3.1.

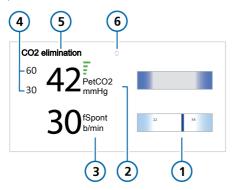
Figure 1-17. CO2 elimination horizon, passive patient



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

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

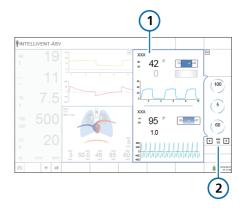
Figure 1-18. CO2 elimination horizon, active patient



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

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

Figure 1-19. CO2 elimination horizon, during active ventilation



- 1 CO2 elimination horizon
- View number and arrows

### 1.5.4 About the Oxygenation map

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

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

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

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

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

The FiO2/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.

#### 1.5.4.1 Reviewing the Oxygenation maps

The Oxygenation maps (PEEP/SpO2 and FiO2/PEEP) are available in two locations:

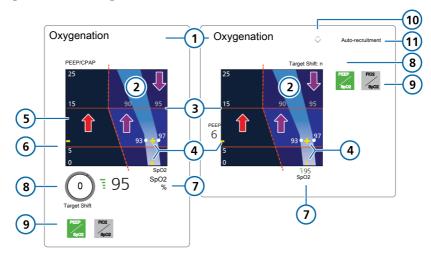
- INTELLIVENT-ASV Settings > Target window
- During active ventilation with INTELLi-VENT-ASV, on the main display in view

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

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

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Figure 1-20. Oxygenation map, PEEP/SpO2, in INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)

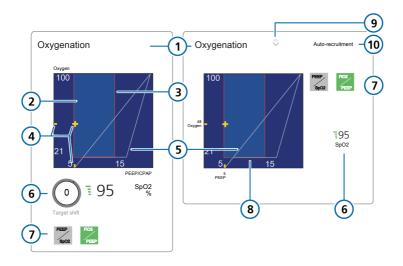


1 Map title 7 Current SpO2 value, quality index 2 8 Target Shift control and setting SpO2 target zone Oxygenation map selection buttons (PEEP/ 3 Upper PEEP limit 9 SpO2 selected) 4 Patient symbol, patient values When PEEP or Oxygen is increasing (^) or 10 decreasing (v), the appropriate indicator appears. When the arrows are the same size, SpO2 is in target zone. 5 Emergency zone 11 When auto-recruitment is enabled, text is displayed on the map<sup>22</sup>

Lower PEEP limit

<sup>22</sup> Not available in all markets.

Figure 1-21. Oxygenation map, FiO2/PEEP, in INTELLiVENT-ASV Settings window (left), main diplay during active ventilation (right)



- 1 Map title
- 2 Lower PEEP limit
- 3 Upper PEEP limit
- 4 Patient symbol, patient values
- 5 PEEP/Oxygen curve

- 6 Current SpO2 value, quality index
- 7 Oxygenation map selection buttons (FiO2/PEEP selected)
- 8 Lower Oxygen limit
- 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.
- 10 When auto-recruitment is enabled, text is displayed on the map<sup>23</sup>

<sup>&</sup>lt;sup>23</sup> Not available in all markets.

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

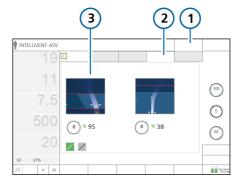
 To open the INTELLIVENT-ASV Settings > Target window, touch the Target button at the top right of the main display.

The Settings window opens, with the **Target** tab selected.

The panel shows the PEEP/SpO2 Oxygenation map, measured SpO2 value, and the Target Shift control.

2. To display the FiO2/PEEP map, touch the FiO2/PEEP button.

Figure 1-22. Oxygenation map, INTELLiVENT-ASV Settings window



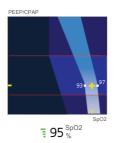
- 1 Target
- 3 Oxygenation map
- 2 Target

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

- 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 SpO2 value. See Figure 1-16.
- 2. To display the FiO2/PEEP map, touch the FiO2/PEEP button.
  - To display the PEEP/SpO2 map, touch the PEEP/SpO2 button.

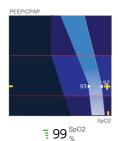
#### 1.5.4.2 About the SpO2 target zone

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



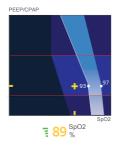
#### Patient symbol within the SpO2 target zone

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



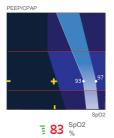
#### Patient symbol above the SpO2 target zone

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 mediumpriority alarm is generated; the SpO2 parameter is shown in the associated alarm color.



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

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

### 1.5.5 About the Oxygenation horizon

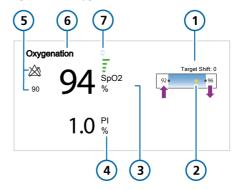
The Oxygenation horizon shows a simplified view of the same data as the SpO2/PEEP Oxygenation map, together with the upper and lower SpO2 alarm limits.

With a Masimo SET SpO2 sensor, the horizon also shows the measured perfusion index (PI).

Notes for the following figure:

- When PEEP or Oxygen is increasing (^) or decreasing (v), the appropriate indicator is highlighted (7 in the following figure). When the arrows are the same size, SpO2 is in the target zone.
- The purple arrows in the following figure are for clarification purposes only; they do not appear on the display.
  - *Up arrow:* Increase treatment zone
  - Down arrow: Decrease treatment zone
- When the SpO2 target range is changed (using the Target Shift control), the setting is shown above the horizon. For details, see Section 1.4.12.3.1.

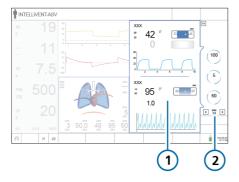
Figure 1-23. Oxygenation horizon



- 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 1-24. Oxygenation horizon during active ventilation



1 Oxygenation horizon

! View number and arrows

# 1.5.6 About the capnogram and plethysmogram

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

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

#### About the capnogram

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

#### To display the capnogram

 During active ventilation with INTELLi-VENT-ASV, touch the left or right view button until the capnogram is displayed

Figure 1-24 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 INTELLi-VENT-ASV, touch the left or right view button until the plethysmogram is displayed.

Figure 1-24 shows the plethysmogram in the bottom part of the display.

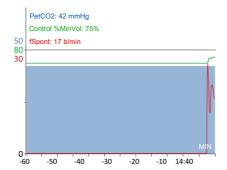
For details about selecting the plethysmogram as a waveform on the ventilator main display, see your ventilator Operator's Manual.

#### 1.5.7 About the Trend panel

#### 1.5.7.1 About trends

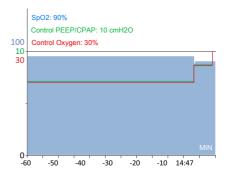
In addition to the trend data available for monitored parameters, you can also trend the actions of the Ventilation and Oxygenation controllers when using INTELLi-VENT-ASV. The same time periods are available as for other parameters, namely, 1-, 6-, 12-, 24-, or 72-h trends. Each parameter is represented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

#### Ventilation controller trend graph



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

#### Oxygenation controller trend graph



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

<sup>&</sup>lt;sup>24</sup> Note that the graphs provided here do not represent actual data, they just illustrate how the different parameters are represented.

## 1.5.8 INTELLiVENT-ASV symbols

Table 1-13. INTELLiVENT-ASV-related symbols and controls

Symbol/Control	Color	Description
View 1/3	White	View selection.  During active ventilation, several views are available; the view navigation arrows change the view between those described in Section 1.5.1.
+	Yellow	Patient symbol. Indicates the current condition of the patient in the graph.
777	Gray (4 bars), Orange (2 bars), Red (1 bar)	Quality index showing unreliable signal quality. Sensor values are not usable or sensor not enabled or connected. When this occurs, the related controller freezes and an alarm is generated indicating the automatic management is turned OFF.
33	Green (3 or 4 bars)	Quality index showing stable acceptable signal quality. The data from the sensor is highly stable and reliable.
45 PetCO2 mmHg	White	Measured PetCO2 sensor value and quality index.
Active patient  13 21  Passive patient  22 53	The inactive component is greyed out.	When the PetCO2 horizon (top) is greyed out, and the fSpont horizon is active, the patient is breathing spontaneously (active).  When the PetCO2 horizon is active, and the fSpont horizon is greyed out, the patient meets the passive criteria.
17 (Spont b/min	White	The fSpont measurement is displayed when spontaneous breathing is detected by the flow sensor and used as physiologic input.

Symbol/Control	Color	Description
89 spo2 %	Yellow	Low SpO2 value. SpO2 is below the set lower alarm limit. A medium-priority Low SpO2 alarm is active.  For details, see the <i>Pulse Oximetry Instructions for Use</i> .
83 spo2 %	Red	Critical SpO2 value. SpO2 is well below the set lower alarm limit. A high-priority Low SpO2 alarm is active.  For details, see the <i>Pulse Oximetry Instructions for Use</i> .
₹	Black or white	Dashes indicate that no sensor value can be detected.
<b>\$</b>	White	Increase arrow, next to the horizon name and to the left of the automated controllers. Indicates that treatment must be increased.
<b>\$</b>	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.
263	White	Time to increase. Counts down the time to the next increase of the control.
<u>4</u>	White	Time to decrease. Counts down the time to the next decrease of the control.
<b>-</b> 240	White	Recruitment symbol. Indicates that a recruitment maneuver will be performed after the next PEEP increase. Counts down the time to maneuver.
20	White	Recruitment in progress. Message displayed, and count-down timer indicating duration of maneuver. Located close to the PEEP control.

Symbol/Control	Color	Description
100 %	Gray circle	Manual management. Indicates that the operator must manage the control.
95 xx %	Blue circle rotating clockwise	Automatic management. Indicates that INTELLi- VENT-ASV is managing the patient and treat- ment has been increased (comets moving clockwise). A faster rotation provides a visual indication of ongoing or recent changes.
95 xx %	Blue circle rotating counter-clockwise	Automatic management. Indicates that INTELLi- VENT-ASV is managing the patient and treat- ment has been decreased (comets moving counter-clockwise). A faster rotation gives a visual indication of ongoing or recent changes.
100 xxx %	Red circle	No automatic management – controller is in a frozen state. A sensor value may be absent.
100	Green circle	Oxygen enrichment in progress. For details, see your ventilator <i>Operator's Manual</i> .

## 1.6 Troubleshooting alarms

### CAUTION

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

#### **NOTICE**

When the device is in Standby, all SpO2-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 SpO2related documentation.

For the following alarm types, see the listed documentation:

- Ouick Wean/SBT-related alarms. see Section 2.8.
- SpO2-related alarms, see the Pulse oximetry Instructions for use.
- PetCO2-related alarms, see your ventilator Operator's Manual.

Table 1-14. INTELLIVENT-ASV alarms, priority, and corrective actions

Alarm/Priority	Definition/Corrective action
FiO2 set to 100% due to low SpO2 <i>Medium priority.</i>	The Oxygenation controller set Oxygen to 100% due to low SpO2 saturation. SpO2 is, or was, in the emergency zone.
	To resolve
	Check patient condition.
	<ul> <li>Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).</li> </ul>
Oscillation PEEP/CPAP	Large variations in PEEP in a short time period.
Medium priority.	To resolve
	Check patient condition.
	• Set PEEP to Manual.
Oscillation %MinVol	Large variations in %MinVol in a short time period.
Medium priority.	To resolve
	Check patient condition.
	• Set %MinVol to Manual.
Oxygenation adjustment off  Medium priority.	The Oxygenation controller is frozen due to poor or absent SpO2 signal.
	To resolve
	<ul> <li>Check pulse oximeter connections.</li> </ul>
	• Set PEEP and/or Oxygen to Manual.

Alarm/Priority	Definition/Corrective action	
Oxygen controller at limit  Low priority.	PEEP and/or Oxygen are at the defined limit and cannot be increased.	
- 1 9	To resolve	
	Check patient condition.	
	Verify limit settings.	
	<ul> <li>Set PEEP and/or Oxygen to Manual.</li> </ul>	
Oxygen control limit exceeded  Medium priority.	Oxygen exceeds the limit defined by the Oxygen message alarm (Alarms window).	
, ,	To resolve	
	<ul> <li>Check patient condition.</li> </ul>	
	<ul> <li>Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).</li> </ul>	
Oxygen supply failed	Oxygen source flow is lower than expected.	
Medium priority.	To resolve	
	Check patient condition.	
	<ul> <li>Check oxygen supply; change supply if necessary.</li> </ul>	
	<ul> <li>Check oxygen supply for leaks.</li> </ul>	
	• Provide alternative ventilation until issue is resolved.	
Recruitment in progress	Notification about ongoing recruitment maneuver.	
Low priority.	Check patient condition.	
Ventilation adjustment OFF  Medium priority.	The Ventilation controller is frozen when any of the following conditions persists for longer than 30 seconds:	
	Poor or absent CO2 signal	
	• fSpont > 60 b/min (> 40 kg IBW)	
	• fSpont > 100 b/min (≤ 40 kg IBW)	
	To resolve	
	Check patient condition.	
	Check CO2 connections.	
	• Set %MinVol to Manual.	
Ventilation controller at limit  Low priority.	%MinVol is at the defined limit (200%) and cannot be increased.	
, ,	To resolve	
	Check patient condition.	
	• Set %MinVol to Manual.	

## 1.7 Management of minute volume (%MinVol)

## ♠ WARNING

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

## CAUTION

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

During automated managment 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 (CO2 elimination) uses the following data to set the minute volume (%MinVol):

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

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

- All ASV safety limits are active for prevention of Apnea, baro- and volutrauma, auto-PEEP, and dead space ventilation, including the tidal volume (Vt) limit of 1.5 x (upper Vt alarm limit).
- The target PetCO2 that is set depends on.
  - The patient's treatment level (peak) inspiratory pressure)
  - Any specific condition(s) set by the operator (Section 1.4.12.1)
  - Operator-set PetCO2 target shift (Section 1.4.12.3)
  - Whether Quick Wean is enabled (Section 2.2)
- The acceptable spontaneous breathing rate is calculated using the information in Table 1-17.

The %MinVol limits that are in force when minute volume management is set to Automatic are listed in Table 1-15. As soon as the upper limit for the management of %MinVol is reached, a Ventilation controller at limit message is generated.

Table 1-15. %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	Maximum %MinVol

## Minute volume (%MinVol) management in Manual mode

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

# 1.7.1 Management of %MinVol, passive patient

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

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

Under normal conditions, PaCO2 is approximately 2–5 mmHg higher than PetCO2 — the difference between the values is referred to as the *PaCO2-PetCO2 gradient*. Under special clinical conditions (including ventilation/perfusion mismatch, such as shunt), the PaCO2-PetCO2 gradient can increase, requiring adjustment of the ventilation targets (using the Target Shift control). For details, see Section 1.4.12.3.

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

The PetCO2 target range depends on:

- Any specific condition(s) set by the operator (Section 1.4.12.1)
- Operator-set PetCO2 target shift (Section 1.4.12.3)
- Current level of ventilator support (Ppeak)

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

Table 1-16. Automated management of %MinVol, passive patient

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

### 1.7.2 Management of %MinVol, active patient

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

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

Table 1-17. Spontaneous breathing rate range calculation<sup>25</sup>

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

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

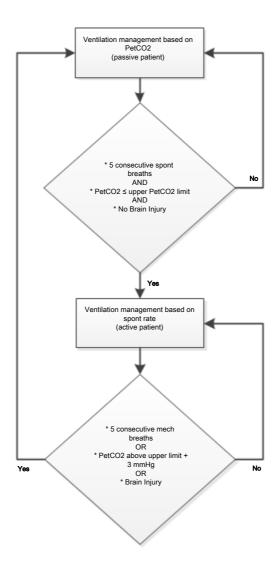
The conditions listed in the following table apply to automated control of %MinVol for an active patient, and refer to the transition process specified in Section 1.7.3.

<sup>&</sup>lt;sup>25</sup> For ASV target rate information, see your ventilator Operator's Manual.

Table 1-18. Automated management of %MinVol, active patient

When these conditions apply	%MinVol change
• The patient complies with the Active state conditions in Section 1.7.3 and	%MinVol increase
<ul> <li>The patient's Rate is above the upper limit of the acceptable spontaneous rate (danger of patient fatigue)</li> </ul>	
• The patient complies with the <i>Active state conditions</i> in Section 1.7.3 and	%MinVol decrease
• The patient's Rate is below the lower limit of the acceptable spontaneous rate	
<ul> <li>The patient complies with the Active state conditions in Section 1.7.3         <ul> <li>and</li> </ul> </li> <li>The patient's Rate value is within the target range</li> </ul>	No change in <b>%MinVol</b> .
	If Quick Wean is enabled, see Section 2.4.1 for details.
The patient's PetCO2 is invalid for more	%MinVol control is frozen.
than 30 seconds	The Ventilation adjustment OFF alarm is generated.
The patient's spontaneous Rate is invalid (> 60 b/min	%MinVol control is frozen.
for patients > 40 kg IBW or > 100 b/min for patients ≤ 40 kg IBW) for more than 30 seconds	The Ventilation adjustment OFF alarm is generated.

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



#### Passive patient

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

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

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

When a reliable PetCO2 measurement is not available (Table 1-20), the Ventilation controller suspends dynamic management of the control, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

#### Active patient

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

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

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

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

If the patient's spontaneous Rate is invalid<sup>26</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 PetCO2 measurement is not available (Table 1-20), the Ventilation controller suspends automated management, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

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 $<sup>^{26}</sup>$  fSpont > 60 b/min (> 40 kg IBW) or fSpont > 100 b/min ( $\leq$  40 kg IBW)

## 1.7.4 Important notes about ventilation management

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

Table 1-19. Important notes about ventilation management

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

#### 1.7.4.1 Quality index and ventilation management

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 1-20. PetCO2 quality index and auto-

mated ventilation management	
Quality indicator	These conditions apply
The data from the sensor is unavailable or not reliable for more than 30 seconds Gray, red, or orange bars	<ul> <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 Operator's Manual.</li> </ul>
The data from the sensor is reliable  Green bars	<ul> <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>

# 1.7.4.2 Actions that temporarily halt automatic ventilation management

Automated ventilation management pauses during the following actions:

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

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 7 4 3 PetCO2 is not available

Any time the PetCO2 measurement is unavailable or unreliable<sup>27</sup>, the minute volume adjustment is the same as in ASV mode, using the %MinVol setting in effect at the time that the PetCO2 signal became unusable.

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

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

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

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

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

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

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

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

# 1.7.4.5 Disconnection or flow sensor failure resolved in more than 5 minutes

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

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

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<sup>&</sup>lt;sup>27</sup> If the PetCO2 value falls below 10 mmHq, the quality indicator bar is red; the value is considered unreliable.

#### 1.7.4.6 Starting active ventilation from Standby

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

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

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

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

## 1.8 Management of PEEP and Oxygen

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

#### NOTICE

- The emergency increase of oxygen rules remain in place for all cases as long as the Oxygen control is set to Automatic
- The Oxygenation controller can only adjust the Oxygen between 21% and 100%.
- When the minimum Oxygen limit is set above 21%, a red line indicating the limit appears on the Oxygenation maps.

- The PEEP controller can only operate between 5 and 24 cmH2O, 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 managment 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 SpO2 range for the patient:

- Measured oxygen saturation (SpO2)
- Any specific condition(s) set by the operator (Section 1.4.12.1)
- Operator-set Target Shift (Section 1.4.12.3)

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

#### Manual oxygenation management

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

# 1.8.1 Management of PEEP/Oxygen for all patients

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

Automated PEEP/Oxygen management comprises two steps:

- The operator's input and the current treatment (PEEP) define the SpO2 target range. The ranges differ based on the selected specific condition(s), if any (Section 1.4.12.1). The SpO2 signal and the SpO2 target range are used to define the treatment action (increase, decrease, no change of treatment).
- The system decides, depending on the current combination of PEEP and Oxygen on the PEEP/Oxygen curve, whether PEEP and/or Oxygen are increased.

For increasing therapy, the relationship between PEEP and Oxygen is based on the ARDSnet guidance (Figure 1-25, the target path is the bold line).

For decreasing therapy, the relationship is based on the Open Lung concept (Figure 1-26, the target path are the bold lines).

Figure 1-25. Increase of oxygenation support, ARDSnet guidance

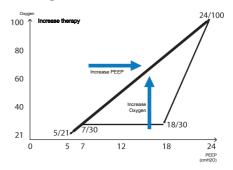
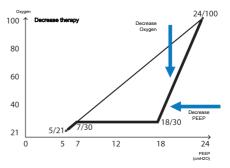


Figure 1-26. Decrease of oxygenation support, Open Lung concept



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

## 1.8.2 Emergency increase of Oxygen

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

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

#### 1.8.3 Oxygenation management rules

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

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

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

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

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

The controller increases oxygenation support.

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 1.8.2.

#### SpO2 measurement is unavailable

The controller is frozen.

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

#### SpO2 is high, above the target zone limit

The controller decreases oxygenation support.

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.

## 1.8.3.1 How the controller adjusts Oxygen and PEEP

#### NOTICE

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

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

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

Table 1-21. Increase/decrease increments of Oxygen and PEEP by automated Oxygenation controller<sup>28</sup>

Oxygenation management/Action	Takes place when
Increase Oxygen stepwise: Increases Oxygen	<ul><li>Oxygen automatically managed</li><li>Increasing Oxygen</li></ul>
by 10% of current Oxygen value every 30 seconds	support
Decrease Oxygen stepwise:	Oxygen automati- cally managed
Decreases Oxygen by 5% of current Oxygen value every 60 seconds	Decreasing Oxygen support
Increase PEEP stepwise:	PEEP automatically managed
Increases PEEP by 1 cmH2O every 6 minutes	• Increasing PEEP support

Oxygenation management/Action	Takes place when
Decrease PEEP stepwise:	• PEEP automatically managed
Decreases PEEP by 1 cmH2O every 6 minutes	Decreasing PEEP support
Decrease PEEP stepwise quickly:	PEEP automatically managed
Exception: Decreases PEEP by 1 cmH2O quickly every 30 seconds	<ul> <li>PEEP is above the upper PEEP limit (if PEEP was set manually above the limit)</li> </ul>

# 1.8.4 Important notes about oxygenation management

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

Table 1-22. Important notes about oxygenation management

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

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<sup>&</sup>lt;sup>28</sup> When the PEEP and/or Oxygen control setting is manually changed and then control is again set to Automatic, these rules still apply. The time interval starts from the time of the last manual change.

#### 1.8.4.1 Quality index and oxygenation

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

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

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

Table 1-23. SpO2 quality index and automated oxygenation management

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

Gray, red, or orange bars



- The PEEP and Oxygen controls are solid red circles; they are frozen.
- The Oxygenation adjustment OFF alarm is generated.
- The ventilator uses the same oxygenation rules as when in ASV mode. For details, see your ventilator Operator's Manual.
- Automatic emergency increase of oxygen management is inactive (Section 1.8.2).

## Quality indicator These conditions apply ...

The data from the sensor is reliable

Green bars



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

# 1.8.4.2 Actions that temporarily halt automated oxygenation management

Automated oxygenation management pauses during the following actions:

- Disconnection
- Oxygen enrichment
- Flow sensor calibration
- Leak test
- Suctioning
- Oxygen sensor calibration
- Oxygen supply failure
- P/V Tool maneuver
- Inspiratory/Expiratory hold maneuver
- Auto-recruitment

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

#### 1.8.4.3 Oxygen level notification

When the Oxygenation controller is set to Automatic and is active, you can set the ventilator to display a message if the Oxygen concentration exceeds a specific limit that you specify. For details, see Section 1.4.12.6.

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

# 1.8.4.4 Starting active ventilation from Standby

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

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

# 1.9 Manual control of ventilation and oxygenation

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

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

#### 1.9.1 Manual control of ventilation

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

Table 1-24. Conditions for manual control of %MinVol

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

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

### 1.9.2 Manual control of oxygenation

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

Table 1-25. Conditions for manual control of PEEP and/or Oxygen

When these conditions are met	This control must be adjust- ed MANUALLY by the operator
PEEP	PEEP is set to
<ul> <li>The Chronic Hyper- capnia or Brain injury patient condition is selected</li> </ul>	Manual
• SpO2 monitoring is disabled	
<ul> <li>SpO2 sensor is disconnected</li> </ul>	

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When these	conditions
are met	

#### Oxygen

- · Oxygen monitoring (O2 sensor) is disabled
- SpO2 monitoring is disabled
- SpO2 sensor is disconnected

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

## 1.10 Assessing results

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

## **Z** Quick Wean

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#### 2.1 Overview

## WARNING

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

## **↑** CAUTION

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

Quick Wean is integrated into INTELLIVENT-ASV, and when activated, provides continuous dynamic monitoring 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 steps:

- 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.

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## 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
- PFFP
- Rate
- APinsp
- Vt/IBW
- RSB or PetCO2 (depending on patient IBW), 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 automated SBTs
- Quick Wean enabled, with automated

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

#### **Ouick 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 PetCO2 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 1.7

When Quick Wean is enabled, two SBTrelated options are available: automated SBTs disabled or enabled

#### Automated SBTs disabled (SBTs can be manually started)

This is the default setting.

- 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.

#### Automated SBTs enabled

Automated 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 automated SBTs, see Sections 2.3 and 2.5

#### 2.2.4 Quick Wean key terms

Term/ Parameter	Description
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.
Automated SBT	When enabled, the device performs an SBT when specified criteria are met. By default, disabled.
To start SBT group of parameters	A list of parameters that must all be within a predefined range for a specific amount of time for the patient to be con- sidered ready for an SBT.
	This set of parameters and values is referred to as the <i>To start SBT criteria</i> .

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Term/ Parameter	Description
To stop SBT group of parameters	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.  This set of parameters and values is referred to as the <i>To stop SBT criteria</i> .
fSpont / %fSpont	fSpont is the absolute number of spontaneous breaths taken. %fSpont is the percentage of spontaneous breaths to total breaths taken.  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.  Only applies during an SBT.
%MinVol (%)	When Quick Wean is enabled, as long as the patient is active and the patient's rate is below the upper limit of the target range (Section 1.7.2), the device gradually reduces %MinVol to 70%.  When SBTs are enabled and an SBT starts, %MinVol is reduced to a default value of 25%.

Term/ Parameter	Description
Oxygen (%)	Inspired oxygen.
PEEP (cmH2O)	Positive end-expiratory pressure. Airway pressure at the end of exhalation.
PetCO2 (mmHg)	End-tidal CO2 pressure.
PetCO2 inc (mmHg)	The absolute increase in PetCO2 (relative to an average calculated prior to the start of the SBT) that is permitted during an SBT. Only applies during an SBT.
ΔPsupport max (cmH2O)	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.  The target ΔPsupport max is configurable.
	Shown as the upper Pinsp limit in the Quick Wean & SBT Status panel.
ΔPsupport min (cmH2O)	The minimum pressure support that will be applied during an SBT.
	The target \( \Delta \text{Psupport min} \) is configurable.  Shown as the lower Pinsp limit in the Quick Wean & SBT Status panel.

Term/ Parameter	Description
Rate (b/min)	Respiratory rate, as number of breaths per minute.  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.  If the upper limit is reached during an SBT, the SBT is stopped.
SBT time range	Defines the hours between which an SBT can be started. 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. If an SBT is in progress when the time is out of range, the SBT continues until it is completed.
SpO2 (%)	Measurement of oxygen saturation in the blood.
Time before starting SBT (min)	Defines the length of time that patient conditions must stay within the <i>To start SBT</i> limits before an SBT can start. Only applies when automated SBTs are enabled.

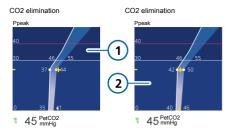
Term/ Parameter	Description
Time between 2 SBTs (min)	Defines the minimum length of time that must pass between two SBTs. Only applies when automated SBTs are enabled.
Tolerance time (s)	The length of time a parameter value can be out of range without affecting the countdown to an SBT or an ongoing SBT.
	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.
Vt/IBW (ml/kg)	Tidal volume per kilogram of ideal body weight.
RSB (1 / (l*min))	Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE). The RSB parameter is only used for patients weighing > 40 kg. For patients weighing less, the PetCO2 parameter is used.

### 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 1.7.2 and 1.7.1

## 2.3 Enabling/disabling and setting up automated SBTs

By default, automated SBTs are disabled. To enable automated SBTs, Quick Wean must be set to Automatic

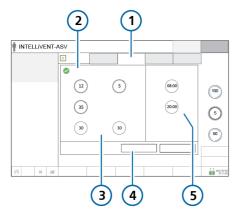
#### To enable/disable automated SBTs

- 1. In the INTELLiVENT-ASV Settings > Auto window, set Quick Wean to Automatic.
- 2. To enable automated SBTs, touch the Ouick Wean tab, then touch the Automatic SBT checkbox.

A checkmark indicates SBTs are enabled.

A gray circle indicates automated SBTs are disabled: the SBT controls are also disabled.

Figure 2-1. INTELLiVENT-ASV Settings > Quick Wean window, automated SBTs enabled



- Ouick Wean
- 4 Manually Start/ Stop SBT buttons
- 2 Automatic SBT. selected
- 5 Automated SBT time range
- 3 SBT controls: ΔPsupport max, ΔPsupport min, Rate, Time before starting SBT, Time between 2 SBTs

- Using the SBT time range controls, set the time period during which automated SBTs can be performed. By default, set to between 8 am and 8 pm.
- 4. Set SBT control values, as appropriate. These values can be modified during ventilation and in Standby, as appropriate. For details, see Table 2-1.
- If displayed, touch **Continue** to accept the settings and proceed to the next step.

Table 2-1. SBT settings, available during ventilation

SBT setting	Description
Automatic SBT	Select checkbox to enable automated SBTs when specified clinical conditions are met.
SBT time range	Hours between which an SBT can be started.
	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 not take place.
	To allow automated 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.

SBT setting	Description	
Start SBT	Touch to immediately start an SBT.	
	The system:	
	<ul> <li>Adjusts %MinVol to the configured setting</li> </ul>	
	<ul> <li>Adjusts PEEP to the configured setting (if automatically controlled)</li> </ul>	
	• Displays the SBT history panel	
	• Displays the Quick Wean & SBT status panel	
Stop SBT	Select to immediately stop an ongoing SBT.	
	The system returns to the previous INTELLIVENT-ASV settings and monitors patient conditions for the next possible SBT.	
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).	
Time between 2 SBTs (min)	The minimum length of time after an automated SBT is executed before another automated SBT can be started.	

SBT setting	Description
ΔPsupport max (cmH2O)	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.
	The target ΔPsupport max is configurable.
	Shown as the upper Pinsp limit in the Quick Wean & SBT Status panel.
ΔPsupport min (cmH2O)	The minimum pressure support that will be applied during an SBT.
	The target $\Delta Psupport min$ is configurable.
	Shown as the lower Pinsp limit in the Quick Wean & SBT Status panel.
Rate (b/min)	The maximum rate allowed before starting an SBT, and an absolute upper limit that it cannot exceed during an SBT.

## 2.4 Conditions for starting weaning activities

Quick Wean continuously monitors the patient's condition against a set of readiness-to-wean criteria that must be met.

The parameter values are shown graphically in the Quick Wean/Quick Wean & SBT Status panel. For details, see Section 2.4.4.

They are referred to as the *To start SBT* parameters and the To start SBT criteria.

- 1. When Quick Wean is enabled, the device starts monitoring the To start SBT parameters.
- 2 When the To start SBT criteria are met and the patient is active, a set of steps occur, depending on whether or not automated SBTs are enabled. They are described in Table 2-2

At any time, you can manually start an SBT, as described in Section 2.5.1.

Table 2-2. Device actions when To start SBT criteria are met

Automated SBTs are enabled



- The device shows the status Conditions fulfilled, starting SBT in XX min in the Quick Wean & SBT Status panel, and starts a timer.
- The measured values for each of the To start SBT parameters must remain within the defined ranges for the length of time specified in the Time before starting SBT parameter.

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 the countdown.

Automated 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 1.7.2, the device decreases %MinVol stepwise to 70%.

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

The device adjusts %MinVoI as follows:

Table 2-3. %MinVol adjustments

Patient status	Quick Wean status	The device
Active, Rate within target range	Quick Wean enabled	Decreases %MinVol to 70%
	Quick Wean disabled	No <b>%MinVol</b> change
Active, 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 IBW > 40 kg. For patients with IBW ≤ 40 kg, the PetCO2 parameter is shown instead

The following parameters are monitored to determine the patient's readiness for weaning activities. They are monitored regardless of whether automated 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 IBW. Where applicable, these differences are marked.

For additional details about:

- Parameter definitions, see Section 2.2.4
- Configuring parameters, see Section 29
- Parameter specifications, see Section 2 10

Table 2-4. Quick Wean To start SBT criteria

Parameter (unit)	Where set/how used	Default <i>To start SBT</i> value
%fSpont	Not configurable	100% during Time before starting SBT
Oxygen (%)	Configuration > Modes > SBT > To start SBT window	≤ 40
PEEP (cmH2O)	Configuration > Modes > SBT > To start SBT window	Patients > 40 kg: $\leq$ 8 Patients $\leq$ 40 kg: $\leq$ 6
ΔPsupport max (cmH2O)	INTELLIVENT-ASV Settings > Quick Wean window	≤ 12
ΔPsupport min (cmH2O)	INTELLIVENT-ASV Settings > Quick Wean window	5
Rate (b/min)	INTELLIVENT-ASV Settings > Quick Wean window	Patients > 30 kg: ≤ 35 Patients ≤ 30 kg: ≤ 45
RSB (1/(l*min))	Not configurable	≤ 105
SpO2 (%)	Not configurable	In INTELLIVENT-ASV nor- mal/high range (within or above target zone)
Vt/IBW (ml/kg)	Configuration > Modes > SBT > To start SBT window	≥ 5
Time before starting SBT (min)	INTELLIVENT-ASV Settings > Quick Wean window	30
Time between 2 SBTs (h)	INTELLIVENT-ASV Settings > Quick Wean window	0.5
SBT time range (hh:mm)	INTELLIVENT-ASV Settings > Quick Wean window	Between 8:00 and 20:00 (8 am to 8 pm)
	To allow automated SBTs to start at any time, set both controls to the same time.	
Tolerance time (s)	Configuration > Modes > SBT > To start SBT window  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 Patients ≤ 40 kg: 60

### 2.4.3 User-modifiable SBT parameters, **INTELLIVENT-ASV Settings window**

The INTELLiVENT-ASV Settings > Quick Wean 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 effective when automated SBTs are enabled. You can adjust the other parameters in this window at any time.

When Quick Wean is set to Automatic. 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 > Quick Wean 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:

- **Ouick Wean or Ouick 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 *Ouick 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 2-5. Vent Status or Quick Wean panel

When	Vent Status or Quick Wean panel
Quick Wean is disabled	INTELLIVENT-ASV displays the Vent Status panel, showing the ventilation parameters. For details, see your ventilator Operator's Manual.
Quick Wean is enabled	INTELLIVENT-ASV displays the Quick Wean panel, showing the monitored weaning parameters (Table 2-10).

## Vent Status or Quick Wean

One or more parameter values are in the weaning zone

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.



All of the parameter values are in the weaning zone

The Quick Wean panel displays:

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



## 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.

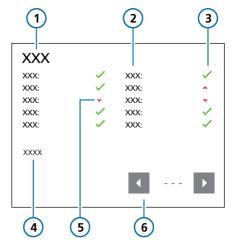
When an SBT is ended, the panel displays information about how the previous SBT ended (successfully completed (fulfilled) or stopped prematurely (stopped).

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 2-2. SBT history panel



- 1 Panel title: SBT history
- 2 Weaning parameters
- 3 Value in range (green checkmark)
- SBT status, time started
- Value out of range (red up arrow: too high; red down arrow: too low)
- 6 View previous SBT data

## 2.5 Conducting an SBT

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

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

- The patient must be active
- Automated SBTs are enabled
- 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 2-6. 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

System changes	For details, see
<ul> <li>Additional parameters are used during the SBT:</li> <li>Rate inc%</li> <li>PetCO2 inc (absolute increase in PetCO2)</li> <li>Rate inc% and PetCO2 inc values are used as <i>To stop SBT</i> criteria. The limits are set in Configuration.</li> </ul>	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).  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 > Quick Wean window.

#### To manually start an SBT

- 1. Open the INTELLiVENT-ASV Settings > Quick Wean window (Section 1.4.11).
- 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 2-6

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 > Quick Wean 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 INTELLi-**VENT-ASV** settings and resumes screening the patient readiness-to-wean criteria.

#### 2.5.2 PetCO2 increases

#### NOTICE

PetCO2 inc is used as part of To stop SBT criteria; it is not displayed.

During an SBT, the system uses the PetCO2 increase as a To stop SBT criterion. You set a maximum allowed value in the To stop SBT window in Configuration.

The changes in PetCO2 can give an indication of whether the patient is experiencing increased work of breathing (WOB). The system monitors the PetCO2 increase, as well as the measured PetCO2 value against the defined target range. For details about how the controller uses this data, see Section 1.7.2.

## 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 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 (automated 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 Disabled 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 > 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 2-7. Quick Wean To stop SBT criteria

Parameter (unit)	Where set/how used	Default <i>To stop SBT</i> value
Oxygen (%)	Configuration > Modes > SBT > To start SBT window Set in the To start SBT window.	> 50
	The Oxygen setting to end an SBT is always the Oxygen setting in the To start SBT window + 10.	
PEEP (cmH2O)	Configuration > Modes > SBT > To start SBT window	Patients > 40 kg: > 8 Patients ≤ 40 kg: > 6
	Set the upper limit that <b>PEEP</b> cannot exceed during an SBT.	
PetCO2 (mmHg)	Used indirectly together with PetCO2 inc as To stop SBT criteria.	If PetCO2 > (upper limit INTELLIVENT-ASV
	For additional details, see Section 1.7.2.	PetCO2 target range + 3 mmHg), an ongoing SBT is stopped imme- diately.
PetCO2 inc (mmHg)	Configuration > Modes > SBT > To stop SBT window	> 8 mmHg
	End-tidal CO2 pressure increase compared to the values before the SBT. Only applies during an SBT.	
ΔPsupport max (cmH2O)	INTELLIVENT-ASV Settings > Quick Wean window Set the upper limit that ΔPsupport cannot exceed during the SBT.	> 12
ΔPsupport min (cmH2O)	INTELLIVENT-ASV Settings > Quick Wean window Set the lower limit that ΔPsupport cannot go below during the SBT.	< 5
Rate (b/min)	INTELLIVENT-ASV Settings > Quick Wean window Set the upper limit that Rate cannot exceed during SBT.	Patients > 30 kg: > 35 Patients ≤ 30 kg: > 45
Rate inc	Configuration > Modes > SBT > To stop SBT window  Percentage increase in respiratory rate as a	> 50% increase over the average rate established just prior
	result of the SBT. Only applies during an SBT.	to the SBT

Parameter (unit)	Where set/how used	Default <i>To stop SBT</i> value
RSB (1/(l*min))	Not configurable.	> 105
SpO2 (%)	Not configurable.	< (INTELLIVENT-ASV- set SpO2 target range)
Vt/IBW (ml/kg)	Configuration > Modes > SBT > To start SBT window	< 5
	Specify the minimumVt/IBW setting allowed during an SBT.	
Tolerance time (s)	Configuration > Modes > SBT > To stop SBT window	Patients > 40 kg: 180 Patients ≤ 40 kg: 30
Max. duration (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 automated) 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 SRTs 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 2-8. Quick Wean alarms and messages

Alarm message	Description	
SBT aborted  Medium priority.	The SBT was stopped. For possible reasons, see Section 2.6.	
	Dismiss the alarm as described in Section 2.8.	
SBT successfully fulfilled  Medium priority.	The SBT was ended because Max. duration was reached.	
	Dismiss the alarm as described in Section 2.8.	
SBT stopped after HHH hours MM minutes	Indicates how long the SBT ran before being stopped. Shown in SBT history panel and Event log.	
SBT started at YYYY-MM-DD HHH hours MM minutes	When an SBT starts automatically, this message records the time.	
	Shown in SBT history panel and Event log.	
SBT fulfilled after HHH hours MM minutes	When an SBT ends successfully, this message records the time. The time is equal to the Max. duration value.	
	Shown in SBT history panel.	
SBT manually started at YYYY-MM-DD HHH hours MM minutes	When an SBT is manually started by selecting the <b>Start SBT</b> button, this message records the time.  Shown in <b>SBT</b> history panel.	
SBT manually stopped after 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.	
	Shown in SBT history panel and Event log.	
Too high (red up arrow) and 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.	
	When a parameter's value is below the allowed range, a red down arrow is displayed.	
Within range (green checkmark) 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 IBW: patients with IBW > 40 kg and those with IBW  $\leq 40$  kg.

For the list of default values, see Table 2-10.

## 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 > Quick Wean window (Section 2.3)

The SBT configuration windows provide access to the following controls:

Table 2-9. SBT default settings configuration windows

Configura- 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/IBW, 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

Fach of these windows is divided into two groups: the controls on the top half apply to patients with IBW > 40 kg; the controls on the bottom half apply to patients with IBW  $\leq 40 \text{ kg}$ .

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/IBW, and Tolerance time.
  - For details about the parameters, see Table 2-4.
- 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, PetCO2 inc, Tolerance time, and Max. duration. For details about the parameters, see Table 2-7
- 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 INTELLi-VENT-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 IBW > 40 kg and  $\leq$  40 kg.

The default values for these controls, ΔPsupport max, ΔPsupport 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 > Quick Wean 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 INTELLi-**VENT-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

For parameter definitions, see Section 2.2.4.

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

Table 2-10. Quick Wean parameters

Parameter	Default values	Where displayed/Where set	Range
%fSpont (%)	To start SBT: 100%	Displayed in:  SBT history panel  Set in: N/A (calculated value)	
%MinVol (%)	Quick Wean enabled: 70 During SBT: 25	Displayed in: INTELLIVENT-ASV main display in the %MinVol control Set in: Configuration > Modes > SBT > SBT settings	%MinVol during SBT: 25 to 70
fSpont		Displayed in:  Quick Wean & SBT status panel  SBT history panel  Monitoring window  Set in: N/A	
Max. Duration (min)	By default, set to 30 minutes.  Off means that there is no limit to how long the SBT can run.	Displayed and set in:  Configuration > Modes > SBT >  To stop SBT	Off, 20 to 240
Oxygen (%)	To start SBT:  ≤ 40  To stop SBT:  > 50  The buttons are interdependent: The To start SBT setting is always 10 below the To stop SBT setting.	Displayed in:  INTELLIVENT-ASV main display in the Oxygen control  Quick Wean & SBT status panel  SBT history panel  Monitoring window  Set in: Configuration > Modes > SBT > To start SBT	To start SBT: 30 to 50 To stop SBT: 40 to 60

Parameter	Default values	Where displayed/Where set	Range
PEEP (cmH2O)	To start SBT: Patient IBW > 40 kg: ≤ 8 Patient IBW ≤ 40 kg: ≤ 6 To stop SBT: Patient IBW > 40 kg: > 8 Patient IBW ≤ 40 kg: > 6 During SBT: PEEP is set to 5 by default.	Displayed in:  INTELLIVENT-ASV main display in PEEP control  Quick Wean & SBT status panel  SBT history panel  Monitoring window  Set in:  Configuration > Modes > SBT > To start SBT  Configuration > Modes > SBT > SBT settings	To start SBT: 5 to 10 PEEP during SBT: 0 to 5
PetCO2 (mmHg)	To stop SBT: PetCO2 > (upper limit INTELLIVENT-ASV PetCO2 target range + 3 mmHg)	<ul> <li>Displayed in:</li> <li>Patient IBW ≤ 40 kg: Quick Wean status panel</li> <li>SBT history panel</li> <li>CO2 elimination horizon and map</li> <li>Monitoring &gt; CO2 window</li> <li>Dynamic Lung panel</li> <li>This value is not configured. You can adjust the target range, if needed. See Section 1.4.12.3.</li> </ul>	Depends on PetCO2 target range
PetCO2 inc (mmHg)	To stop SBT: > 8 increase	Not displayed.  Set in: Configuration > Modes > SBT > To stop SBT	4 to 20
Rate (b/min)	To start SBT: Patient IBW > 30 kg: ≤ 35 Patient IBW ≤ 30 kg: ≤ 45 To stop SBT: Patient IBW > 30 kg: > 35 Patient IBW > 30 kg: > 45	Displayed in:  Quick Wean & SBT status panel (as fSpont)  SBT history panel (as fSpont)  INTELLIVENT-ASV Settings > Quick Wean window  Set in: INTELLIVENT-ASV  Settings > Quick Wean window	25 to 65

Parameter	Default values	Where displayed/Where set	Range
Rate inc (%)	To stop SBT: > 50% increase over the average rate established just prior to the start of the SBT	Displayed in: SBT history panel Set in: Configuration > Modes > SBT > To stop SBT	20 to 100
RSB (1 / (I*min))	To start SBT: ≤ 105 To stop SBT: > 105	Displayed in: Patient IBW > 40 kg: Quick Wean & SBT status panel SBT history panel The RSB parameter is only used for patients with IBW > 40 kg. This value is not configured.	105
SBT time range	To allow SBTs at any time, set both controls to the same time.  Default: Between 8:00 and 20:00.	Displayed and set in: INTELLIVENT-ASV Settings > Quick Wean window	HH:MM
SpO2 (%)	To start SBT: Within or above the INTELLIVENT-ASV SpO2 target range To stop SBT: Below the INTELLi- VENT-ASV SpO2 target range minus 2%	<ul> <li>Displayed in:</li> <li>Oxygenation horizon and map (views 1, 2, 3)</li> <li>Monitoring &gt; SpO2 window</li> <li>SBT history panel</li> <li>Dynamic Lung panel</li> <li>Main display under MMP list</li> <li>This value is not configured. You can adjust the target range, if needed. See Section 1.4.12.3.</li> </ul>	Depends on the SpO2 target range
Time before starting SBT (min)	By default, set to 30 minutes	Displayed and set in: INTELLIVENT-ASV Settings > Quick Wean window	10 to 120

Parameter	Default values	Where displayed/Where set	Range
Time between 2 SBTs (h)	To start next SBT: By default, 0.5 hours	Displayed and set in: INTELLIVENT-ASV Settings > Quick Wean window	<ul> <li> (OFF)</li> <li>0.5 to 4 h (in 0.5 h increments)</li> <li>4 to 24 h (in 1 h increments)</li> </ul>
Tolerance time (s)	less of the Configuration • %fSpont: must be 100	neters, the Tolerance time setting in settings):  0% for a minimum of 60 seconds  1   4   40 kg, the Tolerance Time for	
Tolerance time (s)	To start SBT: Patient IBW > 40 kg: 180 s Patient IBW ≤ 40 kg: 60 s To stop SBT: Patient IBW > 40 kg: 180 s Patient IBW ≤ 40 kg: 30 s	Displayed and configured in:  Configuration > Modes > SBT > To start SBT  Configuration > Modes > SBT > To stop SBT	10 to 300
Vt/IBW (ml/kg)	To start SBT: ≥ 5 ml/kg  To stop SBT: < 5 ml/kg	Displayed in:  Quick Wean & SBT status panel  SBT history panel  Monitoring window  Set in: Configuration > Modes > SBT > To start SBT	3 to 6
ΔPsupport max (cmH2O)	To start SBT: ≤ 12 To stop SBT: > 12	Displayed in:  INTELLIVENT-ASV Settings > Quick Wean window  SBT history panel  Set in: INTELLIVENT-ASV  Settings > Quick Wean window	6 to 25

Parameter	Default values	Where displayed/Where set	Range
ΔPsupport min (cmH2O)	To start SBT: ≥ 5  To stop SBT: < 5	Displayed in:  INTELLIVENT-ASV Settings > Quick Wean window  SBT history panel  Set in: INTELLIVENT-ASV  Settings > Quick Wean window	0 to 10

## 

# Specifications

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## 3.1 Intended use

### **Intended medical purpose**

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

## 3.2 Technical data

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

Table 3-1. INTELLIVENT-ASV technical data

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

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

Monitoring		
Values (numerical)	PetCO2 target range, depending on patient condition and treatment (Ppeak); SpO2 target range, depending on patient condition and treatment (PEEP)	
Current ventilation settings	ExpMinVol, fTotal, fControl, Ppeak (Pinsp + PEEP), Oxygen, PEEP	
Patient status	fSpont, PetCO2, SpO2	
Graphics	f (target)/Vt, PetCO2/target, PEEP/O2, PEEP/SpO2	
Trend parameters	Ventilation control, Oxygenation control	

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

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

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

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

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

# 3.3 Data logging

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

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 oxygena- tion	N/A
Controller PEEP	N/A
Recruitment passive	N/A
Recruitment running	N/A
fSpont	N/A
PEEP limit	cmH2O
%MinVol	%
ExpMinVol	l/min
RRIMV	breaths per min
RRtot	breaths per min
RRtarget	breaths per min
fSpont	breaths per min
Ti	S

Saved parameters	Unit
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-bybreath, but at most one time per second.

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

# 3 4 References

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

#### %MinVol

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

# active patient

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

#### alarm buffer

Contains information on recent alarm occurrences

#### **ARDS**

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

# brain injury

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

# chronic hypercapnia

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

#### CO2 elimination horizon

For a passive patient, shows a zoom into the CO2 elimination map at the current PetCO2 value and target range. For an active patient, shows the spontaneous breathing rate (fSpont). Displayed during active ventilation in INTELLIVENT-ASV. Also called the Ventilation horizon.

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

Shows the current patient PetCO2 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

#### IBW

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

#### 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 SpO2 value and target range. Displayed during active ventilation in INTELLIVENT-ASV

# **Oxygenation map**

The PEEP/SpO2 view shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits. The FiO2/PEEP map shows the patient's current combination of Oxygen/PEEP values.

# PaCO2-PetCO2 gradient

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

# passive patient

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

#### PEEP/CPAP

PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), a control setting and monitored parameter. PEEP and CPAP are constant pressures applied during both the inspiratory and expiratory phases.

#### PetCO2

Measured end-tidal CO2 partial pressure.

#### PetCO2 inc

The absolute increase in PetCO2 (relative to an average calculated prior to the start of the SBT) that is permitted during an SBT. The PetCO2 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 PetCO2 parameter is used.

### **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 automated SBTs are enabled.

#### Time between 2 SBTs

Defines the minimum length of time that must pass between two SBTs. Only applies when automated 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/IBW

Tidal volume per kilogram of ideal body weight.

# **△Psupport** max

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

# **∆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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