

URGENT FIELD SAFETY NOTICE
Puritan Bennett™ 840 Ventilator – Operator’s Manual Update for Loss of GUI Display

DAY MONTH, 2014

Reference: PB840 – Loss of Display, Manual Update 08/14

Dear Valued Customer,

Covidien is issuing this field safety notice (FSN) to its Puritan Bennett™ 840 ventilator customers to provide new information for the Puritan Bennett™ 840 Ventilator Operator’s Manual. Accompanying this notice is a new insert for Table 1-2 in Chapter 1 and an entire new Chapter 13. These new pages provide additional instruction and information for interacting with loss of display events. You are receiving this communication because our records indicate you may have one or more of the Puritan Bennett 840 Ventilator Operator’s Manuals affected by this notice.

The customer reports that initiated these changes to the Operator’s Manual included the graphical user interface (GUI) display screens (both upper and lower) becoming blank or erratic during patient use. This event prevents the clinician viewing and/or changing ventilator settings or clinician-set patient alarm parameters. Loss of display on GUI display screens will result in a patient requiring prompt transfer to an alternate ventilator in a manner consistent with relevant protocols. **The ventilator continues to provide respiratory support during these events.**

If this condition does not occur, the Puritan Bennett 840 ventilator can continue to be used.

Loss of GUI display

Failure of various components may result in screens going blank or becoming erratic. However, mechanical ventilation continues as set. All ventilator alarms remain active and will activate if alarm limits are exceeded.

If you encounter a loss of display, please take the following actions in conjunction with your institutional protocols to minimize risk to the patient.

- Verify the patient’s respiratory and physiological stability.
 - Confirm the patient is receiving ventilatory support by observation of the expansion and contraction of the patient’s chest.
 - Assess current patient status by reviewing other monitoring (e.g., oxygen saturation, heart rate, blood pressure, etc.)
- Promptly transfer the patient to an alternate ventilator in a manner consistent with your institutional protocol.
- Remove the affected ventilator from use until it has been serviced.

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Actions to be taken

- Remove Table 1-2 from Chapter 1 and destroy; replace with the enclosed replacement page. Please note the “Display (GUI) INOP” indicator image and the reference to Table 13-3 for recommended actions.
- Remove the entire Chapter 13 from your existing manual and destroy.
- Replace with the enclosed new section provided. Please review the details in Table 13-3 for information related to loss of GUI display.
- Communicate this new updated information within your facility as needed.
- Complete the attached acknowledgment form and fax or email it to the Covidien contact indicated on the form.

Important Safety Reminders

Always follow the instructions described in the Puritan Bennett™ 840 Ventilator Operator’s and Technical Reference Manual.

- Patients on life-support equipment should be appropriately monitored by medical personnel and suitable monitoring devices. (**Preface**)
- An alternative source of ventilation should always be available when using a critical care ventilator. (**Preface**)
 - When using the ventilator’s selectable alarm volume range, be sure to select an alarm volume level that can be discerned above background noise levels. (**Section 5.5**)
 - To ensure proper ventilator operation, perform the maintenance procedures at the recommended intervals as summarized in Table 7-3 in the Puritan Bennett™ 840 Operator’s and Technical Reference Manual.

This notification is being issued with the knowledge of [add local Competent Authority]. Please communicate this important information within your facility as required. If your facility has distributed Puritan Bennett™ 840 ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients.

If you have any questions regarding this letter, please contact your local Covidien representative **COUNTRY SPECIFIC TELEPHONE NUMBER**. Thank you for your prompt attention to this matter.

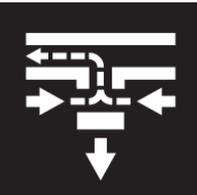
Sincerely,

**Country Specific
Regulatory Affairs**

Enclosed

The indicators on the breath delivery unit are shown in Table 1-2.

Table 1-2: BDU indicators

 <p>VEN_10389_A</p>	<p>Red ventilator inoperative indicator: The ventilator cannot support ventilation and requires service. The ventilator enters the safe state (safety ventilation) and discontinues detection of new patient data or alarm conditions. Qualified service personnel must repair the ventilator to correct the problem and execute EST successfully before normal ventilation is allowed. This indicator is accompanied by an audio signal and cannot be reset.</p>
 <p>VEN_10390_A</p>	<p>Red safety valve open (SVO) indicator: The ventilator has entered its safe state and opened its safety valve to allow the patient to breathe unassisted from room air.</p>
 <p>VEN_1004C</p>	<p>Red loss of GUI indicator: The ventilator has detected a malfunction that prevents the GUI from reliably displaying or receiving information. If you encounter a loss of the GUI display, reference Table 13-3 on page TR 13-21 for a list of recommended actions.</p>

Alarms

This chapter discusses the ventilator's alarm handling strategy and provides supplementary information about selected ventilator alarms for the Puritan Bennett™ 840 Ventilator System. For settings ranges, resolutions, and new patient values of all alarms, see Table A-13 in Appendix A of this manual.

Current alarm settings are saved in nonvolatile memory. All ventilator settings have absolute limits, which are intended to prevent settings outside the safe or permissible operational range of the ventilator. These limits may be fixed or depend on other settings, such as ideal body weight (IBW).

13.1 Alarm handling

The Puritan Bennett™ 840 Ventilator System's alarm handling strategy is to:

- Detect and call attention to legitimate causes for caregiver concern as quickly as possible, while minimizing nuisance alarms.
- Identify the cause and suggest corrective action for an alarm where possible.
- Make it easy to discern an alarm's urgency level.
- Allow quick and easy alarm setup.

Alarm annunciations include a level of urgency, which is an estimate of how quickly a caregiver must respond to ensure patient protection. Table 13-1 summarizes alarm urgency levels.

Table 13-1: Alarm urgency levels

Urgency level	Visual indication	Audible indication	Autoreset handling
<i>High:</i> Hazardous situation requiring immediate response	Red flashing	High-priority tone (repeating sequence of five tones; sequence repeats twice, pauses, then repeats again)	If all high-urgency alarm conditions return to normal, the audible indicator turns off, the red high-urgency indicator switches from flashing to steadily lit, and autoreset is entered in the alarm history log. Press the alarm reset key to turn off the visual indicator.
<i>Medium:</i> Abnormal situation requiring prompt response	Yellow flashing	Medium-priority tone (repeating sequence of three tones)	If all medium-urgency alarm conditions return to normal, the audible and visual indicators turn off and autoreset is entered into the alarm history log.
<i>Low:</i> Change in status, informing clinician	Yellow, steadily lit	Low-priority tone (two tone, non-repeating)	If all low-urgency alarm conditions return to normal, the audible and visual indicators turn off and autoreset is entered in the alarm history log.
<i>Normal:</i> No alarm conditions active (may include autoreset alarms)	Green, steadily lit	None	Not applicable.

13.1.1 Alarm messages

In addition to displaying the urgency level of an alarm, the ventilator displays alarm messages for the two highest-priority active alarms near the top of the graphic user interface (GUI) upper screen. Figure 13-1 shows the format for alarm messages.

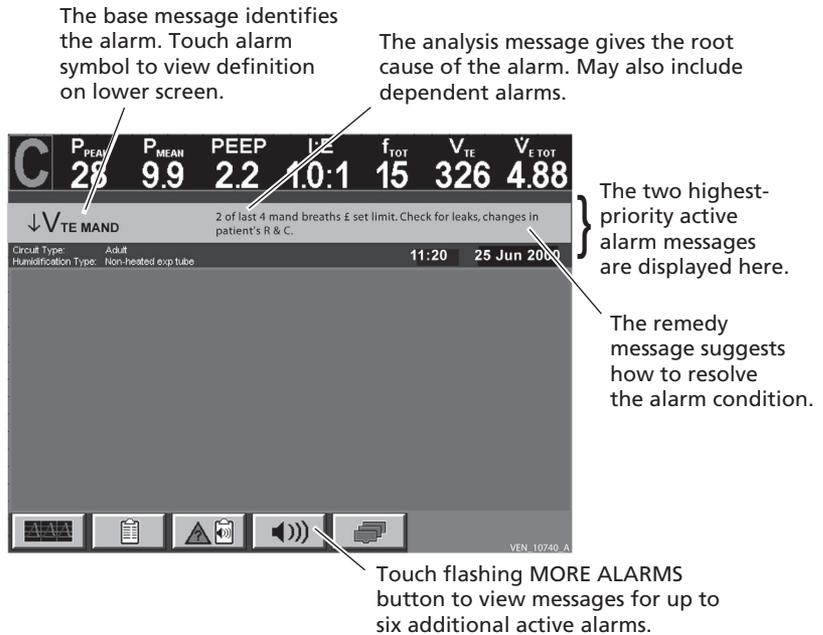


Figure 13-1. Alarm message format (upper GUI screen)

The following rules define how alarm messages are displayed:

- If the ventilator is interfaced to an external device to collect data for trending and other monitoring purposes, that external data is not considered in alarm handling.
- Initial alarms, called *primary alarms* precede any dependent alarms, those alarms arising from *primary alarms*.
- The system adds dependent alarms to the analysis messages of each active primary alarm with which they are associated. If a dependent alarm resets, the system removes it from the analysis message of the primary alarm.

- The urgency level of a primary alarm is equal to or greater than the urgency level of any of its active dependent alarms.
- An alarm cannot be a dependent alarm of any alarm that occurs subsequently.
- If a primary alarm resets, any active dependent alarms become primary unless they are also dependent alarms of another active primary alarm.
- The system applies the new alarm limit to alarm calculations from the moment of change to an alarm limit.
- The urgency level of a dependent alarm is based solely on its detection conditions (not the urgency of any associated alarms).
- When an alarm causes the ventilator to go to idle mode, occlusion status cycling (OSC), or safety valve open (SVO), the patient data display (including waveforms) is blanked. The elapsed time without ventilatory support (that is, since idle mode, OSC, or SVO began) is displayed on the upper GUI screen. If the alarm causing idle mode, OSC, or SVO is autoreset, the ventilator resets *all* patient data alarm detection algorithms.

13.1.2 Alarm summary

Table 13-2 summarizes ventilator alarms, including urgency, messages, and other information.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
AC POWER LOSS	Low	Operating on battery.	Prepare for power loss.	Power switch on, AC power not available, ventilator operating on BPS. BPS operating indicator turns on. Resets when AC power is restored.
	Medium	Operational time < 2 minutes.		

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
APNEA (patient data alarm)	Medium	Apnea ventilation. Breath interval > apnea interval.	Check patient & settings.	The set apnea interval has elapsed without the ventilator, patient, or operator triggering a breath. Resets when patient initiates 2 consecutive breaths. Possible dependent alarm: $\downarrow \dot{V}_{E\text{ TOT}}$.
	High	Extended apnea duration or multiple apnea events.		
CIRCUIT DISCONNECT	High	No ventilation.	Check patient/ventilator status.	Ventilator has recovered from unintended power loss lasting more than 5 minutes, detects circuit disconnect, and switches to idle mode; upper screen displays elapsed time without ventilator support. Resets when ventilator senses reconnection.
	High	No ventilation.	Check patient. Reconnect circuit.	Ventilator detects circuit disconnect and switches to idle mode; upper screen displays elapsed time without ventilator support. Resets when ventilator senses reconnection.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
COMPLIANCE LIMITED V_T (patient data alarm)	Low	Compliance compensation limit reached.	Inspired volume may be < set. Check patient and circuit type.	Compliance volume required to compensate delivery of a volume controlled breath exceeds the maximum allowed for 3 of the last 4 breaths.
COMPRESSOR INOPERATIVE	Low	No compressor air. No operation during low AC power.	No remedy message displayed	Compressor ready indicator turns off. Resets when full AC power is restored.
	Low	No compressor air. No operation during A/C power loss.		Ventilator turns off compressor. Resets when full AC power is restored.
	Low	No compressor air.		Compressor ready indicator turns off.
	Low	N/A	Replace compressor.	Alarm occurs when there are no LOW AC POWER and no AC POWER LOSS alarms for < 15 seconds AND time since power-on > 10 seconds.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT	Low	Breath delivery not affected.	Service required.	Background checks have detected a problem. Resets when ventilator passes EST.
	Low	Ventilation continues as set.	Replace & service ventilator.	
	Low	Breath delivery not affected. Compromised spirometry.		
	Low	Breath delivery not affected. Possible compromise of other functions.	Service required.	POST has detected a problem. Resets when ventilator passes POST.
	Medium	Ventilation continues as set.	Replace & service ventilator.	Background checks have detected a problem. Accuracy of exhalation flow sensor temperature may be affected. Resets when ventilator passes EST.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT (cont)	Medium	Ventilation continues as set.	Replace & service ventilator.	Background checks have detected a problem. Accuracy of oxygen flow sensor temperature may be affected, ventilator using nominal value. Resets when ventilator passes EST.
	Medium	Breath delivery not affected. Compromised spirometry.		Background checks have detected a problem persisting for over 10 minutes. Resets when ventilator passes EST.
	Medium	Ventilation continues as set. Only O ₂ available.		Background checks have detected a problem. Ventilator delivers 100% O ₂ . Resets when ventilator passes EST.
	Medium	Breath delivery not affected. Compromised spirometry.	Check patient. Replace & service ventilator.	Background checks have detected a problem. Accuracy of exhalation flow sensor temperature may be affected. Resets when ventilator passes EST.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT (cont)	Medium	Ventilation continues as set. Only air available.	Replace & service ventilator.	Background checks have detected a problem. Ventilator delivers 21% O ₂ . Resets when ventilator passes EST.
	High	Breath delivery not affected.		Background checks have detected a problem. Loss of GUI indicator lights. Setting changes disabled. Resets when ventilator passes EST. Reference Table 13-3 on page TR 13-21 for information on actions to take.
	High	Unable to determine status of breath delivery.	Check patient. Replace & service ventilator.	Background checks have detected a problem. Loss of GUI indicator lights. Resets when communication between GUI and BDU is re-established.
	High	Ventilation continues as set.	Replace & service ventilator.	Background checks have detected a problem. Loss of GUI indicator lights. Alarms, setting changes, and monitored data disabled. Resets when ventilator passes EST. Reference Table 13-3 on page TR 13-21 for information on actions to take.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT (cont)	High	Ventilation continues as set.	Replace & service ventilator.	Background checks have detected a problem. Setting changes, monitored data, and alarms disabled. Resets when ventilator passes EST.
	High	Ventilation continues as set. Delivery/spiro may be compromised.	Replace & service ventilator.	Background checks have detected a problem. Setting changes not allowed. Resets when ventilator passes EST.
	High	Breath delivery not affected. Compromised spiro. Trig = pres.	Check patient. Replace & service ventilator.	Background checks have detected a problem and flow triggering was selected. Accuracy of exhalation flow sensor temperature may be affected. Resets when ventilator passes EST.
	High	Ventilation continues as set, except O ₂ % = 100	Check patient. Replace & service ventilator.	Background checks have detected a problem. Ventilator delivers 100% O ₂ instead of set O ₂ %. Resets when ventilator passes EST.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT (cont)	High	Ventilation continues as set. Compromised air delivery	Replace & service ventilator. Check patient.	Background checks have detected a problem. Accuracy of air flow sensor temperature may be affected, ventilator using nominal value. Resets when ventilator passes EST.
	High	Ventilation continues as set. Compromised O ₂ delivery	Replace & service ventilator. Check patient.	Background checks have detected a problem. Accuracy of oxygen flow sensor temperature may be affected, ventilator using nominal value. Resets when ventilator passes EST.
	High	Power loss & recovery occurred with a pre-existing Device Alert.	Check Alarm log. EST required.	Background checks have detected a problem. Loss of GUI indicator lights. Resets when ventilator passes EST.
	High	Ventilation continues as set, except O ₂ % = 21.	Check patient. Replace & service ventilator.	Background checks have detected a problem. Ventilator delivers 21% O ₂ instead of set O ₂ %. Resets when ventilator passes EST.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
DEVICE ALERT (cont)	High	No ventilation. Safety Valve Open.	Provide alternate ventilation. Replace & service ventilator.	Background checks have detected a problem. Safety valve open indicator lights. Upper screen displays elapsed time without ventilator support. Resets when ventilator passes EST.
	High	No ventilation. Safety Valve Open.	Check patient. Replace & service ventilator.	
	High	No ventilation. Safety Valve Open.	Provide alternate ventilation. Replace & service ventilator.	Background checks have detected a problem. Ventilator inoperative and safety valve open indicators light. Message may not be visible. If possible, upper screen displays elapsed time without ventilator support. Resets when ventilator passes EST.
↑P _{PEAK} (patient data alarm)	Low	Last breath ≥ set limit.	Check patient, circuit & ET tube.	Measured airway pressure ≥ set limit. Ventilator truncates current breath unless already in exhalation. Possible dependent alarms: ↓V _{TE MAND} , ↓V _{E TOT} , ↑f _{TOT} .
	Medium	Last 3 breaths ≥ set limit.		
	High	Last 4 or more breaths ≥ set limit.		

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
↓P _{PEAK} (patient data alarm)	Low	Last 2 breaths, pressure ≤ set limit.	Check for leaks.	Peak inspiratory pressure ≤ set limit. (Available only when Vent Type is NIV or during INVASIVE ventilation when Mandatory Type is VC+.)
	Medium	Last 4 breaths, pressure ≤ set limit.		
	High	Last 10 or more breaths, pressure ≤ set limit.		
↑O ₂ % (patient data alarm)	Medium	Measured O ₂ % > set for ≥ 30s but < 2 min.	Check patient, gas sources, O ₂ analyzer & ventilator.	The O ₂ % measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more above the O ₂ % setting for at least 30 seconds. (These percentages increase by 5% for 4 minutes following a decrease in the O ₂ % setting.) Alarm updated at 1-second intervals.
	High	Measured O ₂ % > set for ≥ 2 min.		
↑V _{TE} (patient data alarm)	Low	Last 2 breaths ≥ set limit.	Check settings, changes in patient's R & C.	Exhaled tidal volume ≥ set limit. Alarm updated whenever exhaled tidal volume is recalculated. Possible dependent alarm: ↑V _{E TOT} .
	Medium	Last 4 breaths ≥ set limit.		
	High	Last 10 or more breaths ≥ set limit.		

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
$\uparrow V_{E\text{TOT}}$ (patient data alarm)	Low	$\dot{V}_{E\text{TO}} \geq$ set limit for $\leq 30\text{s}$.	Check patient & settings.	Expiratory minute volume \geq set limit. Alarm updated whenever an exhaled minute volume is recalculated. Possible dependent alarm: $\uparrow V_{\text{TE}}$.
	Medium	$\dot{V}_{E\text{TO}} \geq$ set limit for $> 30\text{s}$.		
	High	$\dot{V}_{E\text{TOT}} \geq$ set limit for $> 120\text{s}$.		
$\uparrow f_{\text{TOT}}$ (patient data alarm)	Low	$f_{\text{TOT}} \geq$ set limit for $\leq 30\text{s}$.	Check patient & settings.	Total respiratory rate \geq set limit. Alarm updated at the beginning of each inspiration. Reset when measured respiratory rate falls below the alarm limit. Possible dependent alarms: $\downarrow V_{\text{TE MAND}}$ $\downarrow V_{\text{TE SPONT}}$, $\dot{V}_{E\text{TOT}}$.
	Medium	$f_{\text{TOT}} \geq$ set limit for $> 30\text{s}$.		
	High	$f_{\text{TOT}} \geq$ set limit for $> 120\text{s}$.		
$\uparrow P_{\text{VENT}}$ (patient data alarm)	Low	1 breath \geq limit.	Check patient, circuit & ET tube.	Inspiratory pressure $> 100 \text{ cmH}_2\text{O}$ and mandatory type = VC or spontaneous type= TC or PA. Ventilator truncates current breath unless already in exhalation. Possible dependent alarms: $\downarrow V_{\text{TE MAND}}$ $\downarrow \dot{V}_{E\text{TOT}}$, $\uparrow f_{\text{TOT}}$.
	Medium	2 breaths \geq limit.		
	High	3 or more breaths \geq limit.		

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
INOPERATIVE BATTERY	Low	Inadequate charge or non-functional battery system.	Service/replace battery.	BPS installed but not functioning. Resets when BPS is functional.
INSPIRATION TOO LONG (patient data alarm)	Low	Last 2 spont breaths = IBW based T_I limit.	Check patient. Check for leaks.	Inspiratory time for spontaneous breath \geq IBW-based limit. Ventilator transitions to exhalation. Resets when T_I falls below IBW-based limit. Active only when Vent Type is INVASIVE.
	Medium	Last 4 spont breaths = IBW based T_I limit.		
	High	Last 10 or more spont breaths = IBW based T_I limit.		
LOSS OF POWER	High			The ventilator power switch is on and there is insufficient power from AC and the BPS (if installed). There may not be a visual indicator for this alarm, but an independent audio alarm sounds for at least 120 seconds. Alarm annunciation can be reset by turning power switch to off position.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
LOW AC POWER	Low	Ventilator currently not affected.	Power interrupt possible.	Mains (AC) power has dropped below 80% of nominal for 1 second. Ventilator continues operation as close to settings as possible. Resets when there is no low AC power signal for 1 second.
LOW BATTERY	Low	Operational time < 2 minutes.	Replace or allow recharge.	Resets when BPS has more than approximately 2 minutes of operational time remaining.
↓O ₂ % (patient data alarm)	High	Measured O ₂ % < set O ₂ %.	Check patient, gas sources, O ₂ analyzer & ventilator.	The O ₂ % measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more below the O ₂ % setting for at least 30 second, or below 18%. (These percentages increase by 5% for 4 minutes following an increase in the O ₂ % setting.) Alarm updated at 1-second intervals.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
↓ $V_{TE\ MAND}$ (patient data alarm)	Low	Last 2 mand. breaths ≤ set limit.	Check for leaks, changes in patient's R & C.	Exhaled mandatory tidal volume ≤ set limit. Alarm updated whenever exhaled mandatory tidal volume is recalculated. Possible dependent alarms: ↑ $\dot{V}_{E\ TOT}$, ↑ f_{TOT} .
	Medium	Last 4 mand. breaths ≤ set limit.		
	High	Last 10 or more mand. breaths ≤ set limit.		
↓ $V_{TE\ SPONT}$ (patient data alarm)	Low	Last 2 spont breaths ≤ set limit.	Check patient & settings.	Exhaled spontaneous tidal volume ≤ set limit. Alarm updated whenever exhaled spontaneous tidal volume is recalculated. Possible dependent alarms: ↓ $\dot{V}_{E\ TOT}$, ↑ f_{TOT} .
	Medium	Last 4 spont breaths ≤ set limit.		
	High	Last 10 or more spont breaths ≤ set limit.		
↓ $\dot{V}_{E\ TOT}$ (patient data alarm)	Low	$\dot{V}_{E\ TO} \leq$ set limit for ≤ 30s.	Check patient & settings.	Total minute volume ≤ set limit. Alarm updated whenever exhaled minute volume is recalculated. Possible dependent alarms: ↓ $V_{TE\ MAND}$, ↓ $V_{TE\ SPONT}$, ↑ f_{TOT} .
	Medium	$\dot{V}_{E\ TO} \leq$ set limit for > 30s.		
	High	$\dot{V}_{E\ TO} \leq$ set limit for > 120s.		

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
NO AIR SUPPLY	Low	Ventilation continues as set. Only O ₂ available.	Check air source.	Operator-set O ₂ % equals 100%. Ventilator delivers 100% O ₂ . Resets if air supply connected.
	Low	Compressor inoperative. Ventilation continues as set. Only O ₂ available.		
	High	Ventilation continues as set except O ₂ % = 100	Check patient & air source.	
	High	Compressor inoperative. Ventilation continues as set, except O ₂ % = 100.		
NO AIR SUPPLY and NO O ₂ SUPPLY	High	No ventilation. Safety Valve Open.	Provide alternate ventilation. Check both gas sources.	Safety valve open indicator lights. Upper screen displays elapsed time without ventilator support. Safety valve closes and indicator turns off if either gas supply is connected. Individual gas supply alarm resets when corresponding supply is connected.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
NO O ₂ SUPPLY	Low	Ventilation continues as set. Only air available.	Check O ₂ source.	Operator-set O ₂ % equals 21%. Resets if O ₂ supply connected.
	High	Ventilation continues as set, except O ₂ % = 21.	Check patient & O ₂ source	Operator-set O ₂ % > 21%. Ventilator delivers 21% O ₂ instead of set O ₂ %. Resets if oxygen supply connected.
O ₂ SENSOR	Low	Ventilation unaffected.	O ₂ sensor out of calibration /failure. Press 100% O ₂ CAL or INCREASE O ₂ 2 min, replace or disable.	Background checks have detected a problem. Resets when operator successfully calibrates oxygen sensor, or disables oxygen sensor.
PROCEDURE ERROR	High	Patient connected before setup complete.	Provide alternate ventilation. Complete setup process.	Ventilator begins safety ventilation. Resets when ventilator startup procedure is complete.

Table 13-2: Alarm summary

Base message	Urgency	Analysis message	Remedy message	Comments
SCREEN BLOCK	Medium	Possible blocked beam or touch screen fault.	Remove obstruction or service ventilator.	Background checks have detected a problem. Resets when ventilator passes EST or when blockage is removed.
SEVERE OCCLUSION	High	Little/no ventilation.	Check patient. Provide alternate ventilation. Clear occlusions; drain circuit.	Ventilator enters occlusion status cycling (OSC) and upper screen displays elapsed time without ventilator support.

Table 13-3: Loss of GUI Display

Symptom	Alarm Condition	Ventilator Function	Recommended Action
Loss of GUI display (upper and lower)	<ul style="list-style-type: none"> Loss of GUI indicator  <p style="text-align: center; font-size: small;">VEN_100401_A</p> <ul style="list-style-type: none"> High priority audible alarm 	<ul style="list-style-type: none"> Ventilation continues as set Breath delivery not affected Audible alarms not affected. 	<ul style="list-style-type: none"> Verify the patient's respiratory and physiological stability. Confirm the patient is receiving ventilator support by observation of the expansion and contraction of the patient's chest. Assess current patient status by review of other monitoring indicators (e.g. oxygen saturation, heart rate, blood pressure, etc.). Promptly transfer the patient to an alternate source of ventilation consistent with your institutional protocol. Remove the affected ventilator from use until it has been serviced.

Table 13-3: Loss of GUI Display (cont)

<p>Loss of display (upper, lower, or both) and ...</p>	<p>No alarm messages displayed</p>	<ul style="list-style-type: none"> • Ventilation continues as set • Breath delivery not affected • Audible alarms not affected • Alarm status indicator panel functions 	<ul style="list-style-type: none"> • Verify the patient's respiratory and physiological stability. • Confirm the patient is receiving ventilator support by observation of the expansion and contraction of the patient's chest. • Assess current patient status by review of other monitoring indicators (e.g. oxygen saturation, heart rate, blood pressure, etc.). • Promptly transfer the patient to an alternate source of ventilation consistent with your institutional protocol. • Remove the affected ventilator from use until it has been serviced.
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Table 13-3: Loss of GUI Display (cont)

<p>Loss of GUI display (upper, lower, or both) and ...</p>	<ul style="list-style-type: none"> • VENT INOP displayed on BDU  <p>VEN_10389_A</p>	<p>Ventilator is not providing breaths, ventilator assistance, or supplemental oxygen.</p>	<p>Immediately transfer the patient to an alternate source of ventilation</p>
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13.2 AC POWER LOSS alarm

The AC POWER LOSS alarm indicates the ventilator power switch is on and the ventilator is being powered by the backup power source (BPS). The ventilator annunciates a low-urgency alarm when the ventilator has been operated by the BPS for at least 3 seconds and at least 2 minutes of BPS power are available. The ventilator annunciates a medium-urgency alarm when less than 2 minutes of BPS power are estimated available.

The AC POWER LOSS alarm indicates the ventilator is being powered by the BPS and an alternate power source may soon be required to sustain normal ventilator operation. During an AC POWER LOSS condition, power to the humidifier and compressor is not available.

13.3 APNEA alarm

The APNEA alarm indicates neither the ventilator nor the patient has triggered a breath for the operator-selected apnea interval (T_A). T_A is measured from the start of an inspiration to the start of the next inspiration and is based on the ventilator's inspiratory detection criteria. T_A can only be selected via the apnea ventilation settings.

The APNEA alarm autoresets when the patient initiates two successive breaths, and is intended to establish the patient's inspiratory drive is reliable enough to resume normal ventilation. To ensure the breaths are patient-initiated (and not due to autotriggering), exhaled volumes must be at least half the V_T (this avoids returning to normal ventilation if there is a disconnect).

The ventilator monitors breathing from the start of inspiration to the start of expiration and allows the ventilator to declare apnea when the patient fails to take a breath, rather than when he/she fails to exhale on schedule.

13.4 CIRCUIT DISCONNECT alarm

The CIRCUIT DISCONNECT alarm indicates the patient circuit is disconnected at the ventilator or the patient side of the patient wye, or a large leak is present. The methods by which circuit disconnects are detected vary depending on breath type. Time, pressure, flow, delivered volume, exhaled volume, and the D_{SENS} setting may be used in the circuit disconnect detection algorithms. See Section 10.2 on page TR 10-3 for a complete discussion of the CIRCUIT DISCONNECT detection methods.

You can set the sensitivity of the CIRCUIT DISCONNECT alarm by adjusting the D_{SENS} setting. During a CIRCUIT DISCONNECT condition, the ventilator enters idle mode and delivers a 10 L/min flow of oxygen to detect a reconnection.

When the ventilator determines the patient circuit is reconnected, the CIRCUIT DISCONNECT alarm autoresets and normal ventilation resumes without having to manually reset the alarm (for example, following suctioning).

A disconnected patient circuit interrupts gas delivery and patient monitoring. Notification of a patient circuit disconnect is crucial, particularly when the patient cannot breathe spontaneously. The ventilator does not enter apnea ventilation when a disconnect is detected to avoid changing modes during a routine suctioning procedure.

13.5 DEVICE ALERT alarm

A DEVICE ALERT alarm indicates a background test or power on self test (POST) has failed. Depending on which test failed, the ventilator either declares an alarm and continues to ventilate according to current settings, or ventilates with modified settings, or enters the ventilator inoperative state. The DEVICE ALERT alarm relies on the ventilator's self-testing and notifies you of an abnormal condition requiring service.

13.6 High circuit pressure alarm

The high circuit pressure ($\uparrow P_{PEAK}$) alarm indicates the currently measured airway pressure is equal to or greater than the set $\uparrow P_{PEAK}$ limit. The $\uparrow P_{PEAK}$ limit is active during mandatory and spontaneous breaths, and during inspiration and exhalation. The $\uparrow P_{PEAK}$ limit is active in all normal ventilation modes. The $\uparrow P_{PEAK}$ limit is not active during a SEVERE OCCLUSION alarm.

The $\uparrow P_{PEAK}$ limit cannot be set less than:

$PEEP + 7 \text{ cmH}_2\text{O}$, or

$PEEP + P_I + 2 \text{ cmH}_2\text{O}$, or

$PEEP + P_{SUPP} + 2 \text{ cmH}_2\text{O}$

nor can it be set less than or equal to $\downarrow P_{PEAK}$.

You cannot disable the $\uparrow P_{PEAK}$ limit. The ventilator phases in changes to the $\uparrow P_{PEAK}$ limit immediately to allow prompt notification of a high circuit pressure condition.

The minimum $\uparrow P_{PEAK}$ limit (7 cmH₂O) corresponds to the lowest peak pressures not due to autotriggering anticipated during a mandatory breath. The maximum $\uparrow P_{PEAK}$ limit (100 cmH₂O) was selected because it is the maximum pressure required to inflate the lungs of a patient with very low-compliance lungs.

The ventilator allows circuit pressure to rise according to a computed triggering profile for the initial phase of PC and PS breaths without activating the $\uparrow P_{PEAK}$ alarm. This triggering profile helps avoid nuisance alarms due to possible transient pressure overshoot in the airway when aggressive values of rise time % are selected. A pressure overshoot measured in the patient circuit is unlikely to be present at the carina.

The $\uparrow P_{PEAK}$ alarm is active throughout inspiration and exhalation to provide redundant patient protection (for example, to detect occlusions downstream of the pressure-sensing device).

13.7 High delivered O₂% alarm

The high delivered O₂% ($\uparrow O_2\%$) alarm indicates the measured O₂% during any phase of a breath is at or above the error percentage above the O₂% setting for at least 30 seconds. Although the ventilator automatically sets the $\uparrow O_2\%$ alarm limits, you can disable

the oxygen sensor. (The error percentage is 12% above setting for the first hour of ventilator operation, 7% above setting after the first hour of operation, and an additional 5% above setting for the first four minutes following a decrease in the setting.)

The ventilator automatically adjusts the $\uparrow\text{O}_2\%$ alarm limit when $\text{O}_2\%$ changes due to 100% O_2 , apnea ventilation, occlusion, circuit disconnect, or a NO AIR/ O_2 SUPPLY alarm. The ventilator checks the $\uparrow\text{O}_2\%$ alarm limit against the measured oxygen percentage at 1-second intervals.

The $\uparrow\text{O}_2\%$ alarm detects malfunctions in ventilator gas delivery or oxygen monitor. The $\uparrow\text{O}_2\%$ alarm limit automatically adjusts during 100% O_2 suction, apnea ventilation, patient circuit disconnect, or low air inlet pressure because $\text{O}_2\%$ changes are expected under those circumstances. The ventilator declares a $\uparrow\text{O}_2\%$ alarm after 30 seconds to eliminate transient $\text{O}_2\%$ delivery variation nuisance alarms.

13.8 High exhaled minute volume alarm

The high exhaled minute volume ($\uparrow\dot{V}_{E\text{TOT}}$) alarm indicates the measured exhaled total minute volume for spontaneous and mandatory breaths is equal to or greater than the set $\uparrow\dot{V}_{E\text{TOT}}$ limit. The $\uparrow\dot{V}_{E\text{TOT}}$ alarm is updated whenever a new value is available.

The $\uparrow\dot{V}_{E\text{TOT}}$ alarm can be used to detect a change in a patient's breathing pattern, or a change in compliance or resistance. The $\uparrow\dot{V}_{E\text{TOT}}$ alarm can also detect too-large tidal volumes, which could lead to hyperventilation and hypocarbia.

The $\uparrow\dot{V}_{E\text{TOT}}$ alarm is effective immediately upon changing the setting, to ensure prompt notification of prolonged high tidal volumes.

13.9 High exhaled tidal volume alarm

The high exhaled tidal volume ($\uparrow V_{TE}$) alarm indicates the measured exhaled tidal volume for spontaneous and mandatory breaths is equal to or greater than the set $\uparrow V_{TE}$ limit. The $\uparrow V_{TE}$ alarm is updated whenever a new measured value is available.

The $\uparrow V_{TE}$ alarm can detect increased exhaled tidal volume (due to greater compliance and lower resistance) and prevent

hyperventilation during pressure control ventilation or pressure support. You can turn the $\uparrow V_{TE}$ alarm OFF to avoid nuisance alarms. (Hyperventilation due to increased compliance is not a concern during volume-based ventilation, because the tidal volume is fixed by the clinician's choice and the ventilator's compliance-compensation algorithm.)

13.10 High inspired tidal volume alarm

The high inspired tidal volume alarm indicates the patient's inspired volume exceeds the set limit. When this condition occurs, the breath terminates and the alarm sounds. The selected combination of mandatory and/or spontaneous breath type settings determines the symbol appearing in the alarm message, alarm log, and alarm settings screen ($\uparrow V_{TI}$, $\uparrow V_{TI\ MAND}$, or $\uparrow V_{TI\ SPONT}$). The ventilator system displays monitored inspired tidal volume values in the patient data area on the GUI screen. Table 13-4 shows the symbol corresponding to the ventilator settings in effect.

Table 13-4: Applicability of high inspired tidal volume alarm symbols

Alarm symbol	Alarm setting or patient data symbol	Mandatory or spontaneous type setting
$\uparrow V_{TI}$	V_{TI}	VC+ and TC (concurrently)
$\uparrow V_{TI\ MAND}$	$V_{TI\ MAND}$	VC+
$\uparrow V_{TI\ SPONT}$	$V_{TI\ SPONT}$	VS or TC

When Vent Type is NIV, there is no high inspired tidal volume alarm or setting available, but the monitored inspired tidal volume (V_{TI}) appears in the patient data area on the GUI screen.

13.11 High respiratory rate alarm

The high respiratory rate ($\uparrow f_{TOT}$) alarm indicates the measured breath rate is greater than or equal to the set $\uparrow f_{TOT}$ limit. The $\uparrow f_{TOT}$ alarm is updated whenever a new total measured respiratory rate is available.

The $\uparrow f_{TOT}$ alarm can detect tachypnea, which could indicate the tidal volume is too low or the patient's work of breathing has increased. The ventilator phases in changes to the $\uparrow f_{TOT}$ limit immediately to ensure prompt notification of a high respiratory rate condition.

13.12 INSPIRATION TOO LONG alarm

The INSPIRATION TOO LONG alarm, active only when Vent Type is INVASIVE, indicates the inspiratory time of a spontaneous breath exceeds this time limit:

(1.99 + 0.02 x IBW) seconds (adult and pediatric circuits)

(1.0 + 0.10 x IBW) seconds (neonatal circuits)

where *IBW* is the current setting for ideal body weight in kg.

When the ventilator declares an INSPIRATION TOO LONG alarm, the ventilator terminates inspiration and transitions to exhalation. The INSPIRATION TOO LONG alarm applies only to spontaneous breaths. You cannot set or disable the INSPIRATION TOO LONG alarm.

Because leaks (in the patient circuit, around the endotracheal tube cuff, or through chest tubes) and patient-ventilator mismatch can affect accurate exhalation detection, the INSPIRATION TOO LONG alarm can act as a backup method of safely terminating inspiration. If the INSPIRATION TOO LONG alarm occurs frequently, check for leaks and ensure E_{SENS} and rise time % are properly set.

13.13 Low circuit pressure alarm

The low circuit pressure ($\downarrow P_{PEAK}$) alarm indicates the measured maximum airway pressure during the current breath is less than or equal to the set alarm level during a non-invasive inspiration or during a VC+ inspiration.

The $\downarrow P_{PEAK}$ alarm is active for mandatory and spontaneous breaths, and is present only when Vent Type is NIV or Mandatory Type is VC+. During VC+, if the PEEP level is set to 0 cmH₂O, the $\downarrow P_{PEAK}$ alarm can be turned OFF. The $\downarrow P_{PEAK}$ alarm can always be turned OFF during

NIV. The $\downarrow P_{PEAK}$ alarm limit cannot be set to a value greater than or equal to the $\uparrow P_{PEAK}$ alarm limit.

Warning

Because the VC+ pressure control algorithm does not allow the target inspiratory pressure to fall below PEEP + 5 cmH₂O, attempting to set the $\downarrow P_{PEAK}$ alarm limit at or below this level will turn the alarm off.

Whenever PEEP is changed, $\downarrow P_{PEAK}$ is set automatically to its New Patient value, PEEP + 6 cmH₂O.

There are no alarms dependent upon $\downarrow P_{PEAK}$, and the $\downarrow P_{PEAK}$ alarm does not depend on other alarms.

13.14 Low delivered O₂% alarm

The low delivered O₂% ($\downarrow O_2\%$) alarm indicates the measured O₂% during any phase of a breath is at or below the error percentage below the O₂% setting, or less than or equal to 18%, for at least 30 seconds. Although the ventilator automatically sets the $\downarrow O_2\%$ alarm, you can disable the oxygen sensor. (The error percentage is 12% below setting for the first hour of ventilator operation, 7% below setting after the first hour of operation, and an additional 5% below setting for the first four minutes following a increase in the setting.)

The ventilator automatically adjusts the $\downarrow O_2\%$ alarm limit when O₂% changes due to apnea ventilation, circuit disconnect, or a NO O₂/AIR SUPPLY alarm. The $\downarrow O_2\%$ alarm is disabled during a safety valve open (SVO) condition. The ventilator checks the $\downarrow O_2\%$ alarm against the measured oxygen percentage at 1-second intervals.

The $\downarrow O_2\%$ alarm can detect malfunctions in ventilator gas delivery or the oxygen monitor, and can ensure the patient is adequately oxygenated. The $\downarrow O_2\%$ alarm limit is automatically adjusted during apnea ventilation, patient circuit disconnect, or low gas inlet pressures because O₂% changes are expected under those circumstances. The ventilator declares a $\downarrow O_2\%$ alarm after 30 seconds to eliminate nuisance alarms due to transient O₂% delivery variations. You can view the O₂% measured by the oxygen sensor by touching the More Patient Data button on the upper GUI screen.

13.15 Low exhaled mandatory tidal volume alarm

The low exhaled mandatory tidal volume ($\downarrow V_{TE\ MAND}$) alarm indicates the measured exhaled mandatory tidal volume is less than or equal to the $\downarrow V_{TE\ MAND}$ limit. The $\downarrow V_{TE\ MAND}$ alarm is updated whenever a new measured value of exhaled mandatory tidal volume is available.

The $\downarrow V_{TE\ MAND}$ alarm can detect an obstruction, a leak during volume ventilation, or a change in compliance or resistance during pressure-based ventilation (that is, when the same pressure is achieved but tidal volume decreases). There are separate alarms for mandatory and spontaneous exhaled tidal volumes for use during SIMV, SPONT, and BILEVEL. The ventilator phases in a change to the $\downarrow V_{TE\ MAND}$ alarm immediately to ensure prompt notification of a low exhaled tidal volume condition.

13.16 Low exhaled spontaneous tidal volume alarm

The low exhaled spontaneous tidal volume ($\downarrow V_{TE\ SPONT}$) alarm indicates the measured exhaled spontaneous tidal volume is less than or equal to the $\downarrow V_{TE\ SPONT}$ limit. The $\downarrow V_{TE\ SPONT}$ alarm is updated whenever a new measured value of exhaled spontaneous tidal volume is available.

The $\downarrow V_{TE\ SPONT}$ alarm can detect a leak in the patient circuit or a change in the patient's respiratory drive during a single breath. The $\downarrow V_{TE\ SPONT}$ alarm is based on the current breath rather than on an average to detect changes as quickly as possible. There are separate alarms for mandatory and spontaneous exhaled tidal volumes for use during SIMV. The ventilator phases in a change to the $\downarrow V_{TE\ SPONT}$ alarm limit immediately to ensure prompt notification of a low exhaled tidal volume condition.

13.17 Low exhaled total minute volume alarm

The low exhaled total minute volume ($\downarrow\dot{V}_{E\text{TOT}}$) alarm indicates the measured minute volume (for mandatory and spontaneous breaths) is less than or equal to the set $\downarrow\dot{V}_{E\text{TOT}}$ limit. The $\downarrow\dot{V}_{E\text{TOT}}$ alarm is updated whenever a new value for exhaled minute volume is calculated. You cannot turn off the $\downarrow\dot{V}_{E\text{TOT}}$ alarm.

The $\downarrow\dot{V}_{E\text{TOT}}$ alarm can detect a leak or obstruction in the patient circuit, a change in compliance or resistance, or a change in the patient's breathing pattern. The $\downarrow\dot{V}_{E\text{TOT}}$ alarm can also detect too-small tidal volumes, which could lead to hypoventilation and hypoxia (oxygen desaturation).

The ventilator phases in changes to the $\downarrow\dot{V}_{E\text{TOT}}$ alarm limit immediately to ensure prompt notification of prolonged low tidal volumes.

13.18 PROCEDURE ERROR alarm

The ventilator declares a PROCEDURE ERROR alarm if ventilator is powered up (either by turning on the power switch or following a power loss of at least 5 minutes) and detects a patient attached before Ventilator Startup has been completed. Until ventilator settings are confirmed, the ventilator annunciates a high-urgency alarm and enters safety ventilation.

The PROCEDURE ERROR alarm is intended to require you to confirm ventilator settings whenever ventilator power is restored, in case a new patient is attached to the ventilator. Safety ventilation is an emergency mode of ventilation providing ventilation according to displayed settings until you have confirmed ventilator settings, and is not intended for long-term patient ventilation.

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