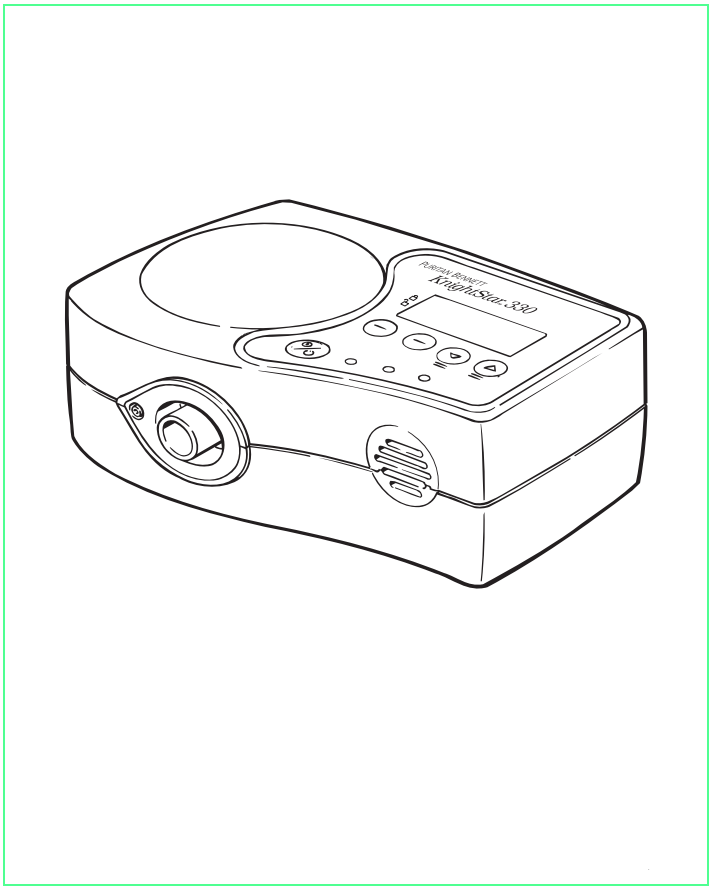
PURITAN
BENNETT

KnightStar® 330
Bi-Level® Ventilator



Y-500008-00 Rev. H

Clinician's Manual

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Introduction

The Puritan Bennett *KnightStar 330* is a continuous bi-level ventilator that provides noninvasive ventilation for the treatment of respiratory insufficiency and obstructive sleep apnea that may occur in the home.

The *KnightStar 330* is also indicated for the treatment of respiratory failure in institutional environments, and is intended to assist the ventilation of spontaneously breathing patients who are over 30 kg (66 lbs) in weight.

CAUTION:
Read this manual and the *KnightStar 330 User's Manual* thoroughly before operating the device. The manuals provide clinical as well as technical information concerning the operation and performance of the Puritan Bennett *KnightStar 330* bi-level ventilator.

The *KnightStar 330* is a microprocessor-controlled pressure generator capable of monitoring the air flow and controlling the pressure delivered to the patient. The *KnightStar 330* possesses the following features:

- Provides three operation modes: CPAP, I/E PAP, and Assist Control (A/C).
- Monitors pressure, tidal volume, respiratory rate, air leaks, peak flow, and the I:E ratio.
- Provides adjustable inspiratory and expiratory trigger sensitivity.
- Provides precise respiratory support and patient comfort.
- Provides audible and visual indicators to alert users to power failure, system leaks, device performance.
- Allows a maximum pressure setting of 30 cmH_2O; with a pressure limitation of 40 cmH_2O for a single-fault condition.
- Compensates for delivered pressure within specification for altitudes from 0 to 8,000 feet (2438 meters), at 4 to 30 cmH_2O; and compensates for leaks up to 60 liters per minute.

There are certain limitations and instructions that must be understood by the clinician and patient before using the *KnightStar 330*. Refer to Appendix C: What the Patient and Caregiver Must Know.

Patient and Clinician Access Levels

The *KnightStar 330* features two access levels:

- Patient access (*Lockout* mode "Active")
- Clinician access

The patient access level enables the patient to turn the device on and off, and to adjust comfort settings.

The clinician access level enables the caregiver to access all of the prescription settings and device controls, as well as the patient access features.

In the sleep lab, the *KnightStar 330* can be operated with either the optional remote control, or the control panel on the device. The device's controls enable the user to input the patient's prescription settings and review the estimated tidal volume, estimated peak flow, estimated leak, respiratory rate, I:E ratio, IPAP, and EPAP settings.

For home care applications, the home care provider can set the patient's prescribed parameters. All prescription parameters programmed by the home care provider are stored in the *KnightStar 330*'s memory.

If the prescription settings are corrupted, the *KnightStar 330* will not operate. Instead, an alarm symbol and error number appear on the display, and the audible alarm will sound.

Figure 1 shows the components that make up the *KnightStar 330* system.

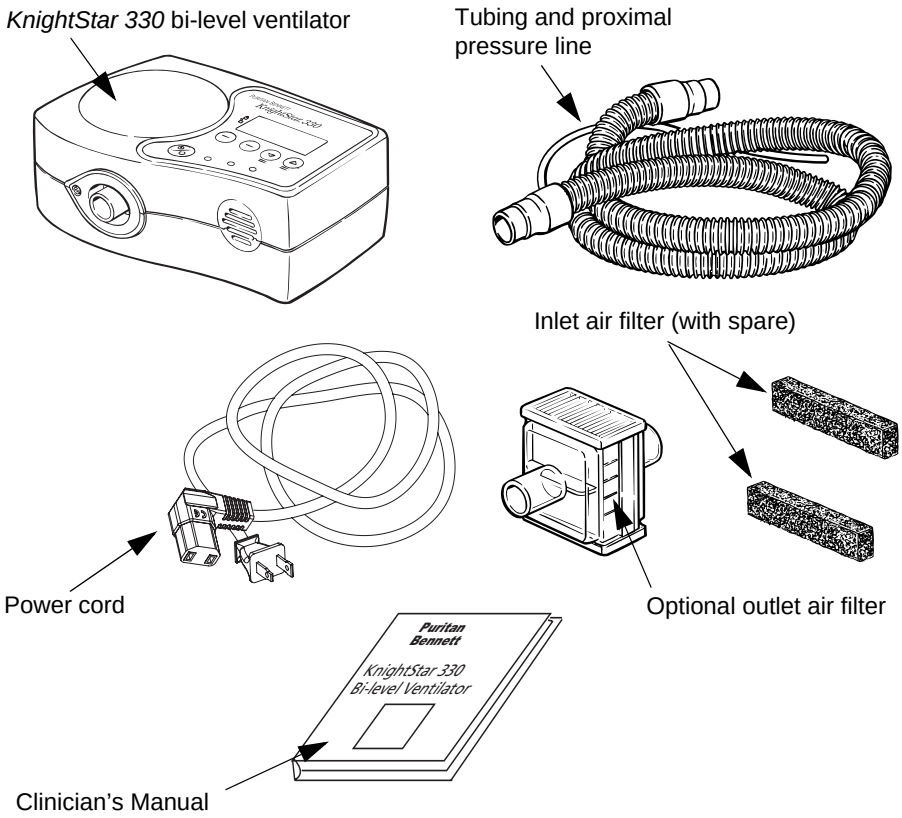


Figure 1. KnightStar 330 Components

It is recommended to use the *KnightStar 330* with 6-ft (1.8 m) or 8-ft (2.4 m) tubing and Puritan Bennett nasal interfaces, and *Breeze*™ or *ADAM*™ circuits.

Three modes of operation are available:

- CPAP (continuous positive airway pressure)
- I/E PAP (inspiratory and expiratory positive airway pressure)
- A/C (Assist Control)

In the *CPAP* mode, the system delivers a continuous positive regulated airway pressure throughout the breath cycle (normal operating range is from 3 cmH_2O to 20 cmH_2O).

In the *I/E PAP* mode, the system tracks patient breathing effort and provides two levels of pressure—a higher level of pressure for inspiration (normal operating range from 3 to 30 cmH_2O) and a lower pressure for expiration (normal operating range from 3 to 20 cmH_2O).

In the *A/C* mode, the system delivers the same two levels of pressure as described for the *I/E PAP* mode with the addition of a backup breath rate (normal operating range from 3 to 30 breaths per minute) and an I:E ratio (normal operating range from 1:1.0 to 1:4.0).

When *Lockout* mode is active, the settings available to the patient are:

- Delay Time
- Ramp Time
- Ramp Starting Pressure

CAUTION:
Before using the Knightstar 330, read all warnings and cautions in the next section.

Warnings, Cautions, and Notes

Information about specific hazards or special significance are presented in the following formats:

WARNING: Indicates a condition that can endanger the patient or the device operator.

CAUTION: Indicates a condition that can damage the device and/or other property.

NOTE:

Indicates information of particular interest for more efficient and convenient device operation.

WARNINGS:

Clinical research indicates that CPAP therapy may be CONTRAINDICATED for patients with the following pre-existing conditions:

- **Bullous lung disease**
- **Pneumothorax**
- **Severe cardiac rhythm disturbances**
- **Extremely low blood pressure**
- **Pneumocephalus or pre-existing CSF leaks or head trauma (Chest 1989; 96: 1425 - 1426)**
- **Acute sinus or middle ear infection (may be an indication to suspend CPAP therapy temporarily)**
- **Unstable airway**
- **Acute facial trauma**

The physician's prescription should be based upon the appropriate diagnostic testing. The prescribed nasal pressure should only be adjusted by trained, authorized personnel in accordance with the physician's prescription.

Use only interfaces and accessories that are approved by Puritan Bennett.

WARNINGS (continued):
The physician's prescription should be followed in accordance with established medical protocols.

An alternate means of ventilation must be available when patients are being treated for respiratory failure.

Alarms should never be disabled for patients who could be injured due to ineffective or interrupted ventilation. The physician should determine secondary or independent alarms.

Alarm volume should be set in accordance with ambient noise level. Respond immediately to all alarm conditions.

Patients receiving supplemental oxygen should be advised of the hazards of combustible materials and flames or sparks in the presence of oxygen. Do not smoke in the presence of oxygen.

To prevent oxygen from accumulating in the device and tubing, turn on the device before turning on the oxygen supply; shut off the oxygen before turning off the device.

Patients receiving supplemental oxygen and nasal pressure therapy should be monitored for arterial blood oxygen saturation.

Configure the KnightStar 330 system as shown in this manual for safe and effective operation.

Always place the KnightStar 330 upright on a firm, flat surface. Setting KnightStar 330 on uneven surfaces or in a position that is not upright may result in damage to the unit.

Do not use the KnightStar 330 with antistatic or electrically conductive tubing.

The KnightStar 330 should never be operated in the presence of anaesthetic gases. The equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide. Placing the unit in such an area may result in an explosion.

WARNINGS (continued):
The KnightStar 330 device should never be operated where the air intake might draw in hazardous gases from external sources such as gas stoves, engine exhaust, or anesthesia machines. Placing the unit in such an area may result in asphyxiation of the patient.

Do not set the device on or within 3 feet (1 m) of electric or electronic appliances, such as space heaters, electric blankets, or televisions. Do not operate cordless phones near the device. Doing so may result in device malfunction.

The KnightStar 330 should be used with care to avoid overheating the patient when the room temperature exceeds 90 °F (32.2 °C), since under certain conditions the patient outlet gas flow can be as much as 6.7 °F (3.7 °C) degrees warmer than room temperature.

The KnightStar 330 should be used only with interfaces recommended by the device's manufacturer. An interface should not be used unless the device is turned on and operating properly. The purge hole(s) associated with the interface should never be blocked. The purge hole(s) allow a continuous flow of air out of the interface. When the device is turned on and operating properly, fresh air from the device flushes most of the expired air out through the interface purge hole(s). However, when the device is not operating, a substantial proportion of expired air and carbon dioxide may be rebreathed. Rebreathing of carbon dioxide can increase levels of CO_2, and in some circumstances cause the patient to become somnolent and may even result in death.

This device must never be operated with an obstructed airway circuit. Prevent foreign matter from entering the airway circuit. Failure to do so could result in asphyxiation of the patient.

Should the patient experience excessive nasal or airway dryness, skin sensitivity, runny nose, ear pain, sinus discomfort, daytime sleepiness, mood change, disorientation, or memory lapse when using this device, discontinue use and call the physician.

WARNINGS (continued):
Do not block or restrict airflow around the device. Unimpeded airflow is necessary to maintain proper pressure and flow to the patient.

For patient health and comfort, it is important to clean the patient interface regularly. Follow the cleaning instructions that came with your patient interface.

Contact the home care company if the equipment malfunctions in any way. Do not attempt to open the device case. Only qualified personnel may service this equipment.

To reduce the risk of strangulation, ensure that the patient tubing is routed away from the patient's head.

The KnightStar 330 equipment has been tested and found to comply with the limits for medical devices to IEC 601-1-2:1993 (or EN 60601-1-2:1994 or Medical Device Directive 93/42/EEC). This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the devices**
- **Increase the separation between the devices**
- **Connect the equipment to an outlet on a different circuit**
- **Consult the manufacturer or your local representative for help**

The factory default setting for Lockout mode is inactive. The clinician is responsible for activating Lockout mode.

Under certain conditions, some alarms may not occur. For example: (1) The leak alarm may not occur if patient breath efforts are not detected, as in the case of excessively large leaks; and (2) The low pressure alarm may not occur under conditions such as an incorrect alarm threshold setting, or air pathway resistance. Check all alarms and settings for correct alarm operation prior to use.

WARNINGS (continued):
Be careful when handling the KnightStar 330 during or immediately after use. Under specified operating conditions, some surfaces of the unit may become hot to the touch. This is a normal occurrence and is typical of this type of device.

CAUTIONS:

Federal (USA) Law restricts this device to sale by or on the order of a physician.

The KnightStar 330 will discontinue operation upon loss of A/C power. The optional, external 12 V battery may be used as an alternate power source, but it is not intended for emergency backup power. Either A/C or external battery power may be connected to the KnightStar 330, but not both simultaneously. Refer to the battery instruction sheet.

Inspect the inlet air filter often. Remove the foam filter from the rear panel and clean it at least once per week.

NOTES:

At the end of the *KnightStar 330's* useful life, return the device to the manufacturer for proper disposal.

Symbols

Table 1 lists descriptions for the various symbols that appear on the *KnightStar 330*.

Table 1. Symbols

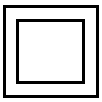
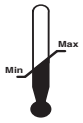
Symbol	Description
	Attention, consult accompanying manual
	Alternating current (AC power from wall outlet)
	Direct current (battery power)
	Type BF equipment, degree of protection against electrical shock
	Class 2 equipment, double insulation design
	Alarm condition
	CE Mark: This device complies with the requirements of Medical Device Directive 93/42/EEC concerning medical devices
	A/C power cord connection
	Air outlet connector (blower connector)
	External Battery/DC power connector
	RS-232 communications connector
	UL mark, classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only in accordance with standards UL2601-1 and CAN/CSA C22.2 No. 601.1-M90.

Table 1. Symbols (continued)

Symbol	Description
IPX1	Drip proof
SN	Serial Number
REF	Product model number
	Storage temperature range

System Description

Control Panel Display

The Liquid Crystal Display (LCD) shown in Figure 2 provides an easy-to-read format for mode, settings, and patient parameters. A backlight illuminates the display when the **Mode** or **Set** button is pressed. The display remains illuminated for approximately 60 seconds after the last button is pressed.

Control Panel Buttons

The control panel buttons are shown in Figure 2 and listed in Table 2.

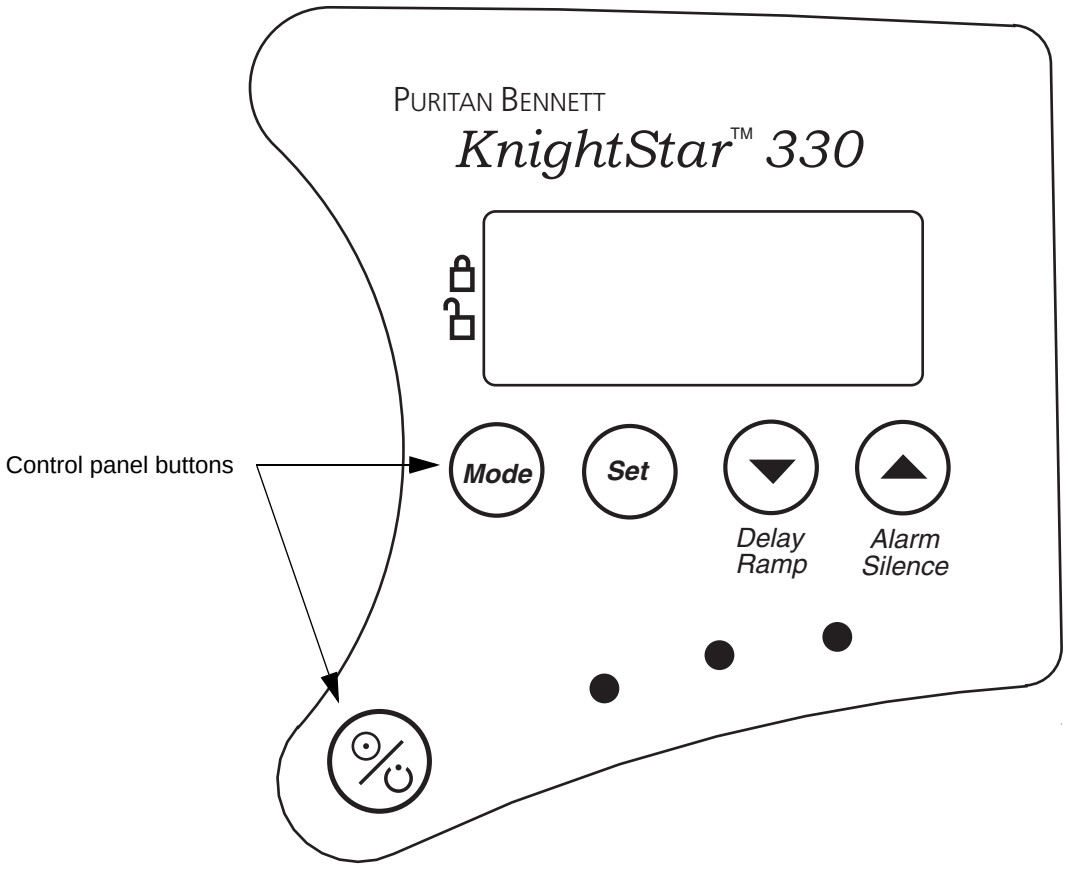


Figure 2. KnightStar 330 Control Panel

Table 2. Control Panel Buttons

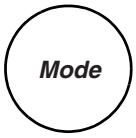
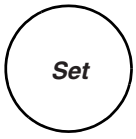
Symbol	Name	Function
	On/Off	Turns the *KnightStar 330* on or off. Turn the KnightStar 330 *on* with a *quick* press and release of the **On/Off** button. The device retains the prescription settings last entered. To turn the device *off*, press and *hold* the **On/Off** button for 3 seconds.
	Mode Leave Settings Mode	Scrolls through various device modes. Press the **Mode** button to scroll through various modes, as follows: *CPAP*, *I/EPAP*, *A/C*. **Note:** If the *Lockout* function is active, the **Mode** button will not operate.
On + **Mode** + ▲	Autoclear three-button combination	Performs a device *Autoclear*. When the KnightStar 330 is in the *Stand-by* mode (plugged in to AC power but not operating), perform an *Autoclear* by pressing and holding the following three buttons simultaneously for approximately 20 seconds: **On**, **Mode**, and ▲ (Up Arrow) Pressing this three-button combination clears the updatable "flash" memory and restores the device's default values. Within approximately 20 seconds after simultaneously *releasing* the buttons, you will recognize that this process is occurring by the "Xs" that appear on the display (in place of the patient ID) during Power On Self Test (POST).
Mode + ▲	Lockout Mode and Toggle	Changes the *Lock* or *Unlock* position. If the *Lockout* mode is active, the patient may only change the delay, start pressure, and ramp duration functions. To change the *Lock* or *Unlock* position, hold the **Mode** button and the ▲ (Up Arrow) button simultaneously for approximately two seconds.
	Set	Scrolls through the available parameters. Press **Set** once to show the patient-settable parameters (delay, start pressure, ramp duration). Press **Set** again to scroll through the remaining parameters. If the *Lockout* mode is inactive, you may scroll through *all* of the available parameter settings. If the *Lockout* mode is active, you may only scroll through the patient-settable parameters (delay, start pressure, ramp duration).

Table 2. Control Panel Buttons (continued)

Symbol	Name	Function
 *Delay Ramp*	Delay/Ramp	Starts or stops the *Delay/Ramp* function. Press the **▼/Delay/Ramp** (Down Arrow/Delay/Ramp) button to start the *Delay/Ramp* function, if inactive; press the **▼/Delay/Ramp** button to stop this function, if active.
	Down Arrow	Decreases a selected setting value when in *Settings* mode. Press the **▼/Delay/Ramp** (Down Arrow/Delay/Ramp) button once to decrease a setting value by one decrement.
 *Alarm Silence*	Alarm Silence	Mutes an active alarm. Press the **▲/Alarm Silence** (Up Arrow/Alarm Silence) button once to silence an active alarm for one minute.
	Up Arrow	Increases a selected setting value when in *Settings* mode. Press the **▲/Alarm Silence** (Up Arrow/Alarm Silence) button once to increase a setting value by one increment.
	Display Secondary Screen	Displays V̇ and I:E ratio. In *AC* or *I/E* mode, when the main display screen is shown, pressing this button displays V̇ and I:E ratio if there are no active alarms.

▼/Delay/Ramp Button. This button is used to activate the *Delay* feature. When *Delay* is activated, both inspiratory and expiratory pressures will decrease to the Ramp Start pressure. The time of delay can be set from 0 (no delay) to 30 minutes. After the delay time has elapsed, pressure will slowly ramp up to the prescription pressures.

The *Delay* mode can be cancelled by again pressing the **▼/Delay/Ramp** button. Once activated, *Delay* can be restarted by again pressing the **▼/Delay/Ramp** button.

Control Panel Indicators

The *KnightStar 330* control panel features visual indicators (shown in Figure 3) that illuminate in the presence of power and in response to specific device or tubing circuit problems.

The presence of power, whether from A/C or external battery, is indicated by an illuminated **green** LED.

A *low priority* condition is indicated by a **steadily illuminated yellow** LED (*without an audible alarm*).

A *medium priority* condition is indicated by a **flashing yellow** LED, along *with an audible alarm* that beeps three times at intervals of 25 seconds.

A *high priority* alarm is indicated by a **flashing red** LED, along with an audible alarm that beeps five times at intervals of 10 seconds.

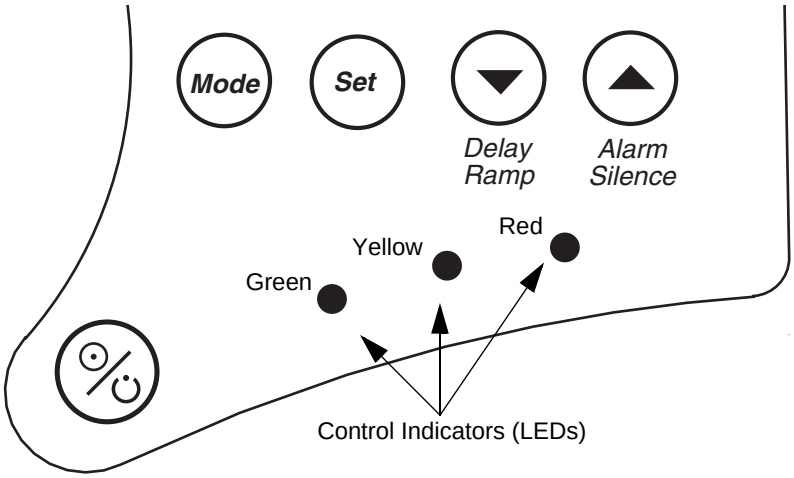


Figure 3. Control Panel Indicators

NOTE:

An audible alarm will sound under both medium and high priority alarm conditions.

Refer to the Troubleshooting section on page 45 for possible causes and corrective actions for visual and audible indicators.

WARNING:

The KnightStar 330 does *not* have an audible alarm to indicate that the patient has stopped breathing.

Air Outlet Assembly

The *KnightStar 330's* air outlet assembly consists of the air outlet and the optional outlet air filter.

Air Outlet. 22-mm conical port where the optional outlet air filter and tubing circuit are connected.

Optional Outlet Air Filter. This optional, single-patient filter removes contaminants and microbes as small as 0.2 microns from the outlet air. It is disposable, and must be replaced between patients. Be sure to inspect the filter regularly and replace it when noticeably dirty or discolored. Refer to "Replacing the Optional Air Outlet Filter" on page 44. Frequency of replacement can vary, depending on usage and environmental conditions. Contact your home care provider for replacement filters.

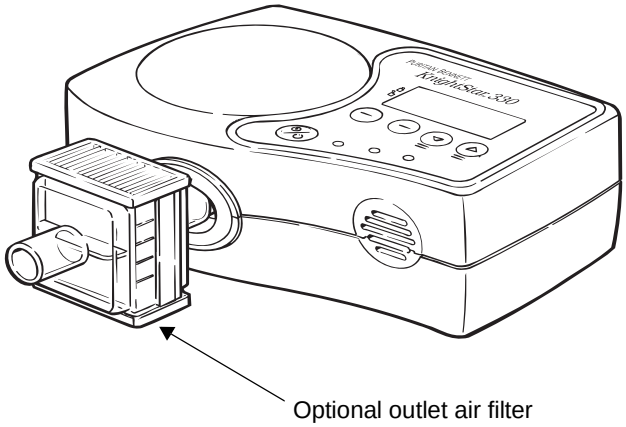


Figure 4. Optional Outlet Air Filter

Inlet Air Filter

The Inlet Air Filter prevents large contaminants (dust and lint) in the incoming air from entering the device. This filter has an efficiency of 90% or greater at 20 microns. It is reusable, and a spare filter is also provided. Refer to "Cleaning Instructions" on page 43.

A removable plastic baffle is installed over the inlet filter to reduce the sound level. Figure 5 shows the air inlet, filter, and baffle.

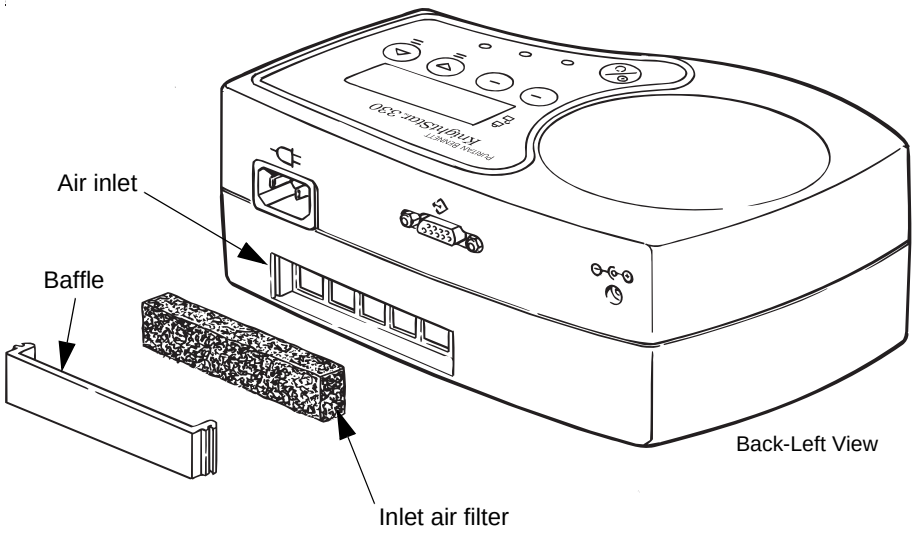


Figure 5. *KnightStar 330*'s Air Inlet, Filter, and Baffle

Connectors

The connectors on the back of the *KnightStar 330* are shown in Figure 6.

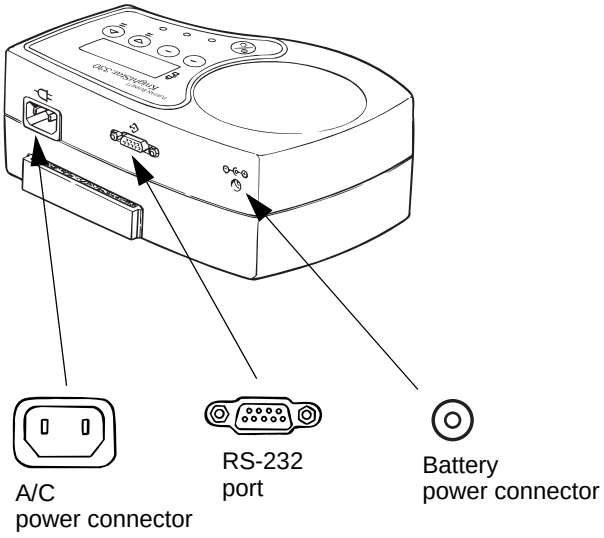


Figure 6. KnightStar 330 Connectors

A/C Power Cord Connector. Electrical input connection. The device operates on 100 V to 240 V ~ at 50 Hz or 60 Hz.

RS-232 Port. This port is used for remote communication.

External Battery Connector. Used for connecting an optional external 12V ⎓ battery, or for use in a car (using the optional cigarette lighter adapter), when A/C power is not available.

System Setup

This section describes how to prepare the *KnightStar 330* system for use.

The *KnightStar 330* system is intended for use in various environments. Patient parameters and data are entered and displayed on the control panel on the top of the device.

In the sleep lab, remote operation and monitoring is enabled using the optional remote control. The remote control and the *KnightStar 330* unit are connected by a cable that attaches to the rear of the unit.

Unpacking

Save all original packing materials and always ship the ventilator in the original box. If you need replacements for your packaging, contact Puritan Bennett. The components used in the setup procedure are identified in Figure 7.

***Note**: You may obtain KnightStar 330 accessories by contacting your Puritan Bennett Customer Service Representative.*

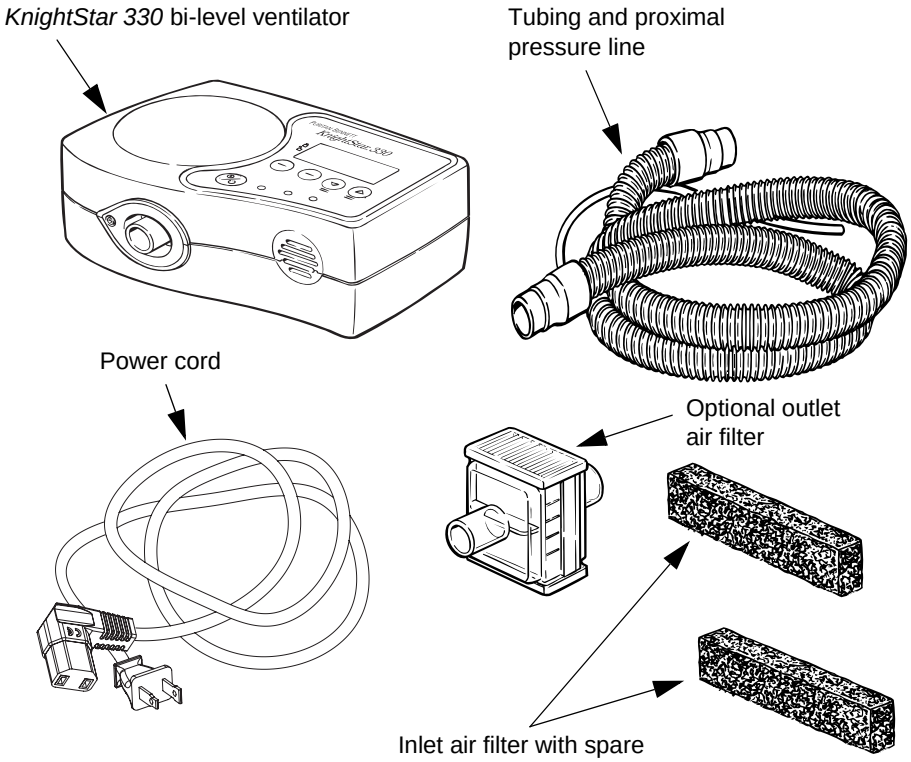


Figure 7. KnightStar 330 Components Used in Setup Procedure

Power On Self-Test

To ensure proper operation of the *KnightStar 330*, a power on self-test (POST) automatically runs each time you turn on the device. Because the POST takes about 9 seconds, you may notice a delay after pressing the device's **On/Off** button as the self-test runs. After the self-test completes, you can operate the *KnightStar 330*.

When you turn the unit on, certain events occur: the front panel displays the copyright notice, the manufacturer's name, and the firmware version; then, the device beeps and flashes its LEDs. If this sequence does not run as described, call for service.

WARNING:
If the audible indicators on the unit are inoperative, the unit must be checked by qualified personnel.

Operating Modes

The *KnightStar 330* operates in one of three modes:

- A/C
- I/E PAP
- CPAP

These modes are described in Table 3.

Table 3. Operating Modes

Mode	Description
A/C	I/E PAP with an adjustable respiratory rate and I:E ratio. If the device is unable to track breathing efforts, or the patient's spontaneous respiratory rate falls to or below the prescribed backup rate, the device will cycle at the prescribed levels of pressure and I:E ratio. If the backup rate cycles for five continuous breaths, the symbol **f** ↓ will appear on the lower left corner of the display, and the yellow LED will illuminate. The symbol **f** ↓ and the yellow LED will remain lit, until the patient breathes on his or her own. When the backup rate is cycling, the patient data for the "f" and "I:E" will be the prescription parameter values.
I/E PAP	Inspiratory/Expiratory Positive Airway Pressure with default to EPAP. This occurs when no inspiration is detected for the average inspiration period plus five seconds. Upon reaching this condition the device will default to the selected EPAP setting (setting range is 3 -20 cm H_2O). When the device is at EPAP pressure for the average exhalation time plus 5 seconds, the patient data will also default to the given values. When an inspiration event is detected, the device will resume normal operation. During the default condition, the patient data will be as follows:
	f = 0 bpm
	P = EPAP setting
	Vt = 0 liters
	Leak = 0 L/min
	$\dot{V}$ = 0 L/min
	I:E = 1:0.0 ratio
CPAP	Continuous Positive Airway Pressure: Pressure is continuously delivered at the set level.

Modes/Settings

Each mode enables a different group of system settings, as shown in Table 4.

Table 4. Modes/Settings

CPAP	I/E	A/C
CPAP	IPAP	IPAP
Alarm volume	EPAP	EPAP
Leak alarm	IPAP sensitivity	Respiratory rate and Backup respiratory setting (f)
Delay before ramp	EPAP sensitivity	I:E ratio
Ramp duration	Rise time	IPAP sensitivity
Start pressure	Alarm volume	EPAP sensitivity
Leak setting	Leak alarm	Rise time
	Low Pressure alarm	Alarm volume
	High Pressure alarm	Leak alarm
	Delay before ramp	Low Pressure alarm setting
	Ramp duration	High Pressure alarm setting
	Start pressure	Delay before ramp
	Leak setting	Ramp duration
		Start pressure
		Leak setting

Display Symbols

The symbols shown in Table 5 appear on the *KnightStar 330* display during operation of the device.

Table 5. Display Symbols

Symbol	Name	Symbol	Name
Start-up Display Symbols		**Settings (cont'd)**	
ON TIME	Total hours of operation	RISE	Rise time setting
USAGE	Total compliance time (usage in hours)	VOL	Alarm volume level
SN	Serial number	LEAK	Leak alarm setting
ID	Patient identification number (12 digits)	LO P	Low pressure alarm setting
Modes		HI P	High pressure alarm setting
A/C	Assist Control mode	DELAY	Delay time prior to start of ramp
CPAP	Continuous Positive Airway Pressure mode or pressure setting	RAMP	Ramp duration
I/E	Inspiratory/Expiratory PAP mode	STRT P	Ramp Start Pressure
Measured Parameters		Mask L	Interface (Mask) leak/type (1–6)
f	Respiratory rate	**Alarms**	
P	Current pressure	P	High pressure alarm condition
Vt	Tidal volume	P	Low pressure alarm condition
L	Leak rate	# #	Malfunction (one or two digit error code, ##, denotes alarm type
V	Peak inhalation flow	L	Leak alarm condition
I:E	Ratio of inspiration time to expiration time (also a setting in A/C mode)	f	Backup respiratory rate active
Settings		**Status Messages**	
IPAP	Inspiratory pressure		Ramp delay active
EPAP	Expiratory pressure		Lockout mode inactive
BACKUP f	Backup respiratory rate setting in A/C mode		Lockout mode active
ISENS	Inspiratory sensitivity		Alarm is muted
ESENS	Expiratory sensitivity		

Display Preferences

Table 6 lists the six numeric indicators on the control panel display, along with an explanation of how they are generated. Patient data is updated for each breath.

Table 6. Measured Parameters

Display	Description
f	Respiratory Rate – This value reflects the inspiration and expiration trigger points of the system based on the patient's respiratory efforts. The value displayed is a four-breath moving average of the sum of inspiration and expiration. Normal operating range: 0 bpm to 60 bpmUnit of Measure: breaths per minute
P	Current pressure Normal operating range: 3 cmH_2O – 35 cmH_2O Unit of Measure: cmH_2O **Note**: 1 cmH_2O = 0.98 hPa
Vt	Estimated Tidal Volume – This value is computed for every detected breath and is displayed as a four-breath moving average. The system flow is integrated during the inspiratory part of the breath cycle, from which the computed leak is subtracted. Normal operating range: 1 mL to 2000 mL Unit of Measure: milliliter
L	Estimated Leak – Using the device's internal flow sensor signal, an average is determined for the flow signal. This average value in a system free of leaks would represent the vent flow; and this value minus the standard purge hole leak rate (depending on the leak setting) is the leak value displayed. Values greater than "0" would indicate an ill-fitting interface. The value is displayed as a four-breath moving average. Normal operating range: 1 L/min to 100 L/minUnit of Measure: liters per minute (L/min)
$\dot{V}$	Estimated Peak Inhalation Flow – This value is computed by detecting the maximum internal flow sensor signal for each inspiration. From this maximum value the estimated leak is subtracted. The value is computed for every breath and is displayed as a four-breath moving average. This measurement is displayed on the secondary screen by pressing the ▲ (Up Arrow) button when in normal operation. Normal operating range: 1 L/min to 100 L/minUnit of Measure: liters per minute (L/min)
I:E	Inspiration:Expiration Ratio – This value reflects the inspiration and expiration trigger points of the system based on the patient's respiratory efforts. The value displayed is a four-breath moving average. This measurement is displayed on the secondary screen by pressing the ▲ (Up Arrow) button when in normal operation. Normal operating range: 1:0.0 to 1:9.9 Unit of Measure: Not applicable

NOTES:

(1) The specified ranges were obtained under dry, ambient temperature and pressure conditions (ATPD).
(2) The maximum value of peak flow (up to 100 liters per minute) will be limited as leaks from interfaces (masks) increase.

Changing Device Settings

Patient prescription parameters may be programmed using the control panel located on the top of the *KnightStar 330*, or by using the optional remote control. The device settings are listed in Table 7; note that the patient-accessible settings are shaded.

NOTE:

To toggle between the *clinician access* mode (the default) and the *patient access* mode (*Lockout* mode), simultaneously press the **Mode** button and the ▲ (Up Arrow) button for two seconds.

To change the clinician-accessible settings, complete these steps:

1. Press the **Mode** button to select the desired mode of operation (*CPAP*, *I/E*, or *A/C*).

2. Press the **Set** button to select the setting that you wish to change.

3. Use the ▲ (Up Arrow) and ▼ (Down Arrow) buttons to change the value of the selected setting.

4. To change settings, repeat steps 2 and 3.

   When the four settings screens have been displayed, or when no button has been pressed for 60 seconds, or when the **Mode** button is pressed: the *Settings* mode is exited and the main screen appears.

Table 7. KnightStar 330 Settings

Setting[1]	Description	Value	Accessibility	Mode
CPAP	Level of CPAP pressure	3 cmH_2O – 20 cmH_2O (increments of 1 cmH_2O)	Top panel, remote control, PC, modem	Only CPAP
IPAP	Pressure during inspiration	3 cmH_2O – 30 cmH_2O (increments of 1 cmH_2O)	Top panel, remote control, PC, modem	Only I/E or A/C
EPAP	Pressure during expiration	3 cmH_2O – 20 cmH_2O (increments of 1 cmH_2O)	Top panel, remote control, PC, modem	Only I/E or A/C
Backup respiratory rate	Rate of machine-initiated breaths	3 bpm –30 bpm (increments of 1 bpm)	Top panel, remote control, PC, modem	Only A/C
I:E ratio	Ratio of inhalation time to exhalation times for backup breath rate	1:1.0 to 1:4.0 (increments of 0.5)	Top panel, remote control, PC, modem	Only A/C
Inspiration sensitivity	Sensitivity at which devices switches from EPAP to IPAP	1 – 5 (1 most sensitive; 5 least sensitive)	Top panel, remote control, PC, modem	Only I/E or A/C
Expiration sensitivity	Sensitivity at which devices switches from IPAP to EPAP	1 – 5 (1 most sensitive; 5 least sensitive)	Top panel, remote control, PC, modem	Only I/E or A/C
Rise-time	Rate of pressure increase	1 – 5 (1 is the fastest setting; 5 is the slowest)	Top panel, remote control, PC, modem	Only I/E or A/C
Alarm volume	Loudness	0 – 3 (0 = Off, 3 = loudest)	Top panel, remote control, PC, modem	All
Leak alarm	Rate of air leaking before alarm sounds	50 – 100 liters per minute (increments of 1 L/min); 0 = Off	Top panel, remote control, PC, modem	All
Low pressure alarm	Pressure below the prescribed IPAP setting at which an alarm will sound	1 cmH_2O below the IPAP setting to 1 cmH_2O above EPAP (in increments of 1 cmH_2O); 0 = Off.	Top panel, remote control, PC, modem	Only I/E or A/C
High pressure alarm	Pressure above the prescribed IPAP setting at which an alarm will sound	1 cmH_2O above the IPAP setting to 35 (in increments of 1 cmH_2O); 0 = Off.	Top panel, remote control, PC, modem	Only I/E or A/C
Delay time*	Time delay before automatic device start	0 minutes – 30 minutes (in increments of 5 minutes)	Top panel, remote control, PC, modem	All
Ramp duration*	Time from device start to prescribed operating pressure	0 minutes – 30 minutes (increments of 5 minutes)	Top panel, remote control, PC, modem	All
Start Pressure*	Pressure at which the unit starts delay ramp sequence	3 cmH_2O –20 cmH_2O (increments of 1 cmH_2O)	Top panel, remote control, PC, modem	All

Table 7. KnightStar 330 Settings (continued)

Setting[1]	Description	Value	Accessibility	Mode
Interface (Mask) leak/ type	Patient interface purge hole leak rate (intended)	1 – 6 (1 is the lowest leak value, and 6 is the highest)	Top panel, remote control, PC, modem	All
Patient ID	Unique patient identifier	12 digits	PC, modem	All
Time for dial-out	Clock day/time device phones home health care dealer	7 days/week, 24 hours/day	PC, modem	All
Device dial-out telephone number	Phone number for device to call home health care dealer	Not applicable	PC, modem	All
Internal Clock	Clock used by device	24-hour clock	PC, modem	All

1. Settings marked with an asterisk (*) are accessible by the patient.

Alarm Tests

Before operating the *KnightStar 330*, you may test the low pressure alarm, the high pressure alarm, and the leak alarm as described below:

Low pressure alarm. In the *I/E* mode, set the low pressure alarm to 1 cmH_2O above the EPAP pressure. Remove the tubing from the outlet. The low pressure alarm should sound within approximately 10 seconds.

High pressure alarm. In the *I/E* mode, set the high pressure alarm to 1 cmH_2O above the IPAP pressure. Use an external source of pressure, and pressurize the circuit for 10 seconds. The high pressure alarm should sound.

Leak alarm. In the *I/E* mode, with a leak alarm threshold setting of 50 liters per minute, remove the interface from the tubing and set the low pressure alarm to “0”. If the system is operating correctly, an alarm will signal an air leak after approximately 60 seconds.

Setting Prescription Parameters

All prescription settings for the *KnightStar 330* must be programmed. Before programming prescription settings, review the physician's prescription. Then, proceed as follows:

1. Choose the appropriate interface.

2. Explain the intended therapy to the patient, and offer reassurance about the procedure.

NOTE:
For correct use, start the *KnightStar 330* system before putting on the mask or interface.

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3. Set the mode according to the physician's prescription (*CPAP*, *I/E PAP*, or *A/C*). If there is no prescription (such as in a sleep lab setting), begin with low IPAP pressures in the range of 5 cm H_2O to 10 cm H_2O, and an EPAP pressure of 3 cm H_2O.

NOTE:
When changing from *I/E PAP* or *A/C* to *CPAP*, the *CPAP* value will default to the set *IPAP* value. Press the **Set** button and use the ▲ (Up Arrow) or the ▼ (Down Arrow) button to change the *CPAP* setting.

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4. Set the respiratory rate to the minimum value required to maintain the patient. Start with a setting of 12 bpm (A/C only).

5. In A/C mode, set the I:E ratio as ordered by the physician.

WARNING:
Some CO_2 rebreathing is possible during normal operation of the KnightStar 330, especially at low airway pressures. When using A/C mode, an I:E ratio of 1:2 or greater is recommended to reduce the possibility of CO_2 rebreathing.

6. Set *IPAP* sensitivity (ISENS) to a value of 2 or 3 to start.

7. Set *EPAP* sensitivity (ESENS) to a value of 2 or 3 to start.

NOTE:

Refer to the following sections for more information about Inspiratory and Expiratory Sensitivity and Rise Time.

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8. Set rise time, alarm volume, leak alarm, low and high pressure alarms, delay time prior to ramp, ramp duration, ramp start pressure, and mask leak settings as required.

9. Initiate noninvasive positive pressure ventilation (NPPV), while gently holding the interface in place.

10. Once the patient is comfortable, secure the interface in place (use headstraps, as applicable). Avoid an excessively tight fit.

Sensitivity Adjustment

The *KnightStar 330* features adjustable triggering sensitivity for both inspiration and expiration. Clinicians should adjust the sensitivity, as needed, so that the *KnightStar 330* cycles with the patient's breathing effort.

Inspiratory Sensitivity

A setting of 1 is the most sensitive setting on the *KnightStar 330;* a setting of 5 is the least sensitive setting.

Inspiratory sensitivity should be adjusted for patient comfort to improve compliance. An inspiratory setting that is too sensitive causes autocycling, which may be uncomfortable for the patient.

NOTE:

Autocycling refers to an automatically delivered breath that was not initiated by the patient.

Expiratory Sensitivity

Figure 8 illustrates the effects of changing the expiratory sensitivity on the *KnightStar 330.*

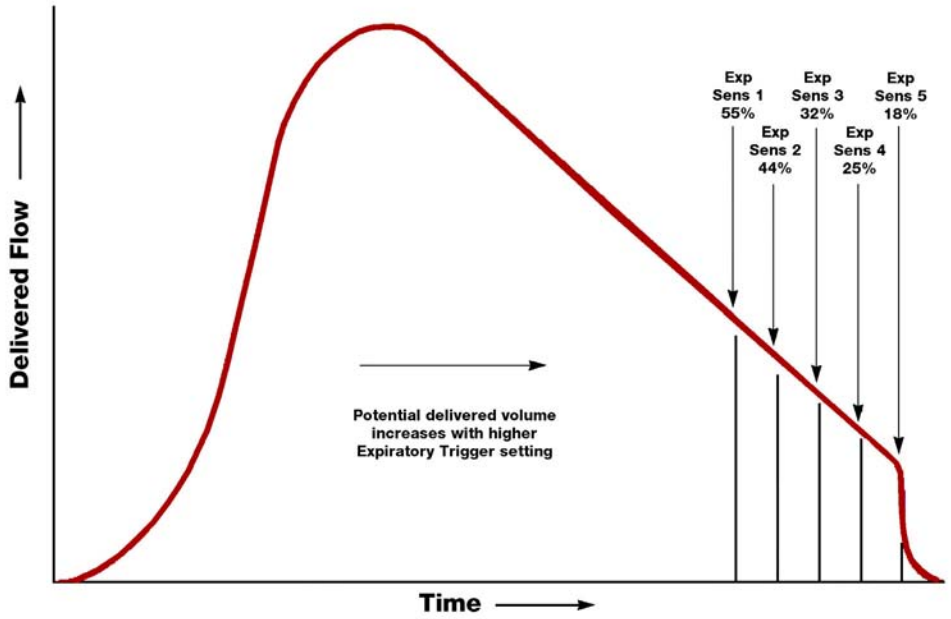


Figure 8. Effects of changing the expiratory sensitivity on the *KnightStar 330*

As shown in Figure 8, a setting of 1 is the most sensitive setting, and causes the *KnightStar 330* to quickly cycle into the expiratory phase.

A setting of 5 is the least sensitive, and inspiratory flow needs to diminish significantly before the *KnightStar 330* cycles into the expiratory phase. The longer it takes for the device to cycle into the expiratory phase, the greater the potential tidal volume delivered to the patient.

Expiratory sensitivity can be adjusted by patient assessment. If inspiratory times appear to exceed the inspiratory efforts of the patient, a lower expiratory sensitivity can be set and the patient observed for signs of increasing comfort. If the breath appears to be terminating prematurely, a higher expiratory sensitivity can be set and patient comfort as well as its effect on tidal volume re-evaluated.

Rise Time

The following graph (Figure 9) depicts the "Rise-time" for settings 1, 3, and 5.

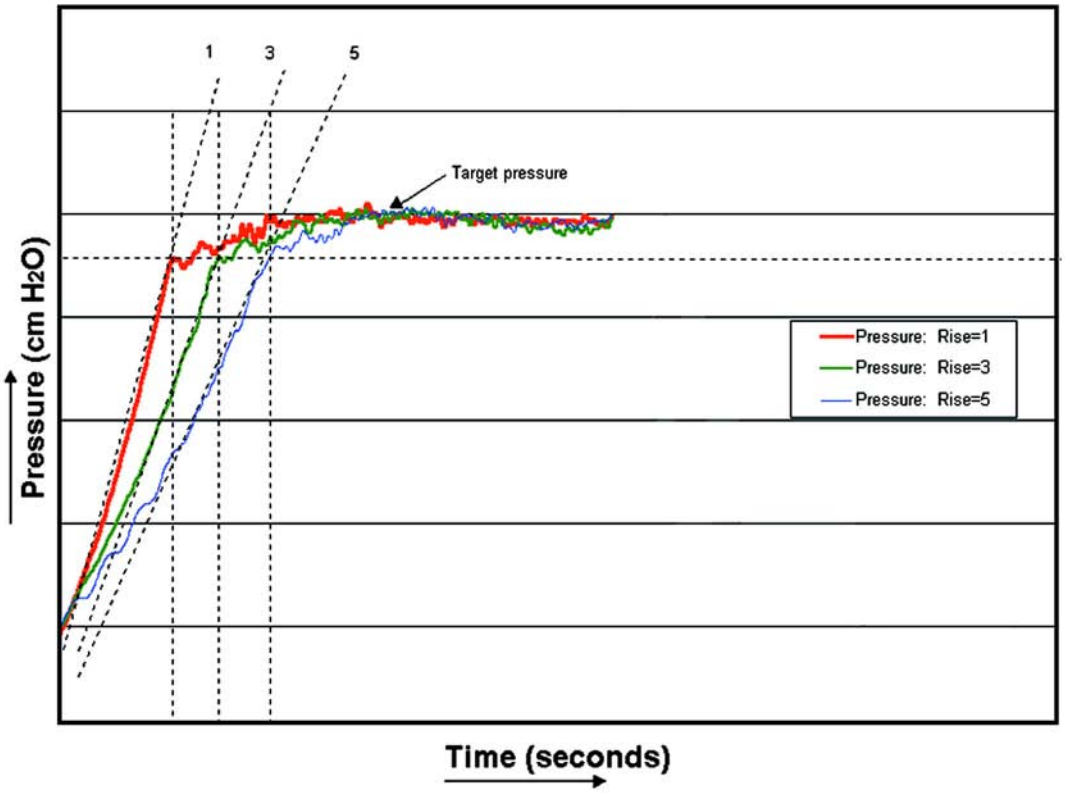


Figure 9. Breath waveform pressures for rise-time settings of 1, 3, and 5

A setting of 1 causes the pressure to rise more rapidly than a setting of 5. Patients with aggressive inspiratory demands may be more comfortable on a setting of 1 or 2.

Some patients are more comfortable with a *gentler* rise to pressure; for these patients, a setting of 4 or 5 may be better suited to their needs. A setting of 3 represents an intermediate rate of pressure change.

The dotted lines in Figure 9 show the relative amount of time required for pressures to reach their peak values at various rise-time settings.

Clinical Application and Use

Figure 10 shows the *KnightStar 330* system configured for use. Before each use, ensure that the system has been connected as described in the section entitled “System Setup” on page 20.

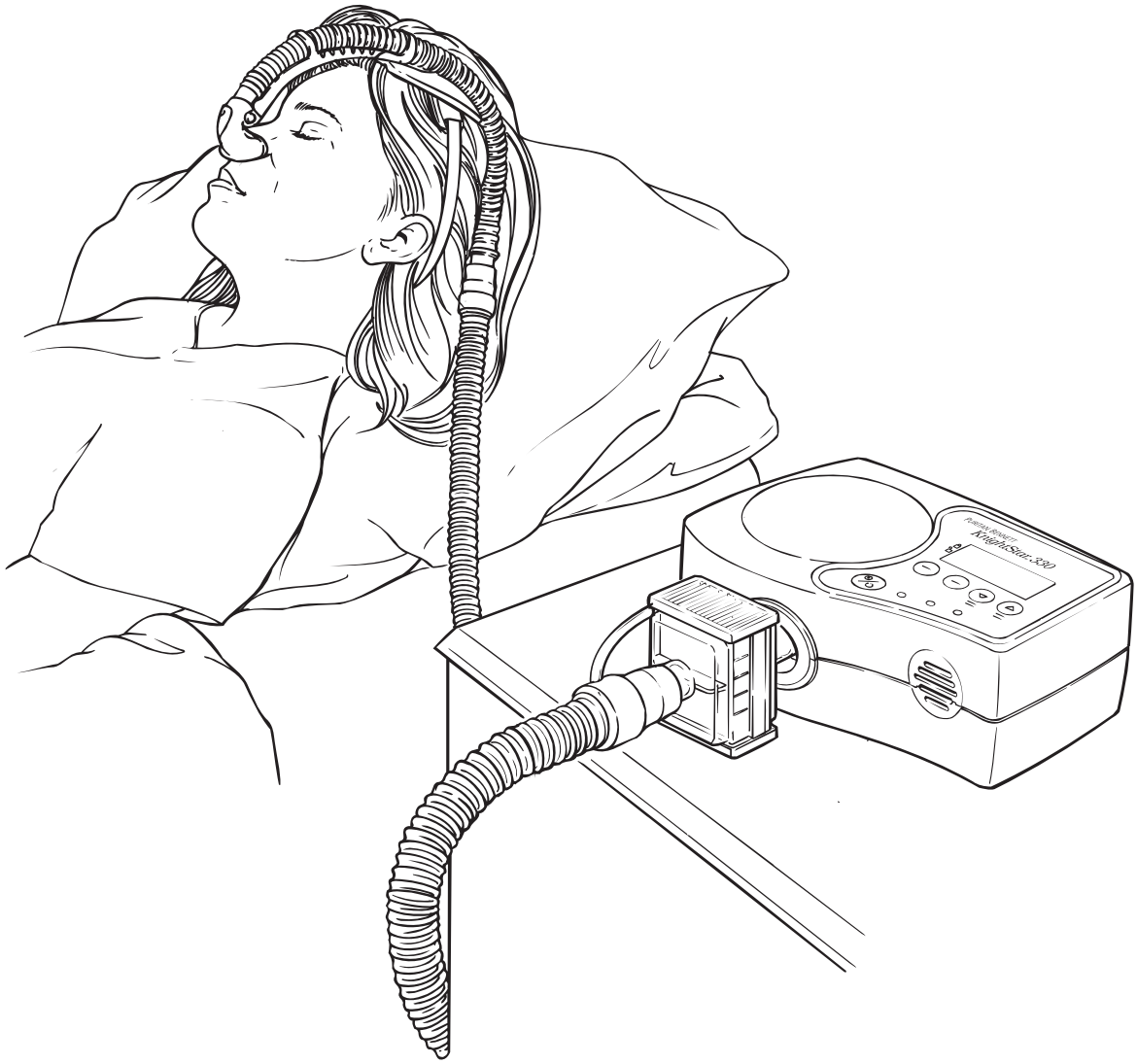


Figure 10. Typical Configuration for Patient Care with the KnightStar 330

The device should be set up in the patient’s room on a level stable surface.

WARNING:
When the KnightStar 330 is powered off, it saves its most recent settings. To avoid exposing the patient to inappropriate settings, review all settings before connecting the system to the patient.

Connecting the Device to the Patient

When connecting the *KnightStar 330* for the first time, complete these steps:

1. Turn the unit on.

2. Explain to the patient that you will be helping them apply the mask to their nose, and hold the mask in place until they are comfortable. The *Delay/Ramp* feature may also be used to provide additional comfort when first using the *KnightStar 330*.

3. Observe the patient and check the mask for fit and leaks.

4. Note the estimated leak rate. (*The leak value is automatically displayed*.) Use this number as a baseline reference during the evaluation period.

WARNING:
Check the estimated leak rate periodically to ensure that the value has not increased significantly due to leaks. Leaks may be caused by ill-fitting, dislodged, or faulty tubing or interfaces.

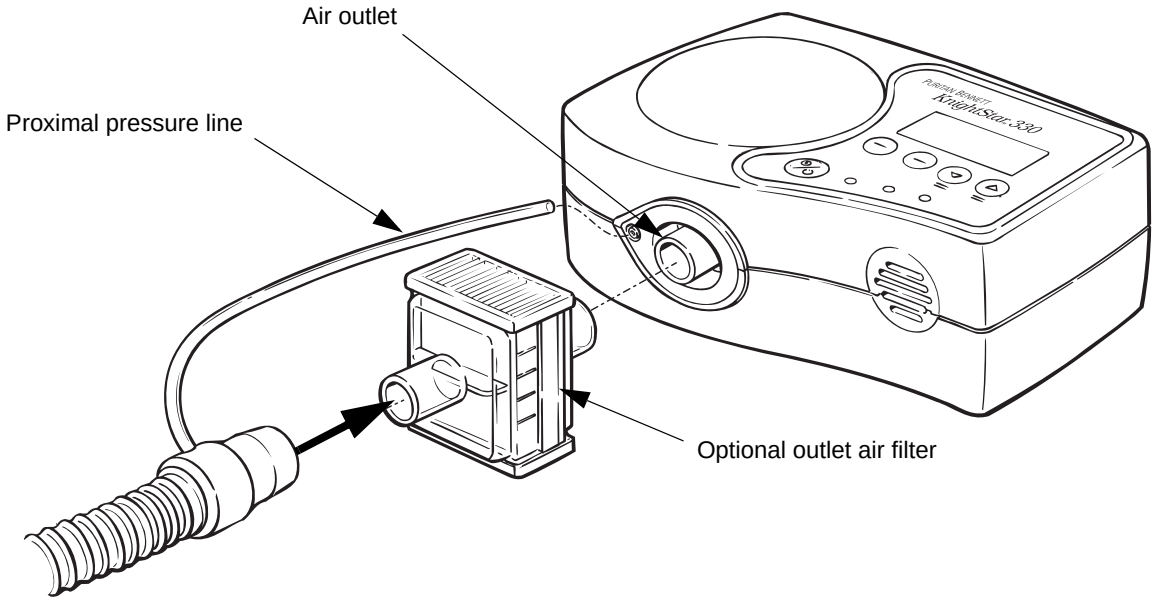


Figure 11. Connecting Device Components

WARNING:

Use only Puritan Bennett-approved accessories in conjunction with the KnightStar 330 bi-level ventilator. The use of other accessories may damage the unit and endanger the patient.

Titrating Therapy

To assist patient therapy by titrating pressures, the clinician should follow these steps:

1. Titrate inspiratory pressure (IPAP) in 2 cmH_2O increments until the desired patient outcome (such as decreased use of accessory muscles, decreased respiratory rate, etc.) is achieved.

2. Titrate the EPAP or PEEP as needed to improve oxygenation or to overcome auto-PEEP, and to facilitate patient-triggering. (EPAP and PEEP are synonymous in regard to the amount of pressure left in the breathing pathway at the end of the expiratory cycle.)

3. Add up to 15 liters per minute of supplemental oxygen, if needed.

4. Continue to coach and reassure the patient, making adjustments to improve the patient's acceptance of the procedure.

5. Adjust the delay and ramp, according to the patient comfort level.

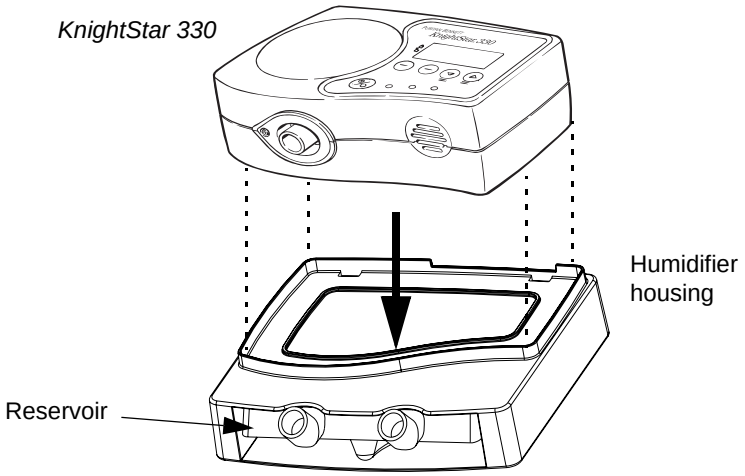
NOTE:

You may want to deactivate the delay once the interface is in place if the patient is in respiratory distress and/or hypoxic.

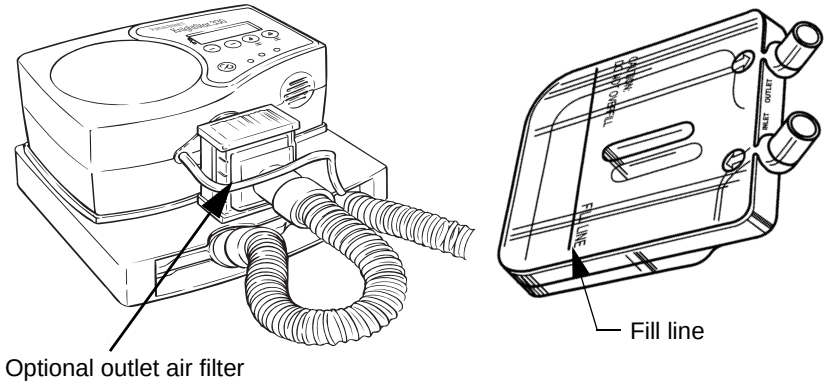
Using the Optional Humidifier

A humidifier may be used with the *KnightStar 330* if the patient is experiencing nasal discomfort due to low moisture content in the input air. To use the humidifier, follow these steps:

1. Place the *KnightStar 330* on top of the humidifier housing.



2. Remove the reservoir from the housing and fill it to the FILL LINE with distilled or sterile water. The reservoir is designed to hold water for only one night's use.



3. Slide the reservoir gently back into the housing.

4. Connect the short humidifier tubing between the *KnightStar 330* and the inlet of the reservoir.

WARNING:

Do not allow water to come into contact with the KnightStar 330 or other electrical apparatus. To prevent electrical hazard, remove the source of power if water is suspected of entering the KnightStar 330.
Do not fill the reservoir when it is in the housing.
Use only distilled or sterile water to fill the reservoir.

NOTE:

For information regarding operation, connection, and cleaning, refer to the instructions included with the humidifier.

Using Supplemental Oxygen

If the physician orders supplemental oxygen for the patient, the adequacy of the prescribed flow rate should be determined by pulse oximetry. Oxygen may be titrated either directly at the patient interface or by using a supplemental O_2 adapter.

To administer oxygen with the *KnightStar 330* system, oxygen may be titrated as follows:

- Using an O_2 adapter between the optional outlet filter and the patient circuit
- At the outlet of the blower
- At the interface

Connecting Oxygen to the Device

Connect the oxygen adapter to the air outlet; or, if it is present, to the optional outlet air filter. Connect the oxygen supply tubing to the small port on the oxygen adapter, as shown in Figure 12 on page 40.

The oxygen supply tubing may also be connected directly to the patient interface if it is equipped with a small port.

WARNING:
At a fixed flow of supplemental oxygen, the FiO_2 will vary depending on the pressure settings, patient breathing pattern, interface selection, and leak characteristics of the patient interface.

WARNING:
Always observe all fire and safety rules associated with the use of oxygen. Oxygen vigorously accelerates combustion. Do not smoke or have an open flame in any room where oxygen is in use.

WARNING:

Always power on the system before starting oxygen flow. Stop oxygen flow before powering the system off. Oxygen delivered into the ventilator tubing may accumulate within the device, creating the risk of fire. Do not use supplemental oxygen at flows above 15 L/min.

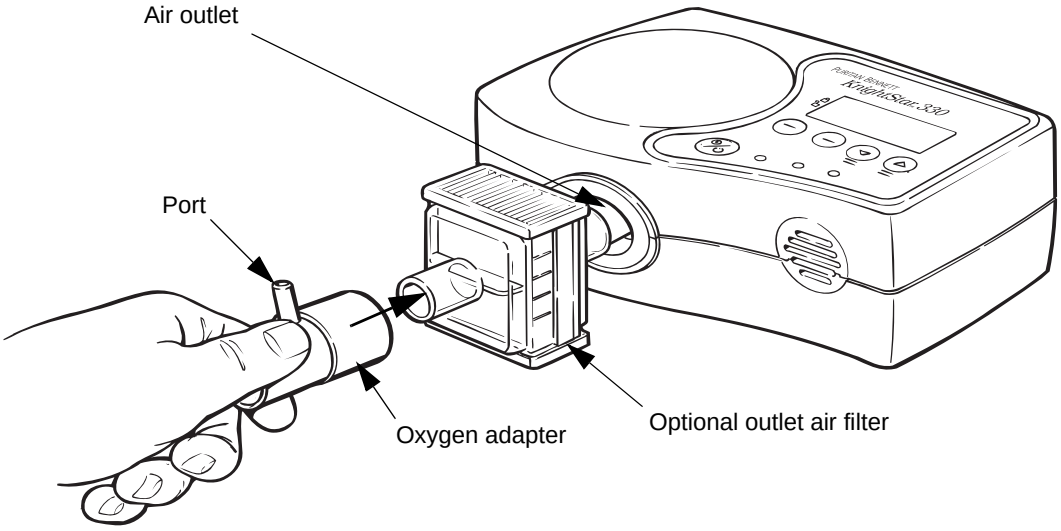


Figure 12. Connecting the Oxygen Adapter to the Air Outlet

Rebreathing of Carbon Dioxide

All CPAP and bi-level devices may increase the quantity of CO_2 rebreathed because the expired air is forced back into the supply tubing. The expired air is purged through the purge hole(s) in the interface. The quantity of CO_2 rebreathed will vary depending on the pressure settings, patient breathing pattern, interface selection, and the leak characteristics of the patient interface.

WARNING:

Some CO_2 rebreathing is possible during normal operation of the KnightStar 330—especially at low airway pressures. When using A/C mode, an I:E ratio of 1:2 or greater is recommended to reduce the possibility of CO_2 rebreathing.

Testing for rebreathing was performed using a CO_2 monitor sampling at the nose, while a healthy adult breathed through an *ADAM*™ or *Breeze*™ interface. The test results are shown in Table 8.

Table 8. $C0_2$ Rebreathing Test Results

IPAP	EPAP	Vt	BPM	I:E	Result
15	3	1.2	14	1:2.2	CO_2 was not completely cleared before inspiration began.
15	5	0.8	15	1:2.3	CO_2 was rapidly dropping at the beginning of inspiration.
15	7	0.9	15	1:2.5	CO_2 was completely cleared at the beginning of inspiration.
15	9	0.8	15	1:2.4	CO_2 was cleared 1.4 seconds before beginning of inspiration.

Note:

The *KnightStar 330* is designed to show “0” leaks based on a leak setting appropriate to a given interface. Interfaces other than the *ADAM* or *Breeze* may show a positive leak value, unless the leak setting is adjusted for that device.

Under the test conditions listed in Table 7 on page 27, CO_2 rebreathing was minimal when the EPAP pressure was greater than 5 cmH_2O. Rebreathing will vary depending on respiratory rate, tidal volume, I:E ratio, and EPAP pressure. IPAP pressure will, to a lesser degree, affect rebreathing.

Purge hole flow is an important factor in clearing CO_2 from the circuit. In general, for any specific set of conditions, interfaces with higher purge hole flows are expected to reduce the quantity of CO_2 remaining in the circuit. Puritan Bennett interfaces with higher purge hole flows than the *ADAM* interface are available. Table 9 lists the purge flows for Puritan Bennett interfaces.

It is important to properly fit the patient with an interface that will provide comfort and proper treatment. Each interface listed has different characteristics of fit and dead space. These are important factors in interface selection.

Table 9. Purge Flows for Various Interfaces

Interface Model	Purge Hole Flow (L/min) at 3 cmH_2O	Purge Hole Flow (L/min) at 15 cmH_2O	Leak Setting
ADAM™	12	25	2
Breeze™	13	30	3
Companion®	14	34	5
SoftFit® and SoftFit Ultra	16	35	5
Sullivan® Modular	19	40	6

Table 10 on page 43 shows the purge hole leak values associated with different leak settings. It is important to select the correct leak setting for a given interface so that the device will display the correct tidal volume and leak.

For interfaces produced by manufacturers other than Puritan Bennett, you may contact them for instructions and use Table 10 to select the correct leak setting.

Table 10. Purge Flow at 15 cmH_2O

Leak Setting	Purge Hole Flow (L/min) at 15 cmH_2O
1	23
2	27
3	31
4	33
5	35
6	42

Cleaning Instructions

To increase the life of your equipment, it is important to clean all components regularly. Cleaning methods other than those indicated here are discouraged. The *KnightStar 330* requires little maintenance other than regular cleaning.

Cleaning the Exterior

WARNING:
Always unplug the unit from all electrical power sources before cleaning. Do not let water drip into any opening on the unit.

Clean the surfaces of the *KnightStar 330* by wiping them with a cloth dampened with warm soapy water, then wiping them dry.

Cleaning the Inlet Filter

Inspect the inlet filter often by removing the inlet baffle.

1. Wash the inlet filter in warm soapy water. Inspect it often and clean it at least once a week.

2. Rinse the filter thoroughly to remove all soap.

3. Pat the filter dry with a towel.

4. Allow the filter to air dry completely before reinstalling; or, install the spare filter.

5. Replace the filter if it is torn or soiled.

6. Reinstall the filter on the rear of the unit.

7. Reattach the baffle.

Replacing the Optional Air Outlet Filter

The optional outlet filter is disposable, and should be inspected regularly and replaced when noticeably dirty or discolored. Frequency of replacement can vary, depending on usage and environmental conditions. Contact your home care provider for replacement filters.

In addition, air outlet filters are intended for single-patient use and must be changed between patients. Your Puritan Bennett Customer Service representative can assist you in selecting the proper optional air outlet filter, and advise you on an appropriate replacement schedule.

For optimal performance, use only Puritan Bennett-approved filters with the *KnightStar 330*.

Troubleshooting

Any unusual system event results in one or all of the following:

- Displayed error code(s)
- Illuminated yellow or red LED(s)
- Audible alarm

To mute an alarm for one minute, press the ▲/**Alarm Silence** button.

Alarms are classified as follows: high priority, medium priority, or low priority.

- A *high priority* alarm is indicated by a flashing red LED, along with an audible alarm that beeps five times at intervals of 10 seconds.
- A *medium priority* alarm is indicated by a flashing yellow LED, along with an audible alarm that beeps three times at intervals of 25 seconds.
- A *low priority* condition is indicated by an illuminated yellow LED (*without an audible alarm*). An illuminated *green* LED indicates the presence of power, whether from A/C or external battery.

Alarm conditions are shown in Table 11 on page 46.

WARNINGS:
Respond immediately to all alarm conditions.

Under certain conditions, some alarms may not occur. For example: (1) The leak alarm may not occur if patient breath efforts are not detected, as in the case of excessively large leaks; and (2) The low pressure alarm may not occur under conditions such as these: an incorrect alarm threshold setting, or air pathway resistance.

Table 11. Alarm Conditions

Type	Priority	Description	Display	Alarm Volume	Reset Conditions
High pressure	Medium	Pressure at interface rises above setting for 10 seconds; flashing *yellow* LED.	P ⤒	Adjustable 0–3: 0=Off; 3=Loudest	Pressure decreases to less than the alarm limit.
Low pressure	High	Pressure at interface falls below setting for 10 seconds; flashing *red* LED.	P ⤓	Adjustable 0–3: 0=Off; 3=Loudest	Pressure rises above the alarm limit.
Leak	High	Estimated leak rate rises above setting for 60 seconds; flashing *red* LED.	L ⤒	Adjustable 0–3: 0=Off; 3=Loudest	Leak flow rate decreases to less than alarm limit.
Internal malfunction	High	Internally detected failure; flashing *red* LED.	# #	Always enabled; Loudness =3	Unplug from power source, wait 30 seconds, then reconnect to power source. Verify correct settings if device functions normally.
Apnea	Low	Patient's spontaneous respiratory rate remains at or below the prescribed respiratory rate for 5 breaths in A/C mode. *Yellow* LED is on.	f ⤓	Not applicable	Breath detected.
Power Loss	High	Loss of A/C and external battery power. Flashing *red* LED.	Display is blank	Always enabled; Loudness =3	Restore A/C or external battery power.
Overpressure	High	Pressure > 40 cmH_2O. Flashing *red* LED.	55	Always enabled; Loudness =3	Unplug from power source, wait 30 seconds, then reconnect to power source. Verify correct settings if device functions normally.

In the event of a system malfunction, use Table 12 to identify possible causes and solutions.

Table 12. Troubleshooting Checklist

Problem	Indicators	Possible Cause	Corrective Action
No airflow out of device	No alarm or displayed symbol.	1. Internal electronic failure. 2. Corrupted prescription settings.	1. Contact the home care provider for repair. 2. Contact the home care provider.
Low airflow out of device	No alarm or displayed symbol.	1. Delay activated. 2. Internal electronic problem. 3. Blocked device air inlet.	1. Stop the delay. 2. Contact the home care provider for repair. 3. Move rear of device away from the wall and all objects.
Power loss	Blank display. LED flashes and alarm sounds No *green* LED.	1. Faulty power cord connection. 2. Wall outlet power failure.	1. Check power cord connections at back of device and wall outlet. 2. Verify Mains A/C power is available at wall outlet. If not, connect external battery. Ensure *green* LED on top of device is illuminated. LED stops flashing upon resuming operation from standby mode.
Internal malfunction	Alarm and flashing LED. Displayed symbol 🔊## with ## being the 2-digit error code.	Internal electronic problem.	Disconnect power, then reapply power. If condition persists, contact the home care provider for repair.
Overpressure	Alarm and flashing LED. Displayed symbol is 🔊55.	Internal electronic problem.	Disconnect power, then reapply power. If condition persists, contact the home care provider for repair.
High pressure	Alarm and flashing *yellow* LED. Displayed symbol is 🔊P.	Kinked or blocked tubing.	Verify that the tubing has not collapsed, and that there are no sharp bends. Reposition the device, tubing, or accessories, as applicable.

Table 12. Troubleshooting Checklist (continued)

Problem	Indicators	Possible Cause	Corrective Action
Low pressure	Alarm and flashing LED. Displayed symbol is P.	1. Tubing circuit leak, or tubing is disconnected. 2. Small, proximal pressure tubing is not connected to port next to device air outlet.	1. Reposition interface pillows or mask. Check tubing connections at device air outlet and patient interface. If tubing is punctured or disconnected, replace it or reconnect it, as applicable. 2. Verify proper tubing connection. Disconnect tubing and reinstall, as applicable.
Circuit leak	Alarm and flashing LED. Displayed symbol is L.	Tubing circuit leak, or tubing is disconnected.	Reposition interface pillows or mask. Check tubing connections at device air outlet and patient interface. If tubing is punctured or disconnected, replace it or reconnect it, as applicable.
Low breath rate	No alarm. Steady *yellow* LED. Displayed symbol is f.	The patient's breath rate is lower than the prescribed setting.	If the patient experiences signs of distress, contact physician.

Appendix A:
KnightStar 330
Setup
Checklist

Table 13. KnightStar 330 Setup Checklist

Procedure	Pass ✔	Fail ✔
General Exterior Appearance		
Any dents, scratches, or loose parts that may indicate dropping or other abuse?	❑	❑
Inlet baffle missing?	❑	❑
Check the condition of A/C power cord.	❑	❑
Check for fluid residue in and around KnightStar 330 openings and housing joints.	❑	❑
Ensure that the inlet filter is clean and in place.	❑	❑
Ensure that a new optional outlet air filter is used.	❑	❑
KnightStar 330 Setup		
Ensure that the KnightStar 330 is placed in such a manner that there is at least one inch of clearance at the back of the device.		
Connect one end of the A/C power cord into the rear panel of the KnightStar 330, and the other end into an A/C wall outlet.		
Turn the **on/off** button *on*. Both the yellow and indicators should flash for approximately one second; the green indicator remains lit.	❑	❑
CAUTION: If an error code appears on the display, or an alarm stays activated following system power-up, turn the on/off button *off*. Then turn the on/off button *on*; if the system fails again, the KnightStar 330 must be serviced before installation can continue.		
Functional Test		
With the unit turned on, select the *CPAP* mode and set an alarm volume of 0.		
Set the CPAP prescription pressure to 3 cmH_2O, then increase the pressure to 20 cmH_2O. As the pressure increases, you should be able to hear the motor blower speed increase.	❑	❑
Set the alarm volume to 1.		
Turn the KnightStar 330 off and wait for the motor to stop rotating.		

Table 13. KnightStar 330 Setup Checklist (continued)

Procedure	Pass ✔	Fail ✔
Turn the KnightStar 330 on and let it run for approximately three minutes. Verify that the LEAK alarm indicator 🔊 L ⤒ is illuminated, and that the audible alarm activates. See the lower left corner of the display.	❑	❑
Turn off the KnightStar 330.		
Sensitivity and Pressure Test 1. Attach patient circuit and bacteria filter to air outlet. 2. Attach proximal pressure line to pressure outlet. 3. Attach calibration shell to end of patient circuit; connect circuit to manometer. 4. Turn on the KnightStar 330.	❑	❑
Set the Following Parameters: **Mode**: I/E PAP; **IPAP**: 20 cmH_2O; **EPAP**:10 cmH_2O; **ISENS**:1; **ESENS**:1	❑	❑
After a short time, the KnightStar 330 should begin to cycle between *IPAP* (20 cmH_2O) and *EPAP* (10 cmH_2O).	❑	❑
Increase ESENS to 5. The KnightStar 330 should begin to cycle at a slower rate.	❑	❑
Make a note of the IPAP and EPAP pressure at these settings.		
Decrease IPAP and EPAP pressure settings in 3 cmH_2O intervals until the IPAP set pressure is 14 cmH_2O, and EPAP set pressure is at 4 cmH_2O. Make a note of both IPAP and EPAP output pressure at each interval.		
Output pressure should be within 1 cmH_2O in any of the pressure settings.	❑	❑
NOTE: Accuracy of measured output pressure is dependent on the specified/actual accuracy of the manometer. For proper readings, ensure that the manometer has recently been calibrated in accordance with the manufacturer's recommendation.		
Reset IPAP and EPAP pressure back to 20 cmH_2O and 10 cmH_2O, respectively.		
Increase ISENS to 5. The KnightStar 330 should not cycle to IPAP and should remain at EPAP pressure (10 cmH_2O).	❑	❑
Delay Test		
Set the delay time for 5 minutes. Set the START pressure to 4.0; and press the **Mode** button.		
Press the **Delay/Ramp** button and, using the manometer, verify that the pressure has dropped to 4.0 cmH_2O.	❑	❑
Verify that the delay symbol ⎽◢ appears on the KnightStar 330 display.	❑	❑

Table 13. KnightStar 330 Setup Checklist (continued)

Procedure	Pass ✔	Fail ✔
Power Failure Indicator Verification		
While KnightStar 330 is turned on and running, disconnect the A/C power cord.		
Verify that the audible alarm activates. To mute the alarm, press the **Alarm Silence** button.	❑	❑

Appendix B:
KnightStar 330
Specifications

Table 14. KnightStar 330 Specifications

Electrical Characteristics	Rated A/C Input Voltage: 100 – 240 V~ Rated Input Frequency: 50 Hz – 60Hz Rated Input Power: 140 VA The *KnightStar 330* is designed for continuous operation. The equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.
External Battery Time	Direct current power from a 12-volt external battery pack can operate the *KnightStar 330*. The 32 ampere-hour external battery provides power for at least 8 hours. The 7 ampere-hour external battery provides power for 3 hours. If needed, cables are available for connecting the *KnightStar 330* to a car or truck cigarette lighter outlet. Rated Input Voltage: 12 V Rated Input Current: 6.0 A Rated Input Power: 140 W
Performance	Working Pressure: 3 cmH_2O to 30 cmH_2O (1 cmH_2O = 0.98 hPa) Pressure Limit: 40 cmH_2O Static Pressure Regulation: 4 cmH_2O to 30 cmH_2O CPAP $\pm$ 0.5 cmH_2O Bi-Level $\pm$ 1.0 cmH_2O
Displayed Patient Parameters	Vt: 20 mL + 20% of reading (between 50mL and 2000 mL) Peak Flow: 5 LPM + 20% of reading (between 1 LPM and 100 LPM) Leak: 5 LPM + 20% of reading (between 1 LPM and 100 LPM) Respiratory Rate: 1 BPM (between 1 BPM and 50 BPM) I:E Ratio: 15% of reading (between 1:1 and 1:9.9) Pressure: 1 cmH_2O + 10% of reading (between 3 cmH_2O and 35 cmH_2O)
Noise	30 dBA for IPAP/EPAP = 10 cmH_2O (measured 1 m in front of device)
Circuit Resistance	Inspiratory: 0.9 cmH_2O at 60 L/m 0.2 cmH_2O at 30 L/m Expiratory: 5.0 cmH_2O at 60 L/m 4.1 cmH_2O at 30 L/m
Physical Characteristics	Device Size: 3.75 in. x 8.25 in. x 5.62 in. (9.52 cm x 20.95 cm x 14.27 cm) Device Weight: 2.7 lb (1.21 kg) Device Airway Volume: 65 mL Tube Airway Volume: 695 mL (6 ft/1.8 m) 927 mL (8 ft/2.4 m)
Environmental Requirements	Operating Temperature: +41 ^oF to +104 ^oF (+5 ^oC to +40 ^oC) Humidity: 15% to 95% noncondensing Altitude: 0 to 8000 ft (0 to 2438 m) Storage Temperature: -40 ^oF to 158 ^oF (-40 ^oC to +70 ^oC) Humidity: 10% to 95% noncondensing

Appendix C: What the Patient and Caregiver Must Know

The checklist in Table 15 presents a summary of the topics that patients and caregivers must understand in order to use this device successfully. Some topics do not apply to some patients; some patients may require additional information. It is the responsibility of the clinician or clinical educator to ensure that the patient and caregiver understand the appropriate topics fully.

For a detailed list of learning objectives for patients and caregivers, see *Learning Objectives for Positive Pressure Ventilation in the Home* (National Center for Home Mechanical Ventilation, Denver, CO., July 1993). This publication is available from Puritan Bennett.

Table 15. Patient/Caregiver Checklist

The patient and caregiver must understand:	
❑	The need for bi-level ventilation.
❑	The schedule for ventilation.
❑	The supplies required for ventilation, and the sources of each.
❑	Whom to contact for medical emergencies, equipment emergencies, or power emergencies.
❑	How to contact other resources for assistance (health aides, attendants, therapists, and so on).
❑	The principles of operation for the bi-level ventilator.
❑	Power sources for the ventilator, and how to connect each.
❑	The settings for the bi-level ventilator parameters, and the importance of each.
❑	How to perform a user self-test of the bi-level ventilator, and how to respond if the self-test fails.
❑	The ventilator alarm settings, with the purpose and function of each.
❑	How to respond to bi-level ventilator alarms.
❑	What to do if the bi-level ventilator alarms inappropriately.
❑	The parts and purpose of the patient circuit.
❑	How and when to clean and replace the patient circuit.
❑	How to recognize and respond to problems with the patient circuit.
❑	The parts and purpose of the nasal interface or mask.
❑	Care of the nasal interface or mask.
❑	How to recognize and respond to problems with the nasal interface or mask.
❑	The oxygen setting, and why it is required.
❑	How to connect the oxygen source to the bi-level ventilator.
❑	How to determine the quantity of oxygen being delivered, and how to adjust the quantity.
❑	Safety rules for the use of oxygen.
❑	How and why to monitor the patient’s condition.

Table 15. Patient/Caregiver Checklist (continued)

The patient and caregiver must understand:	
❑	How to check the patient's vital signs.
❑	The significance of the patient's ease of breathing.
❑	What to note about the patient's skin, mucous membranes, and secretions, with their significance.
❑	How to recognize the signs of infection, and how to respond.
❑	The importance of routine medical appointments and medical testing.
❑	Equipment and phone numbers to have available in cases of emergency.
❑	How to respond to dyspnea.
❑	How to recognize and respond to problems with the bi-level ventilator.
❑	How to recognize and respond to problems with the oxygen supply.
❑	Techniques to prevent aspiration of vomit.
❑	The importance of coordinating care for the patient.
❑	Resources for respite care.
❑	Choices about future care.
❑	The purpose of advanced directives.
❑	Optional outlet air filters should be replaced in accordance with the filter manufacturer's instructions.

Appendix D: Service Information

KnightStar 330 ventilators are warranted against defects in workmanship and materials. The full text of the warranty provides the details. Do not make any service repairs on this equipment during the stated warranty period. Any unauthorized work immediately voids the warranty.

If you need information or assistance, or if the information in this manual is insufficient, contact Puritan Bennett at:

- 800.255.6774 (North America)
- 760.603.5300

Nellcor Puritan Bennett Incorporated does not recognize the owner of a ventilator as an authorized trained service representative. Puritan Bennett will not be liable for any repairs attempted by the owner. Any such attempted repairs other than specified non-warranty repairs void the warranty. Parts and labor costs incurred by the owner will not be reimbursed by Puritan Bennett.

Puritan Bennett will make available on request: diagrams, component parts lists, descriptions, calibration procedures and instructions to assist in the repair of parts classified by Puritan Bennett as repairable.

Before returning any device to Puritan Bennett, you must get a *Return Goods Authorization (RGA)* number by calling Puritan Bennett at one of the phone numbers listed above.

Appendix E: Limited Warranty

Puritan Bennett warrants to the owner that the *KnightStar 330* ventilator, exclusive of expendable parts and other accessories, shall be free from defects in material and workmanship for twelve months from the original date of sale. Puritan Bennett's sole obligation, with respect to any such defect, is limited to the repair or, at Puritan Bennett's option, replacement of the ventilator. Purchaser pays return freight charges.

This warranty is made on the condition that prompt notification of a defect is given to Puritan Bennett within the warranty period, and that Puritan Bennett has the sole right to determine whether a defect exists.

The warranty does not apply to ventilators that have been partially or completely disassembled; altered; subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by Puritan Bennett. This includes repair by unauthorized personnel.

This warranty represents the exclusive obligation of Puritan Bennett and the exclusive remedy of the purchaser regarding defects in the ventilator.

THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

No person is authorized to modify, in any manner, Puritan Bennett's obligation as described above.

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Note:
Digits of the device serial number refer to the date of manufacture. For example, May 21, 2001 would be represented as 010521 (Y-502**010521**22).

CE
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This device complies with the requirements of Medical Device Directive 93/42/EEC.

Y-500008-00 Rev. H

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tyco Healthcare

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