CareFusion

Infant Flow™ SiPAP

Operator's Manual

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Revision History

Date	Revision	Changes
September 2003	675-101(3)	Release
August 2004	D	Release manual in VIASYS Respiratory Care template using VIASYS Respiratory Care nomenclature. Revise part number list in Appendix B approved accessories.
November 2004	E	Revised contact/ordering information. Ch 4. Sec. 5.b revised transducer LED illumination conditions. Appendix A corrected units from "Pm" to bpm. Appendix E added dimension ranges to bonnet sizes. Appendix E Was 467350 Transducer Assembly Is: 677-002 Transducer Interface.
March 2005	F	Updated the contact information. Updated the Declaration of Conformity Notice.
May 2006	G	Updated the company name.
		Updated the Contact and Ordering Information.
		Update the figures.
		Added a Caution regarding back pressure. Added a Note regarding the Hudson RCI Humidification System.
		Added the sentence "Ensure there is a minimum 8 LPM set on the NCPAP/PRES Low Flow meter" to the first paragraph under "Two Point O_2 Sensor Calibration.
		Changed step 8 regarding the nCPAP pressure.
		Changed the second and third paragraphs under Changing a Control.
		Added "Setting a Manual Breath."
		Added a note regarding the enabling of manual breath or back-up apnea breath.
		Added a warning concerning infant flow consumables.
		Added the statement "Disconnect the air and oxygen gas sources when the Infant Flow SiPAP is not in use."
		Removed Appendix E.
February 2009	H	Changed Ti to T-High and Inspiratory Time to Time High.
		Replaced reference to VIASYS Respiratory Care accessories with reference to Cardinal Health accessories.
		Added "TM" superscript to "SiPAP".
		Added reference to AirLife™ Infant nCPAP System Generator. Removed "inspiratory time" or "inspiration time".
		Replaced "Inspiratory Time (Time High)" with "Time High

Date	Revision	Changes
		(Thigh)”
		Changed 1 cmH_2O to 1.5 cmH_2O; Added “or 60 psi” to clarify 4 bar.
		Added the parts list for both Infant Flow Products and AirLife™ Products.
		Added reference to Cardinal Health contact information on page v.
		Added reference to AirLife™ Infant nCPAP System accessories.
		Added a warning about using an external oxygen monitor. Added reference to factory trained technician and Service Manual P/N 675-120.
		Added “®” (registered symbol) superscript to Infant Flow.
		Updated CAUTION label: from “Back pressure from the humidifier chamber to some auto-feed water bags may occur.” To “Back pressure from some auto-feed humidifier chambers may cause the water bags to fill with air.”
		Replaced Figure 5.
		Add content concerning a depleted or damaged internal oxygen cell. Added a warning about using an external oxygen monitor. Added content to explain fault code E5X. Replaced “key” with “button”; clarified oxygen alarm by adding “the audible”; added clarification of the internal monitoring being disabled and that an external oxygen monitor must be used.
		Added a Note regarding the 2nd Flow Meter being used for manual breath delivery; Added hyphen in “T-High”.
		Clarified the “Mode Select Screen”
		Added “Directions for using the AirLife™ Infant nCPAP System.
		Changed 1 cmH_2O to 1.5 cmH_2O; Corrected low battery voltage level from 10 to 11.10.
		Added “or trained biomedical engineer”.
		Added a table entry for the oxygen monitor and alarms disable.
		Changed 1 cmH_2O to 1.5 cmH_2O; corrected low battery voltage level from 10 to 11.10.
		Updated Table 10.
		Updated Table 11.
		Clarified the meaning of T-High.
February 2010	J	Revised to comply with the revised Medical Device Directive 2007/42/EC.

Date	Revision	Changes
March 2010	K	Rebranded the manual to the CareFusion style. Updated the part number table.
January 2011	L	Changed the logo and company references to VIASYS.
January 2011	M	Changed the logo and company references to CareFusion.
March 2013	N	Corrected the pneumatic supply range specification. Corrected the atmospheric and environmental storage specification.
June 2013	P	Removed TM from SiPAP. Changed ® to TM for the name Infant Flow. Updated the address information to include symbols. In the “Flow/Pressure Relationship” section, added the Flow pressure nomogram for the Infant Flow LP generator. In the Leak Test procedure, step 4, added “(for the Infant Flow LP generator, adjust the flow meter to 9 L/M).” In the “Alarms Test” section, in the Alarm Test Initial Settings table, added “Infant Flow LP: 9L/min (for delivery of 5 cmH2O)” to the NCPAP / Pres Low flow meter specification. Updated figures to remove references to VIASYS. Corrected the Intended Use Notice. Added the “SiPAP Gas Monitor” section. Added the “Electromagnetic Environment Specifications” section. Fixed paragraph misalignment where needed.

Warranty

Infant Flow™ SiPAP is warranted to be free from defects in material and workmanship and to meet the published specifications for One (1) year from date of shipment.

The liability of CareFusion Corporation (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company will not be liable under this warranty unless (A) the Company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. In no event shall the Company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

The Company warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation of Liabilities

This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of One (1) year from date of shipment, with the following exceptions:

1. Components for monitoring of physical variables such as temperature, pressure, or flow are warranted for ninety (90) days from date of receipt.
2. Elastomeric components and other parts or components subject to deterioration, over which the Company has no control, are warranted for sixty (60) days from date of receipt.
3. Internal batteries are warranted for ninety (90) days from the date of receipt.

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of the Company.

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Notices

EMC Notice

This equipment radiates and is susceptible to radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in BS EN60601-1-2 for Medical Electrical Equipment Part 1-2: General requirements for safety-collateral standard, Electromagnetic compatibility – requirements and tests. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals) described in this manual.

This device is also designed and manufactured to comply with the following standards:

Safety: UL 60601-1: 2003 Medical Electrical Equipment, Part 1: General Requirements for Safety.

CAN/CSA C22.2 No 601.1-M90, Medical Electrical Equipment - Part 1: General Requirements for Safety including C22.2 No. 601.1S1-94 (IEC601-1, Amendment 1:1991) Supplement No. 1-94 to CAN/CSA 22.2 No. 601.1-M90, EN ISO 21647

Electrical Safety:

Class 1 equipment

Contains type BF patient applied parts

Continuous Operation

MRI Notice

This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.

Do not operate this device in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

Electromagnetic Environment Specifications

Guidance and manufacturer's declaration – electromagnetic emissions		
Sipap is intended for use in the electromagnetic environment specified below. The customer or the user of Sipap should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Sipap uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Sipap is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	n/a	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Sipap is intended for use in the electromagnetic environment specified below. The customer or the user of Sipap should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

Sipap is intended for use in the electromagnetic environment specified below. The customer or the user of Sipap should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of Sipap, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sipap is used exceeds the applicable RF compliance level above, the Sipap should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Sipap.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Sipap

Sipap is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Sipap can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Sipap as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Intended Use Notice

The Infant Flow nCPAP System, consisting of the Infant Flow SIPAP Driver and Generator assembly plus NCPAP Prongs and Masks, is intended for the provision of nasal CPAP and BiPhasic CPAP (SiPAP) to produce a sigh. Nasal CPAP should only be used on a spontaneously breathing infant. The system is for use in hospitals, hospital-type facilities, and intra-hospital transport environments and is indicated for the treatment of newborn and infant patients. The Infant Flow SiPAP driver should only be operated by properly trained clinical personnel, under the direction of a physician.

Regulatory Notice

Federal law restricts the sale of this device except by or on order of a physician.

Reuse of single-patient use accessories may degrade the performance of the product or cause cross contamination.

Classification

Type of Equipment: Medical Equipment, Class 1 and internally powered, IPX1 Protected, and uses type BF applied parts. Equipment is not suitable for use in presence of flammable anesthetics.

Declaration of Conformity Notice

This medical equipment complies with the Medical Device Directive, 93/42/EEC, and the following Technical Standards, to which Conformity is declared:

EN60601-1 and EN60601-1-2
EN 10993
EN 14971

CE
0086

EU Notified Body:

BSI (Reg. No. 0086)

Trade names:

Infant Flow

SiPAP

Manufactured by:

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, CA 92887-4668

If you have a question regarding the Declaration of Conformity for this product, please contact CareFusion.

Infant Flow SiPAP

Chapter 1 Product Description

Infant Flow™ SiPAP driver provides a non-invasive form of respiratory support designed for infants in hospital environments such as Neonatal and Pediatric Intensive Care Units. It can also be used when transporting these patients within the hospital environment.

Infant Flow SiPAP driver is currently available in a Plus or Comprehensive* configuration. The Plus configuration provides NCPAP and time triggered BiPhasic modes with and without breath rate monitoring. The Comprehensive* configuration offers these features plus a patient triggered BiPhasic mode with apnea backup breaths. The Infant Flow SiPAP driver comes standard in all configurations with an LCD touch screen display, pressure time waveform graphics, integrated patient monitoring, alarms for high and low pressure and FiO_2 and up to 2 hours of backup battery power.

As a result of the unique, patented design, the Infant Flow, Infant Flow LP or AirLife Infant nCPAP System Generators have been proven to provide the most stable CPAP at the lowest work of breathing for patients compared to other devices [(1)]. The outstanding performance of variable flow generators is irrespective of patient demand or expiratory flows. The SiPAP driver has been designed and tested to perform optimally when used only with accessories available from CareFusion. These accessories include the variable flow generator, single limb breathing circuit, nasal prongs, nasal masks, and fixation device, either bonnet or headgear.

Infant Flow SiPAP Features

The expanded capabilities of the Infant Flow SiPAP Plus and Comprehensive* configurations allow for applications to broader range of patients who may otherwise not be candidates for non-invasive respiratory support from NCPAP alone [(2,3)].

NCPAP – continuous positive airway pressure based on clinician set pressure. Breath rate monitoring/alarm can be activated in this mode.

BiPhasic – time triggered pressure assists are delivered based on clinician set Time-High, rate and pressure criteria. Breath rate monitoring/alarm can be activated in this mode.

BiPhasic tr* – patient triggered pressure assists delivered based on clinician set Time-High and pressure criteria. Breath rate monitoring/alarm and Apnea backup breaths are automatically active in this mode.

Infant Flow, Infant Flow LP, or AirLife Infant nCPAP System Generator – The Infant Flow Generator is a fluidic device for the generation of consistent infant nasal CPAP with a low work of breathing compared to other devices[(1)].

Fully integrated alarm package – Supply gases failure, High Patient Pressure, Low patient pressure, high and low delivered Oxygen concentration, change from AC to DC power source, low and flat battery charge status and Low breath rate/apnea alarm.

Battery Backup – Up to 2 hours of battery backup allows for intra-hospital transport. Clear indicators are provided for power supply in use (AC or DC), and battery charge level.

Screen Lock – After 120 seconds of no screen inputs, the screen changes to the Locked Screen to prevent inadvertent changes. Upon activation of a high priority alarm the screen changes to an unlocked state to allow access to controls.

Table 1 Functions and Accessories

Functions and Accessories	Plus	Comprehensive*
NCPAP	●	●
NCPAP with breath rate monitoring and alarm	●	●
BiPhasic	●	●
BiPhasic with breath rate monitoring and alarm	●	●
BiPhasic tr*		●
Internal Battery	●	●
Manual Breath	●	●
Apnea Back up rate		●
Screen lock	●	●
Prioritization of alarms	●	●

***Comprehensive configuration not available for sale in the United States**

(1) Decreased imposed work with a new nasal continuous positive airway pressure device. Klausner, James F., PhD, Lee, Amy., Hutchison, Alastair A., FRACP. Pediatric Pulmonology 22: 188-194; 1996

(2) A Prospective Randomized, Controlled Trial Comparing Synchronized Nasal Intermittent Positive Pressure Ventilation versus Nasal Continuous Positive Airway Pressure as Modes of Extubation. Khalaf Nabeel, M., Brodsky Nancy, Hurley John, Bhandari Vineet. PEDIATRICS 108 (1): 13-17: 2001

(3) Efficacy of Nasal Intermittent Positive Pressure Ventilation in Treating Apnea of Prematurity. Lin Chyi-Her, MD, Wang Shan-Tair, PhD, Lin Yuh-Jyh, MD, Yeh Tsu-Fuh, MD: Pediatric Pulmonology: 26 (5): 349-53; 1996

Chapter 2 Product Specifications

Modes

- NCPAP
- NCPAP with breath rate monitoring and low rate alarm
- BiPhasic (time triggered)
- BiPhasic (time triggered) with breath rate monitoring and low rate alarm
- BiPhasic tr (patient triggered) with breath rate monitoring, low breath rate alarm and apnea back up (Comprehensive models only)

Controls

- Time High (T-High) – 0.1 – 3.0 seconds
- Rate (R)
  - 1-120 (Non-U.S. Configuration Parameters)
  - 1-54 (U.S. Configuration Parameters)
- Apnea Interval
  - (T_{apnea}) – 10-30 seconds, 5 second intervals (Non-U.S. Configuration Parameters)
  - (TLBR) – 10-30 seconds; 5 second intervals (U.S. Configuration Parameters)
- NCPAP / Pres Low flow meter – 0-15 L/min, accuracy $\pm$ 15% of selected output
- Pres High flow meter – 0-5 L/min, accuracy $\pm$ 15% of selected output
- Manual Breath – X 1
- $\%O_2$ – 21 -100%

Monitors

- CPAP
- PEEP
- MAP
- PIP
- $\%O_2$
- I:E ratio
- Spontaneous rate (Rsp)
- Battery charge level

Alarms

- High airway pressure – 3 cmH_2O above measured airway pressure
- Airway over-pressure limit alarm
  - maximum 11 cmH_2O in NCPAP and time triggered BiPhasic mode
  - maximum 15 cmH_2O in patient triggered BiPhasic tr mode
- Low airway pressure – 2 cmH_2O below measured airway pressure or 1.5 cmH_2O if otherwise would be zero
- High and Low delivered Oxygen concentration ±5% of setting. Minimum and maximum delivered FiO2 is 18 and 104% respectively.
- Low breath rate alarm
- Low battery charge level
- Flat battery
- Input gases failure
- Alarm volume (electronic alarms) 70 dBa at 1 meter

Pneumatic Supply

- Patient Gas Outlet: 15 mm standard taper fitting
- Patient Pressure Input: 4.5 mm Luer taper fitting
- Gas Supply: Nominal 4 bar or 60 psi, clean, dry medical air and oxygen
- Range: 4.8 to 6 bar (40.6 to 87 PSI); Maximum differential pressure 2 bar, (30 psi)
- Manometer: Range 0 to + 20 cmH_2O, accuracy, $\pm$ 2% of span
- Gas Connections: Standard DISS, NIST or Air Liquide connectors

Electrical Supply

- Input Voltage: 100-230 VAC
- Input Frequency: 50/60 Hz
- Power Consumption: 50 VA maximum
- Fuse Rating For 220 V nominal operation: “T” Type 2.5 A at 250 V
- Device Housing Protection rating level: IPX1
- Battery Working Time: 2 hours (from fully charged state)
- Battery Charging Time: max. 16 hours

Atmospheric and Environmental

- Temperature Range
  - Operating: 5 to 40° C
  - Storage: - 20 to 60° C
- Relative Humidity -Operating: 0 to 95% non-condensing
- Storage: 0 to 95% non-condensing

Physical

- Dimensions (Driver only)
  - (W x H x D) 26 x38 x 23.5 cm
  - (W x H x D) 10.25 x15 x 9.25 in
- Weight (Driver only)
  - 8.8 kg
  - 19.5 lb

Accessories

- Silencer / Bacterial Filter - The additional resistance of the D1420/100 Silencer / Bacterial Filter and adaptor is less than 0.56 cmH_2O at 15 LPM, and less than 0.40 cmH_2O at 5 LPM.

SiPAP Gas Monitor

- Total system response time: 8.61 seconds
- Drift: No drift after six hours of operation
- Cyclical pressure: Up to 10 Kpa (100 cmH_2O)—has no effect on the gas monitor accuracy
- Accuracy of the oxygen reading at 30, 40 and 60%: No drift when cycling the ventilator
- With non-diverting flow at 10 mL/min at a pressure of 60 Kpa (60 cmH_2O), the ventilator and sensor show no leaks.
- The gas monitor uses the internal battery and is not affected by power interruptions or fluctuations of the external power.

Infant Flow SiPAP

Chapter 3 Summary of Warnings and Cautions

Please review the following safety information prior to operating the Infant Flow SiPAP driver. Attempting to operate this equipment without fully understanding its features and functions may result in unsafe operating conditions.

Warnings and Cautions, which are general to the use of the device under all circumstances, are included in this section. Some Warnings and Cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

If you have a question regarding the installation, operation, or maintenance of the device, contact CareFusion (see page ii).

Terms

WARNINGS identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

CAUTIONS identify conditions or practices that could result in damage to the driver or other equipment.

NOTES identify supplemental information to help you better understand how the driver works.

Warnings

- Infant Flow SiPAP driver is intended for use by a trained practitioner, under the direct supervision of a qualified physician.
- When the Infant Flow SiPAP driver is connected to a patient, a trained health care professional should be in attendance at all times to react to an alarm or other indications of a problem.
- Always have an alternate means of ventilation available whenever the Infant Flow SiPAP driver is in use.
- Do not attach the Generator to the patient until User Verification and initial set up into NCPAP mode is complete.
- Water in the air supply can cause this equipment to malfunction. Check the water trap at least every 24 hours (more frequently if needed, depending on amount of water in the air supply).
- The operator should not touch the electrical connectors of the Infant Flow SIPAP driver or its accessories, and the patient simultaneously.
- An audible alarm indicates an anomalous condition and should never go unheeded.

- Anti-static or electrically conductive hoses or tubing should not be used within the patient circuit.
- If a mechanical or electrical problem is recognized while operating the Infant Flow SiPAP driver, it must be removed from use and referred to qualified service personnel for servicing. Using inoperative equipment may result in patient injury.
- Prior to patient application, ensure that all User Verification testing and calibration procedures are successfully completed. User Verification testing and calibration procedures must be done off patient.
- The  indicates a connection between the Transducer Assembly and the driver. It does not indicate attachment or correct positioning of the Abdominal Respiratory Sensor.
- Under certain conditions (minimum supply pressure and maximum gas demand, including auxiliary output) output flow rates and therefore pressure delivered to the generator may be reduced.
- The Pres High flow meter must be adjusted to zero when not required for the patient.
- Whenever a patient is attached to respiratory care equipment, constant attendance is required by qualified personnel. The use of an alarm or monitoring system does not give absolute assurance of warning for every malfunction that may occur in the system. In addition, some alarm conditions may require immediate attention.
- Nasal CPAP therapy in general can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to the recommended usage instructions for the Infant Flow nCPAP System and AirLife Infant nCPAP System may reduce the incidence of these complications.
- It is strongly recommended that regular monitoring for gastric distention be carried out for patients receiving noninvasive ventilatory support. Refer to your facility's policy and procedure for further guidance.
- This device exhausts O2 during normal operation. Oxygen vigorously accelerates combustion. To avoid fire hazard, do not place flammable materials or sources of heat close to the exhaust.
- The Abdominal Respiratory Sensor is used only to enable features associated with certain modes from the Infant Flow SiPAP driver. When using the Abdominal Respiratory Sensor, always use an additional, external device for monitoring of the respiratory rate and detection of apneic episodes as well as an appropriate monitor for continuous SaO2 monitoring.
- If the Infant Flow SiPAP driver is shelf mounted, ensure that the driver is stable and that all circuit tubing, hoses and cables are restrained to avoid hazard of toppling.
- If a patient water trap is to be used, empty it before using it, and empty it frequently during use (at least every hour). Empty the water trap according to approved, hospital procedures.
- Do not block or restrict the exhaust port located on the instrument back panel. Equipment malfunction may result.

- Do not use the equipment without the expiratory tubing connected to the generator.
- Only use the supplied AC cable to connect to the power supply.
- The Transducer LED indicator on the front panel of the driver only signifies connection to the driver. It does not indicate connection to or proper positioning of the Abdominal Respiratory Sensor.
- Do not overload the pole and stand.
- Oxygen vigorously accelerates combustion. To avoid explosion hazard, do not use any instrument or other equipment that may have been exposed to oil or grease contamination.
- When a low gas supply alarm occurs, the oxygen concentration delivered to the patient will differ from that set on the %O2 control.
- A source gas failure will change the FiO2 and may result in patient injury.
- The functioning of this equipment may be adversely affected by the operation of other equipment nearby, such as high frequency surgical (diathermy) equipment, defibrillators, short-wave therapy equipment, “walkie-talkies”, or cellular phones.
- Due to possible explosion hazard, the Infant Flow SiPAP driver should not be used in the presence of flammable anesthetics.
- Electric shock hazard – Do not remove any of the Infant Flow SiPAP covers or panels. Refer all servicing to an authorized CareFusion service technician or factory trained technician (see Service Manual P/N 675-120).
- A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. Upon loss of protective earth ground, all conductive parts including knobs and controls that may appear to be insulated can render an electrical shock. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the ventilator, and make sure the power cord is in good condition.
- The Infant Flow SiPAP driver is designed to ensure that the user and patient are not exposed to excessive leakage current per applicable standards. However, this cannot be guaranteed when external devices are attached to the driver. In order to prevent the risk of excessive enclosure leakage current from external equipment attached to the driver, isolation of the protective earth paths must be provided to ensure proper connection. This isolation should ensure that the cable shields are isolated at the peripheral end of the cable.
- When the Infant Flow SiPAP driver is connected to a patient, and the internal oxygen monitor is disabled, the Infant Flow SiPAP driver must be used with an external oxygen monitor.
- To ensure a full battery charge, the Infant Flow SIPAP driver should be plugged into an AC outlet when not in use.
- Always disconnect the infant from the SIPAP driver, before turning off the SiPAP device and disconnection from gas source.

Cautions

- Before use, verify that this equipment has been authorized for use by qualified technical service personnel.
- Ensure that the voltage and installed fuses are set to match the voltage of the wall outlet, or damage may result.
- A battery that is fully drained (i.e. void of any charge) may cause damage to the driver and should be replaced.
- All accessory equipment that is connected to the driver should comply with CSA/IEC601/ETL.
- Although failure of any of the user verification tests (page 17) will not prevent the ventilator from functioning, the ventilator should be checked to make sure it is operating correctly before use on a patient.
- The Infant Flow SiPAP driver has been designed and tested using only CareFusion accessories. Only accessories approved for use by CareFusion should be used. If in doubt, please contact your local sales representative.
- Employ safe lifting procedures when assembling the unit.
- Do not sterilize the driver. The internal components are not compatible with sterilization techniques.
- Do not submerge the SiPAP driver, spray the driver with liquid, or pour cleaning liquids over or into the driver.
- Following each alarm verification test, ensure that control settings and alarm limits are reset as instructed before proceeding to the next test.
- Only use power cords supplied by CareFusion. Failure to use CareFusion parts may result in loss of electrical or mechanical safety in unanticipated ways during operation.
- If the Infant Flow SiPAP is turned off or if the battery is depleted, the current patient settings will be lost. The Infant Flow SiPAP will return to the default settings when turned back on.

Notes

- CareFusion cannot ensure product performance as stated in this manual with the use of Non-CareFusion accessories.

Chapter 4 Unpacking and Setup

Assembly and physical setup

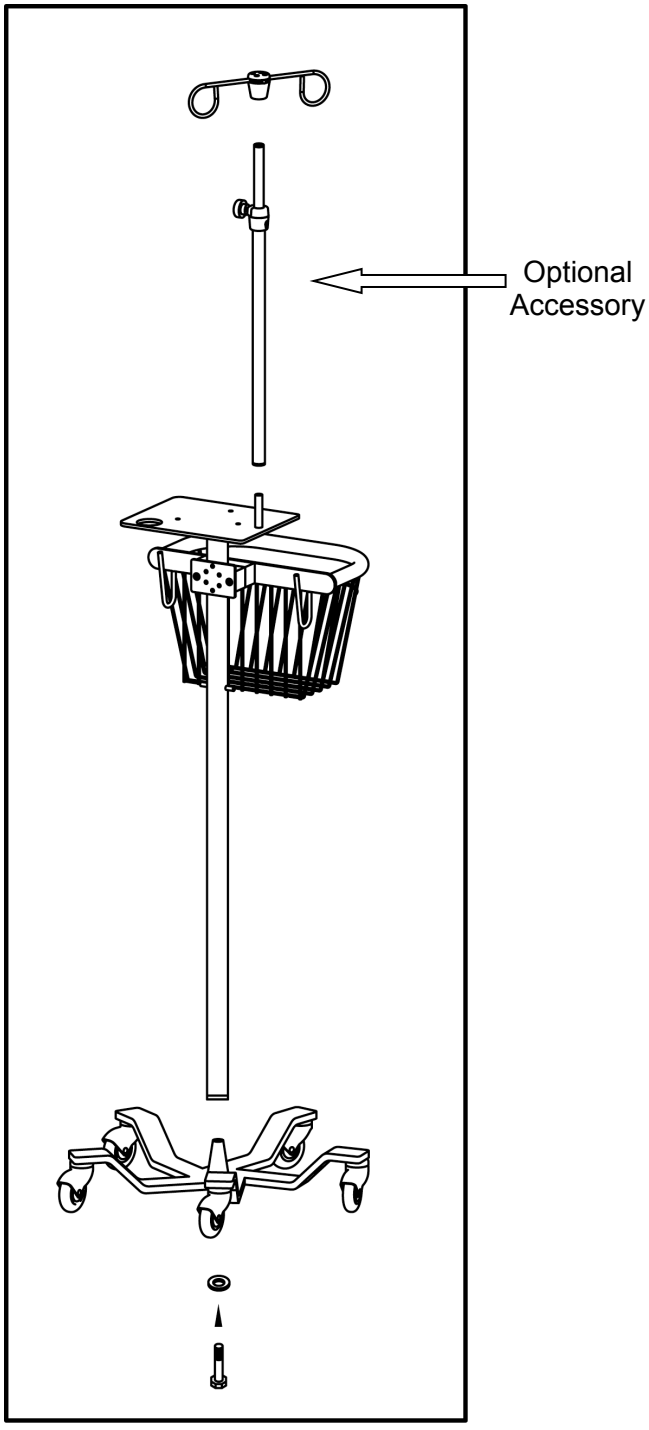


Figure 1 Stand unpacking and assembly

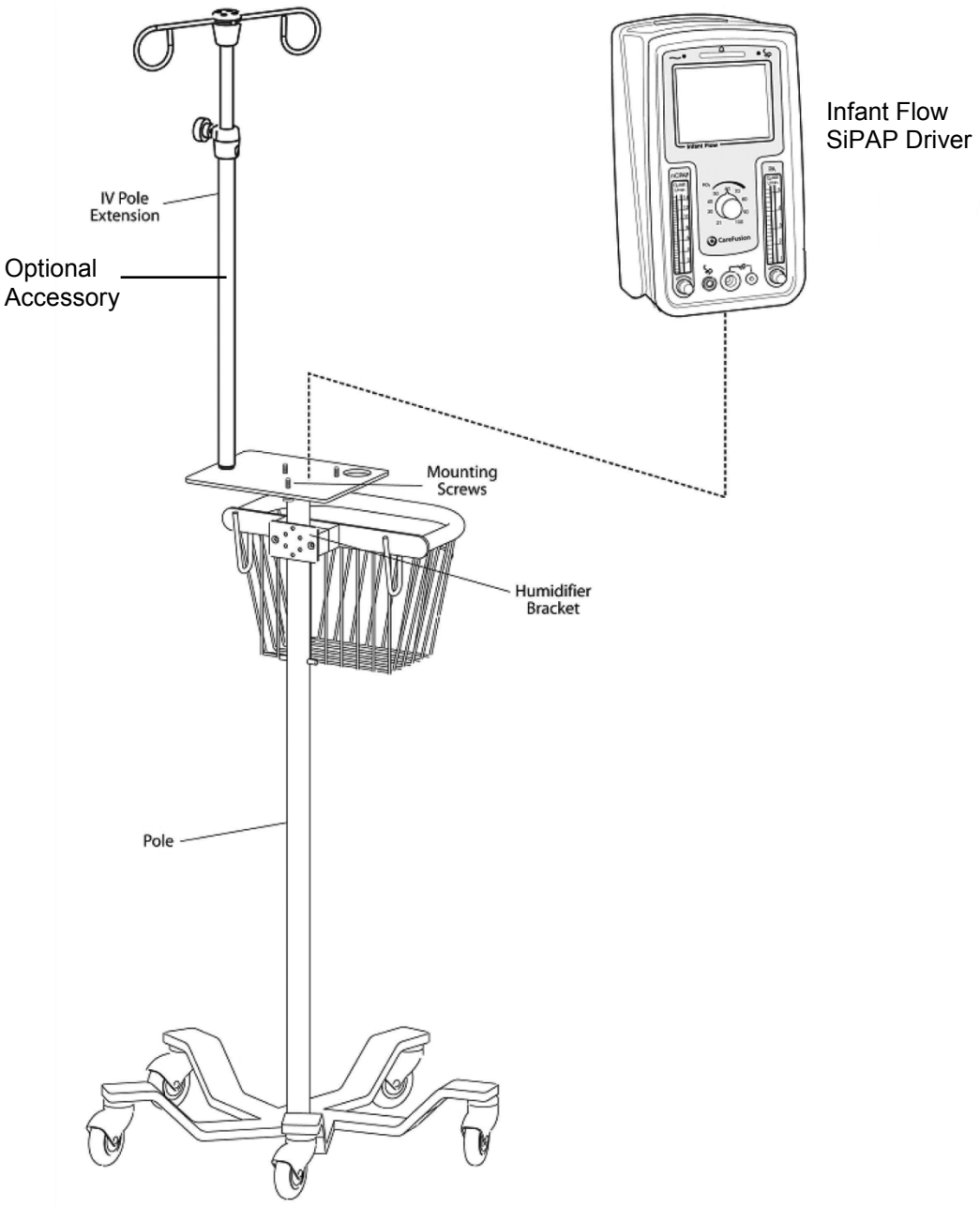


Figure 2 Stand and Driver assembly

Attaching a patient circuit

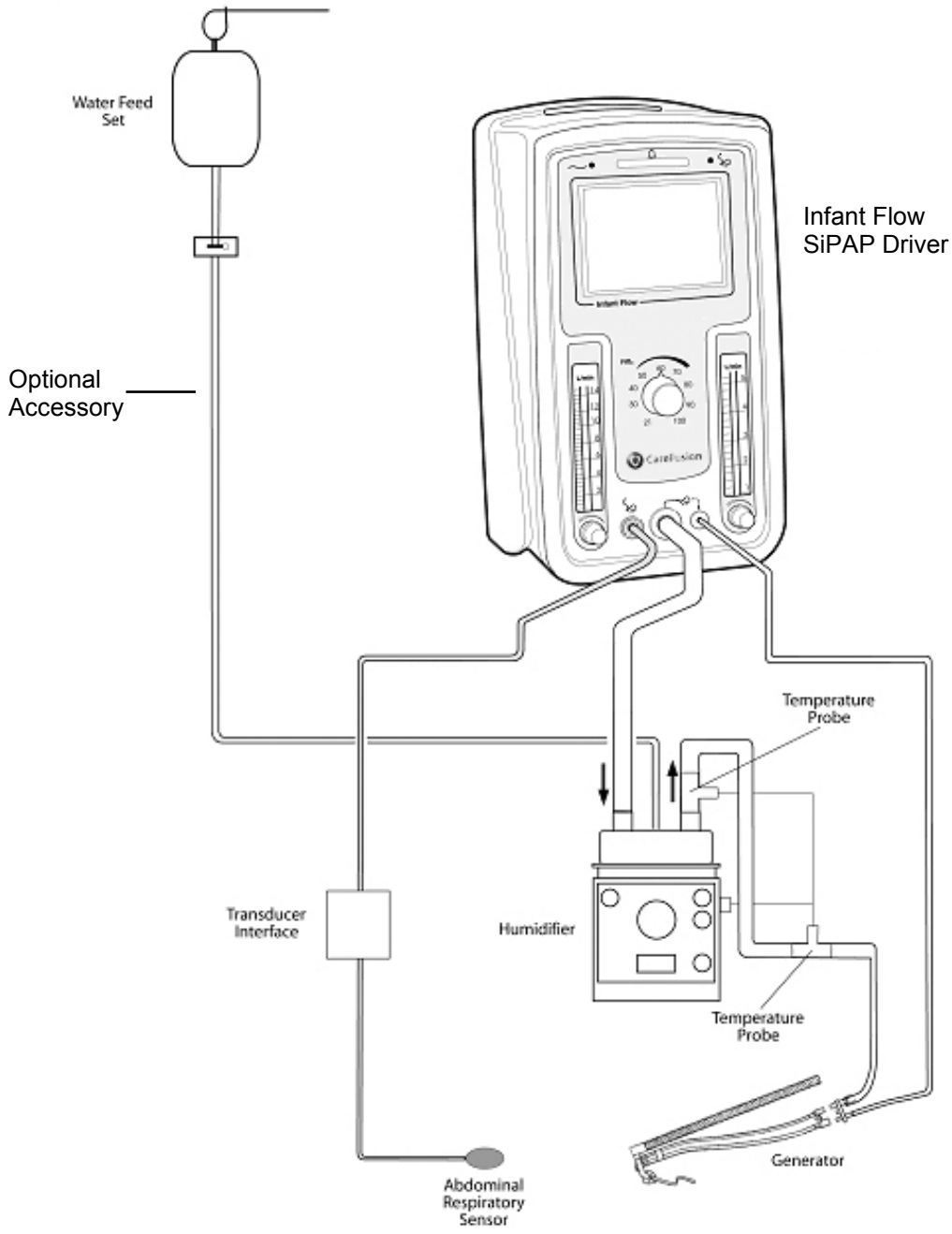


Figure 3 Driver assembled with patient circuit and /humidifier

Note

We recommend between 96.8 °F (36 °C) and 98.6 °F (37 °C) but never higher than 98.6 °F (37 °C) for inspired gases.

CAUTION

The drive pressure may create back pressure in some auto-feed humidifier chambers and cause the water bags to fill with air. If this occurs, ensure the humidifier chambers are adequately filled and the water bag is placed at the correct height according to the manufacturer's instruction. A pressure cuff placed around the water bag may prevent air entering the water bag.

Note

When the Hudson RCI Humidification System is being used with Infant Flow SiPAP driver, it is recommended that the standard compliance column be used.

Attaching the Abdominal Respiratory Sensor

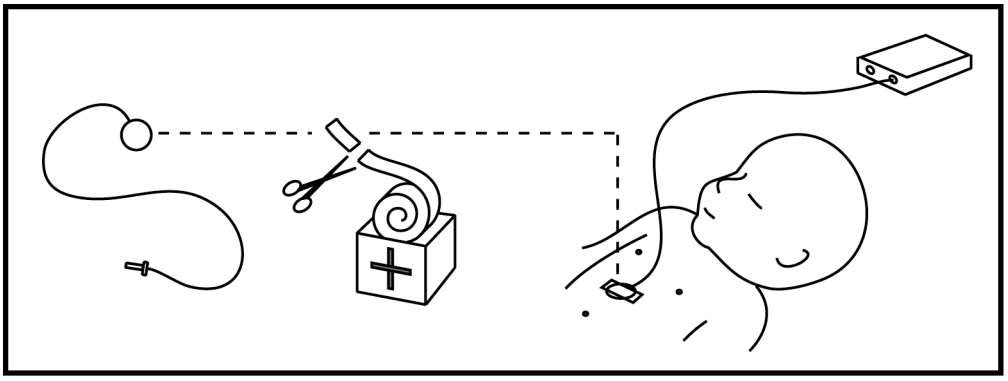


Figure 4 Attaching the Abdominal Respiratory Sensor

1. Connect the Transducer Assembly to the front panel of the driver (Figure 3)
2. Connect Abdominal Respiratory Sensor to the Transducer interface.
3. Apply gentle compression to sensor. Verify function with illumination of LED on transducer interface.
4. Apply the sensor with suitable tape (Figure 4) according to the adhesive protocols of the hospital.
   a. Pressure line perpendicular to tape
   b. Sensor between umbilicus and xiphisternum
   c. Placement on the side of the abdomen may be necessary
5. Verify correct placement
   a. Observe spontaneous breathing
   b. Transducer LED illuminates on expiration; Front panel Transducer LED illuminates on inspiration

Flow / Pressure Relationship

The Infant Flow SiPAP driver is subject to a direct relationship between the controlled enriched gas flow and airway pressure. A nomogram illustrating the relationship between constant airway pressure and flow settings is shown in Figure 5. For example, 8 L/min gas flow provides approximately 5 cmH_2O.

Note

Individual devices have a tolerance of up to ± 10% from that illustrated in the nomogram and in particular, at pressures below 2 cmH_2O.

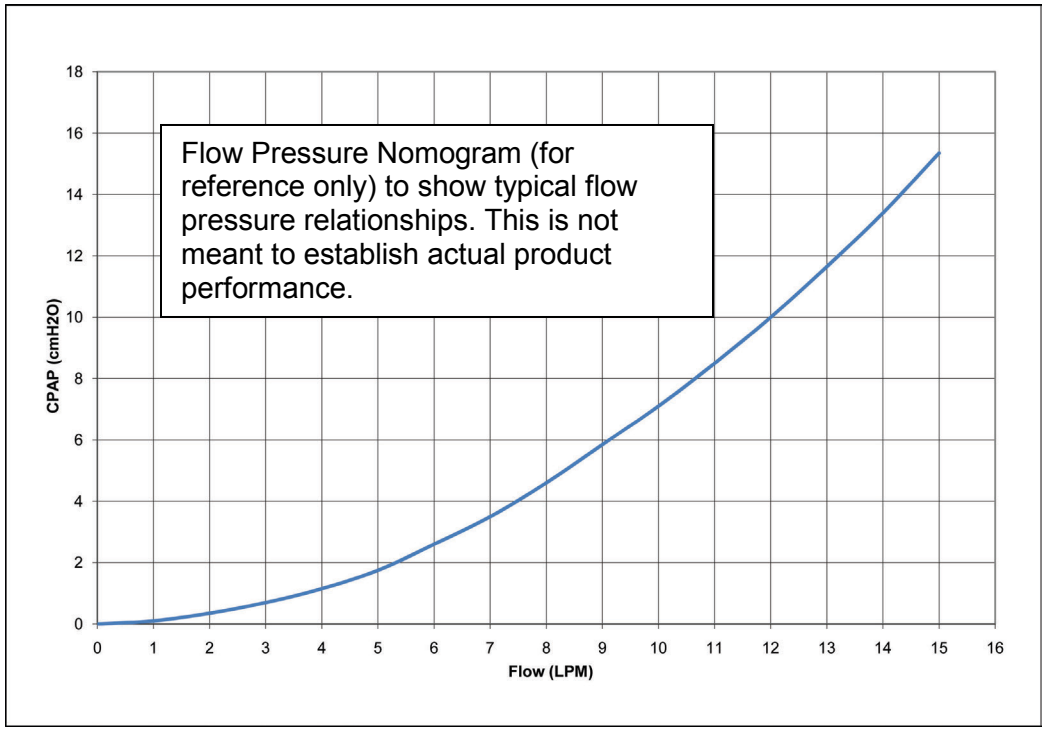


Figure 5: Flow pressure nomogram for 675-CFG-XXX when used with the Infant Flow variable-flow generator

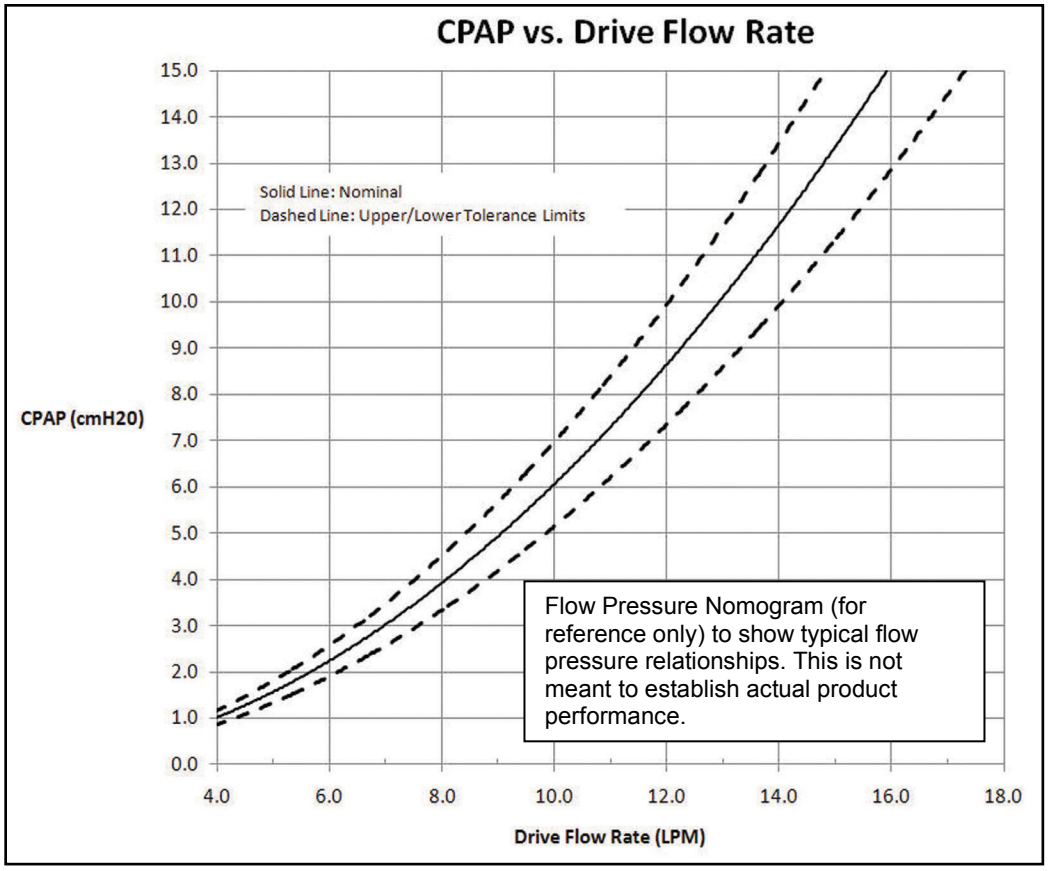


Figure 6: Flow pressure nomogram for 675-CFG-XXX when used with the Infant Flow LP or AirLife variable-flow generator

Individual devices have a tolerance of up to ±15 percent from that illustrated in the nomogram and, in particular, at pressures below 2cmH_2O.

User Verification Test

WARNING

Do not attach Generator to the patient until User Verification and initial setup into NCPAP mode is complete.

CAUTION

Although failure of any of the user verification tests described in this section will not prevent the ventilator from functioning, the ventilator should be checked to make sure it is operating correctly before use on a patient.

Power-on Check

This test is run automatically on power up of the driver and automatically performs the following checks:

- Flash ROM
- Hardware Inputs/Outputs
- Audible and visual alarms indicators
- Test and calibration of pressure sensor
- Test of dump valve

The unit carries out a full functional check during this time. If unsuccessful, the screen remains darkened and the warning bar remains on. In this case, check for the following;

- Power Supply not connected
- Battery voltage low

If the checks are successful, the screen changes to Power Up Screen.

During the Power Up check:

- Screen image shown in negative
- Warning bar comes on for one second
- Transducer Assembly LED comes on for one second
- Audible alarm sounds for one second
- Dump valve is tested
- Pressure is set to zero

After two seconds screen changes to Setup Screen. Alarm limits are disabled and a flashing question mark appears under the NCPAP / Pres Low flow meter screen indicator.

Two Point O_2 Sensor Calibration

Enter the Calibration Screen from the Setup Screen by pressing the calibration button on the lower right hand corner of the touch screen. Ensure there is a minimum 8 LPM set on the NCPAP/PRES Low Flow meter. In addition, ensure there is a minimum of 3 LPM set on the NCPAP/High Flow meter. Adjust the $\%O_2$ control to 21%. Allow the $\%O_2$ display to stabilize. Confirm the calibration by touching the associated flashing button.

Adjust the $\%O_2$ control to 100%. Allow the $\%O_2$ display to stabilize. Confirm by touching the associated flashing button. Return to the Startup Screen by pressing the Exit button.

Note

If O_2 calibration fails, a red "X" is shown. Refer to the Service Manual.

If the internal oxygen cell is depleted or damaged, it may not be possible to calibrate the O_2 sensor. The internal oxygen monitor may be disabled using the Disable O_2 button. This will disable oxygen monitoring and the audible oxygen alarms until the device is powered off. Whenever the device is operating with oxygen monitor and alarms disabled, a fault code E55 displays, and measured FiO_2 displays as dashes.

WARNING!

When the Infant Flow SiPAP unit is connected to a patient, and the internal oxygen monitor is disabled, the Infant Flow SiPAP unit must be used with an external oxygen monitor.

If calibration is attempted, and fails, or if the oxygen cell fails while the device is in normal use, a Fault Code E55 displays, as tabulated in appendix D, and a high priority alarm is indicated visually and audibly. To enable continued operation, the internal oxygen monitoring may be disabled by pressing and holding the alarm mute / reset button for 3 seconds. This disables the internal oxygen monitor and alarms and clears the alarm condition. The E55 code remains to indicate that the oxygen monitor is inoperative. An external oxygen monitor must be used.

Leak Test

1. Have the patient circuit and generator assembled as shown in Figure 3.
2. Connect the patient interface (prong or mask) to the generator (see Chapter 5, Step by Step Fixation) and occlude the opening to the patient.
3. If not powered up already, switch on the power to the driver.
4. Adjust the NCPAP / Pres Low flow meter to 8 L/min (for the Infant Flow LP generator, adjust the flow meter to 9 L/min). Verify that the measured pressure is 5 $\pm$1 cmH_2O. Touch the associated flashing screen icon to confirm.
5. Adjust $\%O_2$ control as prescribed for the current patient. Verify that the blender setting and the measured oxygen value are within 3%. Touch the associated flashing screen icon to confirm.
6. Adjust the Pres High flow meter as prescribed for the current patient. Touch the associated flashing screen icon to confirm.
7. Connect the Transducer Interface to the front panel of the driver if breath monitoring is desired in treatment. Touch the associated flashing screen icon to confirm.
8. The display screen changes to the Alarm Set/Confirm Screen. Press the NCPAP button or Alarm Mute/Reset button to set alarms and begin monitoring.
9. Monitored parameter for CPAP should be 4-5 cmH_2O. If not, check circuit for leaks or blockages, (including the humidification system).
10. Remove the occlusion to the patient interface. The monitored CPAP display should be 0-2 cmH_2O. If not, check that the interface is not still occluded.

Alarms Test

WARNING

Prior to patient application, ensure that all User Verification testing and calibration procedures are successfully completed. User Verification testing and calibration procedures must be done off patient.

NOTE

The audible and visual alarm indicators run automatically on power up of the driver and allow the audible and visual alarms to be checked.

NOTE

Following each alarm verification test, ensure that control settings and alarm limits are reset as instructed before proceeding to the next test.

Alarm Test Initial Settings	
Air Supply Pressure	> 30 psig (2.1 bar)
O_2 Supply Pressure	> 30 psig (2.1 bar)
Patient Circuit	Infant Flow or AirLife Infant nCPAP System Patient Circuit
Generator	Infant Flow or AirLife Infant nCPAP System Generator
NCPAP / Pres Low flow meter	Infant Flow: 8 L/min (for delivery of 5 cmH_2O) Infant Flow LP: 9L/min (for delivery of 5 cmH_2O)
% O_2	30%
Pres High flow meter	3 L/min
Mode	NCPAP
For Step 9 Use the settings provided below	
Rate	30 bpm
T-High	0.3 sec
Tapnea (Non-U.S. Configuration) / T_{LBR} (U.S. Configuration)	20 sec

Perform the Alarms Test on the Infant Flow SiPAP driver using the following steps and the initial settings provided above.

1. Make appropriate connections for air and oxygen gas supply. Connect power cord to appropriate AC outlet. Attach patient circuit, generator and patient interface (mask or prong) as shown in Figure 3. Occlude the opening to the patient.
2. Power up the driver and allow Power On Check to complete.
3. Low airway pressure alarm: From NCPAP operating mode, with alarms set, remove occlusion from opening to patient. Verify that the low airway pressure alarm activates. Restore the patient interface occlusion and press the Alarm Mute / Silence button for 3 seconds to reset the alarms.
4. High airway pressure alarm: Adjust the NCPAP / Pres Low flow meter to 11 L/min. Verify that the high airway pressure alarm activates. Return the NCPAP / Pres Low flow meter to 8 L/min and press the Alarm Mute / Silence button for 3 seconds to reset the alarms.
5. High $\%O_2$ Alarm: Adjust the % O_2 control to 35%. Verify that the High $\%O_2$ alarm activates. Return the O_2 control setting to 30%. Reset alarms by pressing the Alarm Mute / Reset button for 3 seconds.
6. Low % O_2 Alarm: Adjust the % O_2 control to 25%. Verify that the Low $\%O_2$ alarm activates. Return the O_2 control setting to 30%. Reset alarms by pressing the Alarm Mute / Reset button for 3 seconds.
7. Loss AC Alarm: Disconnect the AC power cord from the wall outlet. Verify that the Loss AC alarm activates. Reconnect the AC power cord. Clear the alarm by pressing the Alarm Mute / Reset button.
8. High Circuit Pressure Alarm: Increase nCPAP pressure to 11.1 cmH_2O by increasing the NCPAP/PRES Low Flow meter. Verify that the High Circuit pressure alarm activates. Return NCPAP/PRES Low Flow meter to 8 LPM and press the Alarm Mute/Silence button for three seconds to reset the alarms.
9. Low Breath Rate (Apnea) Alarm: Select and confirm BiPhasic+Apnea/LBR (U.S. configuration). Using the abdominal sensor, manually tap the abdominal sensor to simulate a spontaneous breath rate. The default mandatory breath rate should be left alone. No alarms should be present. Change the mandatory rate control setting to 1 bpm and stop tapping the abdominal sensor. Verify that the Low Breath rate alarm activates after the default interval of 20 seconds. Resume simulating spontaneous breath rate, turn the rate control to the default setting and clear the alarm by pressing the Alarm Mute/Reset button for 3 seconds. Note: a transducer must be connected to perform the alarm check.

Infant Flow SiPAP User Verification Test Checklist

Driver Serial Number:_____ Test Date:_____

TEST	PASS	FAIL
Automated Tests		
Power On Check	☐	☐
Manual Tests		
Two Point O_2 Sensor Calibration	☐	☐
Patient Circuit Leak test	☐	☐
Manual Alarms Checks		
Low Airway Pressure Alarm	☐	☐
High Airway Pressure Alarm	☐	☐
High O_2 Alarm	☐	☐
Low O_2 Alarm	☐	☐
Loss AC Alarm	☐	☐
High Circuit Pressure Alarm	☐	☐
Low Breath Rate (Apnea) Alarm	☐	☐

Signature of tester:_____

Title_____

Chapter 5 Operation

Front Panel Indicators and Controls

The front panel consists of a LCD touch screen display with key pad, separate flow meter controls for adjustment of NCPAP /Pres Low and Pres High and a $\%O_2$ blender control. Patient circuit connections are located along the bottom panel. LEDs along the top of the front panel indicate power on, connection to wall AC, active alarms and Transducer Interface connection to the driver. An ambient light sensor is located under the front panel to adjust the backlight of the screen display in high and low light environments

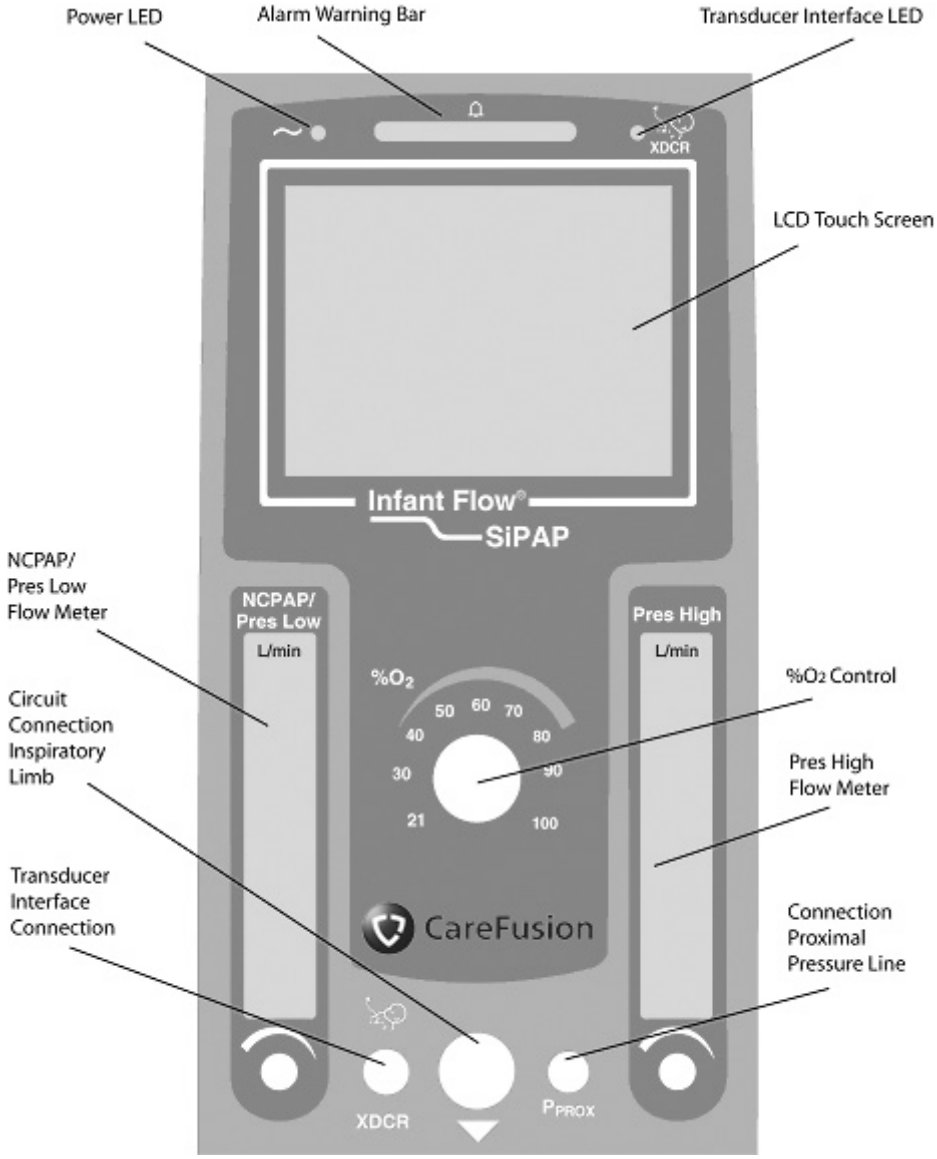


Figure 7 Front Panel

Rear Panel

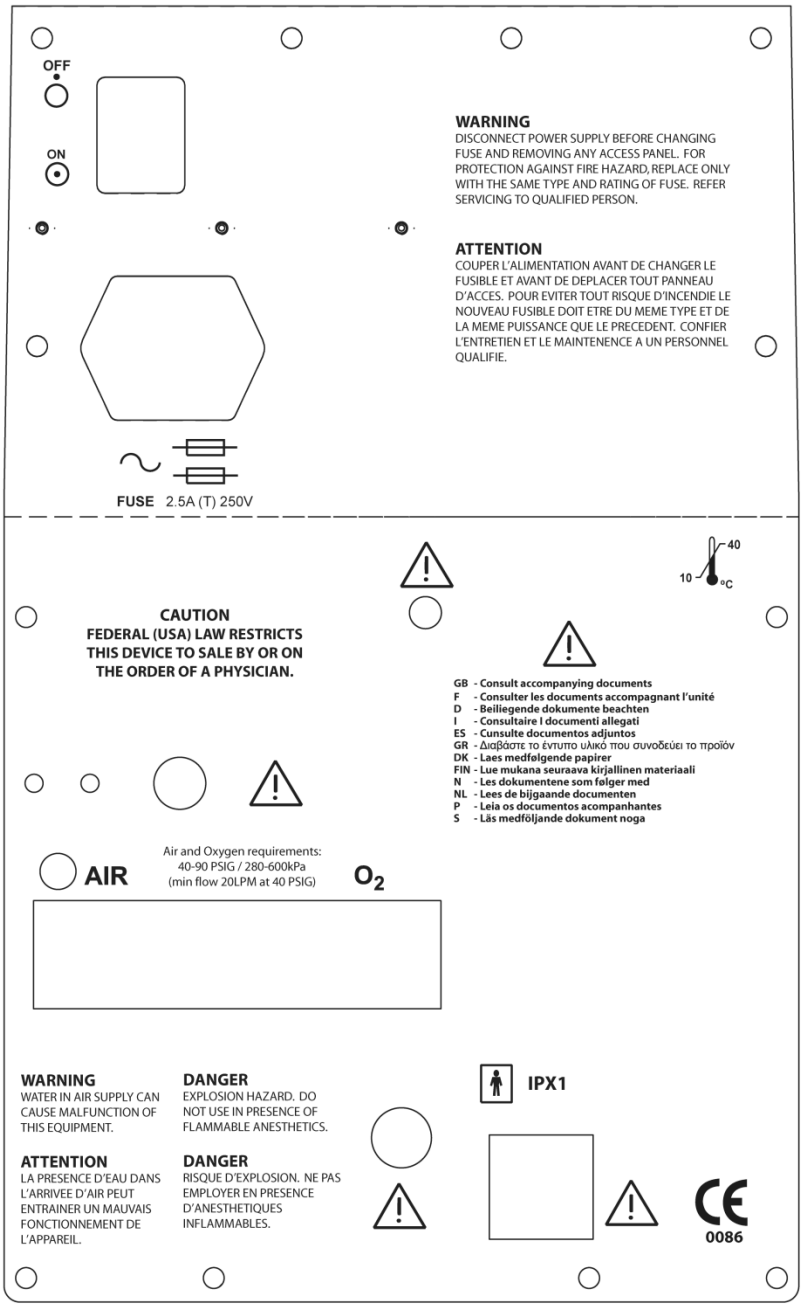


Figure 8 Rear Panel

Table 1 Soft-key operation

Description	Example
A button which is enabled.	
A button which is inhibited due to non-availability of the designated feature or pending acknowledgement of an active alarm condition.	
A selected mode or control pending confirmation is visually highlighted and intermittently flashes between yellow and white text.	
While a button is pressed the edges are highlighted to provide a pressed appearance.	
When there is an active alarm associated with a measured value the measured value concerned is displayed with RED FLASHING text. The associated limit value (if any) is displayed in RED.	
When an alarm that is associated with a measured value is resolved, the device remains in a LOW priority alarm state, with the measured value displayed in YELLOW FLASHING text and the associated limit displayed in YELLOW, until the alarms are cleared by the operator.	
When parameter adjustments cause a reduction in another parameter to maintain requirements for minimum breath interval, the reduced parameter is displayed in RED for 15 seconds	

Changing a Control

When a control such as Time-High is selected, increase and decrease buttons appear. The control and the displayed value for the selected parameter are highlighted. Use the decrease or increase keys to adjust the parameter. You may accept the action by pressing the control button again. If no action is taken, the new parameter will take effect after 15 seconds.

In normal treatment screens, parameter changes take immediate effect.

When you change the mode, such as NCPAP to BiPhasic, press the flashing mode button to accept the change.

If no screen interactions occur for a period of 120 seconds and there are not active alarms, then the screen goes to a 'locked' state to prevent inadvertent entries. To unlock the screen, press the screen lock button. In the case of a high priority alarm, the screen immediately unlocks to allow access to controls.

CAUTION!

When changing a control, use the pad of your finger (not your fingernail). Damage to the touch screen may result by using your fingernail, a pen, or similar item to make changes.

Increase / Decrease Buttons

Pressing the 'increase' or 'decrease' buttons causes a currently-selected control to be changed to the next valid greater or lesser value. Each press of the increase or decrease button is accompanied by an audible click. If the control limit is reached an audible beep sounds to alert the operator.

Displays of calculated values (such as I:E ratio) dependent on a control setting change will change with acceptance of the parameter change.

Incompatible Control Settings

When a change to one control requires a change to a separate control to avoid an incompatible control setting, the required change is made automatically by the driver software.

If the adjusted control setting is restored prior to 15 seconds elapsed time or prior to pressing any other control, then the required change action is reversed.

For example *in BiPhasic mode with T-High = 2.0, as R is increased above 28 b/min the constraint on minimum T-Low can be met only through a reduction in T-High. If R is increased to 29, then T-High shall reduce automatically to 1.9s. If R is then* ***immediately*** *reduced to 28, the previous setting for T-High shall be restored.*

Parameter Default Value on Change of Mode

Some controls are active in more than one operating mode. In these instances, there is a separate default value for operating modes as illustrated with the following table. Settings that are changed by the operator in one specific mode will be maintained if the mode is changed to another mode within the same mode group. All defaults shall revert to factory default on power-cycling or software restart.

Setting a Manual Breath

The manual-breath function is available in CPAP, Biphasic, and Biphasic tr modes. For manual breath to be active when the manual button is selected, the pre-use pressure-high check has been completed and the pressure high-flow meter is set for preferred manual breath. One manual breath is delivered per button-press.

Note:

The Pressure High Flow Meter must have flow above zero in order to deliver manual breaths.

Table 2 Parameter Default Value

Mode / Parameter	NCPAP	NCPAP + rate monitoring	BiPhasic	BiPhasic + rate monitoring	BiPhasic tr
T-High	Default for NCPAP apply		Default for BiPhasic apply		Default for BiPhasic tr
Rate			Default for BiPhasic apply		
Rb					Default for BiPhasic tr
T_{apnea} / T_{LBR}	This setting applies to all modes: system-wide default applies to all modes				

User Interface Display

Screen Displays

1. Setup Screen – The Setup screen prompts the user to confirm settings for base line pressure level (NCPAP / Pres Low), $\%O_2$, upper level pressure (Pres High) controls and confirmation of connection of the Transducer Interface (XDCR) to the driver.

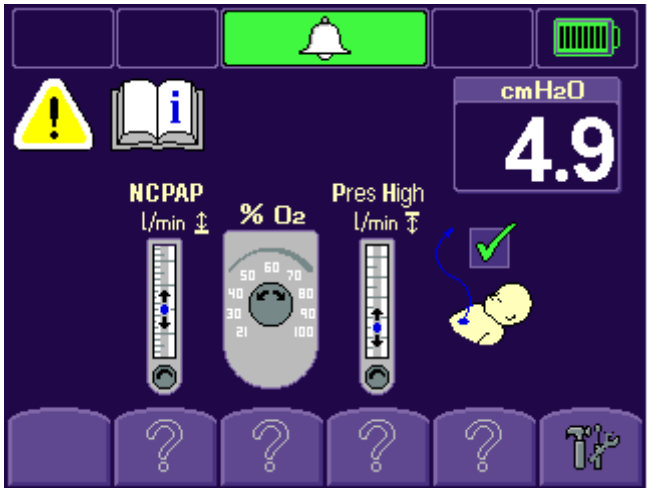


Figure 9 Setup Screen

Adjust the NCPAP / Pres Low flow meter counter clockwise to increase the control to the required flow rate and clockwise to decrease the flow. Touch the associated flashing icon to confirm. The icon changes to a check mark and the next button flashes.

Set the $\%O_2$ as prescribed. Touch the associated flashing button to confirm. The icon changes to a check mark and the next button flashes.

Adjust the Pres High flow meter as desired for delivery of BiPhasic, BiPhasic tr or manual breaths using counterclockwise turns to increase and clockwise turns to decrease the flow. Touch the associated flashing button to confirm. The icon changes to a check mark and the next button flashes.

If breath rate monitoring is desired, attach the Transducer Interface and the abdominal sensor. Refer to Chapter 4 for instructions on application of the Abdominal Respiratory Sensor. Touch the flashing button to confirm.

If an alarm is activated as a result of any of the settings, the button displays a flashing “X”. Alarm conditions must be cleared and all settings must be confirmed with a green check mark before other screens can be entered.

2. Alarm set/confirm Screen

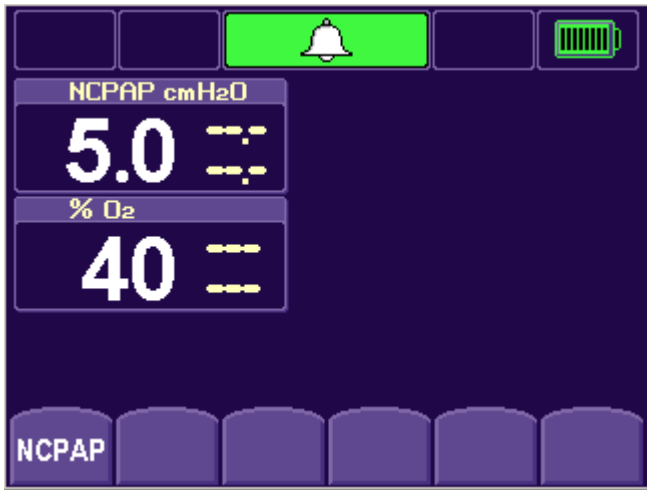


Figure 10 Alarm set/confirm Screen

Touch the NCPAP button or the Alarm Mute / Reset button for 3 seconds to set the alarms and to move to the next screen. If either button is not touched within 2 minutes, the alarm limits will be set automatically. When the alarm limits have been set, the screen display changes to the Mode Select Screen with the driver operating in NCPAP mode.

Note:

Press High Flow meter must be checked through the Start-up screen and be set during operation. This enables manual breath or back-up apnea breath, where applicable, to be active.

CAUTION

Do not adjust any of the Alarm Limit settings to an extreme value. Selecting an extreme value can make the alarm system inadequate for the patient.

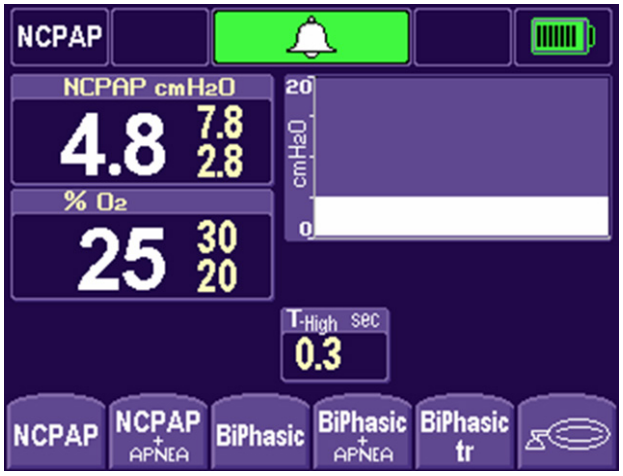


Figure 11 Mode Select Screen

3. **Mode Select Screen** - Here the operator can select the desired mode of operation. Once selected, the operator has the ability to adjust the screen controls for the mode selected. Only the relevant controls available for the selected mode are visible.

   To make a change to a control, touch the control. Both the control and its associated numeric display highlight and the adjust buttons appear. Press up or down buttons to adjust the setting as desired. Confirm the change by pressing the control again.

4. **Parameter Adjust Screen** – During normal operation, active controls for the current operating mode can be adjusted by touching the control, using the increase or decrease arrows to make the adjustments and then pressing the control again to confirm the change.

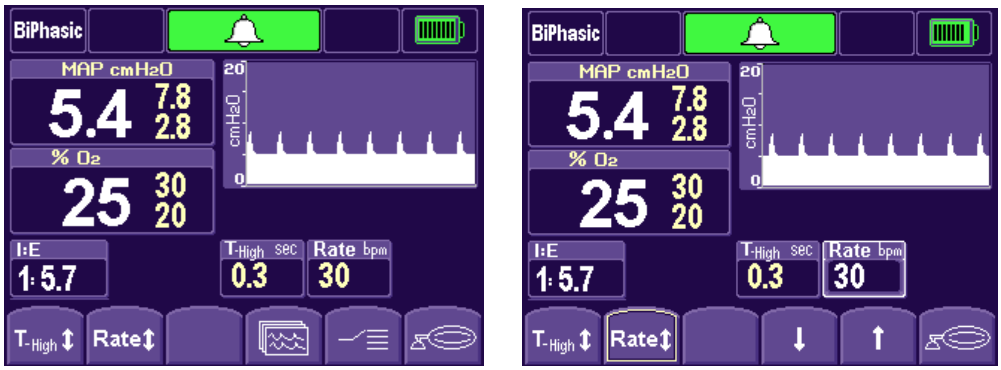


Figure 12 Parameter Adjust Screens

5. **Main screen**– The Main Screen provides the operator with displays of current mode of operation, alarm status, battery charge status, monitored parameters and a pressure time graphic display. Active controls are available for adjustment in this screen.

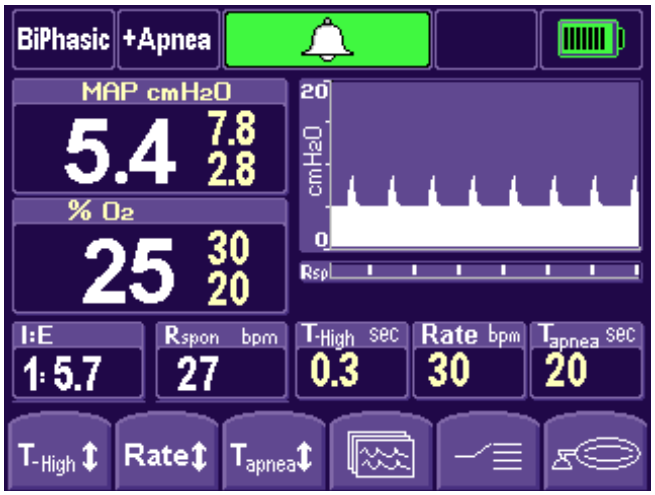


Figure 13 Main Screen

6. **Monitored Parameter Screen –** This screen is accessed by pressing the change screen button. The monitored parameters screen displays measured values and control settings. Adjustments to controls active for the currently selected mode are possible from this screen. To return to the main screen press the screens button again.

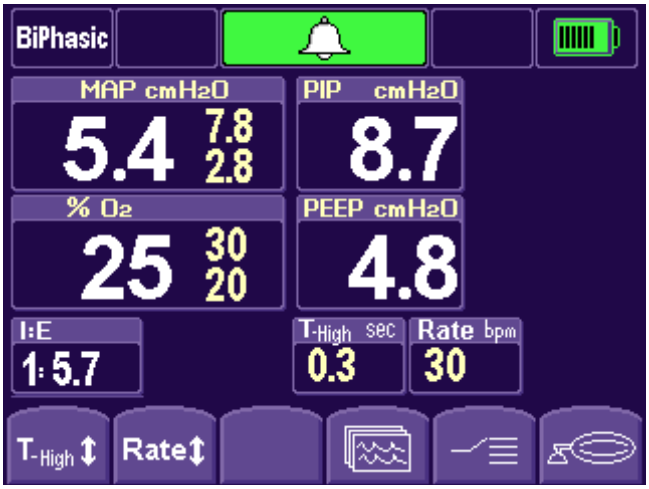


Figure 14 Monitored Parameters Screen

Step by Step Fixation for Infant Flow System Generators

Following this fixation technique closely helps to ensure:

- Enhanced stability of the Generator
- Minimal disturbance to the infant

WARNING

Do not attach Generator to the patient until User Verification and initial set up into NCPAP mode is complete.

Patient interfaces from CareFusion accommodate a wide range of patients. Application of an incorrectly sized prong, mask or bonnet will affect stability of the generator. The clinician may consider alternating the use of prong and mask interfaces at set intervals for a single patient in order to change pressure points on the infant's face and reduce the risk of skin breakdown.

1. Measure for prong/mask size using the nose guide. Connect the interface to the generator.
2. Measure for bonnet size from the middle of the forehead to the nape of the neck and then back to the middle forehead. **DO NOT use a "head circumference" measurement to determine bonnet size.**
3. Loosely weave Generator straps through the buttonholes. Begin from the inside of the colour coded buttonhole. Place the Generator on top of the bonnet above the central Velcro strip.
4. Place the bonnet onto the infant's head, checking that the ears are in a normal position. Ensure the bonnet is pulled well down over the ears and down to the nape of the neck.

   Switch on the power to the driver and complete Set Up Screen steps to enter NCPAP mode with the prescribed settings for the current patient.
5. Lift the Generator from the top of the bonnet and bring towards the nose. Gently insert the nasal prongs/mask into position while supporting the Generator. Secure the generator straps horizontally across the infant's cheeks. **Do not over tighten.**
6. Secure all three tubes from the Generator with the central Velcro strip. Split the inspiratory and pressure lines and secure with secondary Velcro strips. Tie the open end of the bonnet if desired.
7. Final check:
   - Nose in neutral position; eyes visible; ears not folded
   - Desired upper and lower pressure levels and FiO_2 are delivered
   - Infant settles quickly after fixation

Every hour

Repeat the checks listed above in Final Check.

Every 3-4 hours

Loosen the generator straps and release the tubes from the central Velcro strip. The nasal area can be cleaned with warm sterile water. Do not apply creams or ointments.

Ensure that:

- Nasal prongs/mask is not occluded with mucus/water droplets
- Patient prongs/mask and bonnet continue to fit appropriately.
- Re-apply the generator as described above.

Power Off

To power off:

1. Disconnect infant from SIPAP driver.
2. Turn off SIPAP driver.

If therapy has been discontinued, after turning off power:

1. Turn the flow rate of the low pressure flow meter and the high pressure flow to zero.
2. Disconnect air and oxygen high pressure hoses from wall outlet.
3. Remove nCPAP circuit and generator and dispose of per hospital procedure.

Directions for using the AirLife Infant nCPAP System

Please refer to P/N 36-5569 included in the AirLife Infant nCPAP Fixation Device for the *Directions for Use*. (The AirLife Infant nCPAP system is only available in the United States and Canada.)

WARNING!

CareFusion consumables are specifically designed to be used with Infant Flow Drivers and are the only consumables validated for use with Infant Flow devices.

Infant Flow SiPAP

Chapter 6 Operating Modes

NCPAP

The Nasal CPAP mode can be enabled to have breath rate monitoring displayed (NCPAP +Apnea Mode, or NCAP +LBR Mode), or the system can operate without having the breath rate monitoring displayed (NCPAP Mode). Breath rate monitoring requires the use of the Transducer Assembly (part number 677-002) and the Abdominal Respiratory Sensor (part number 467349).

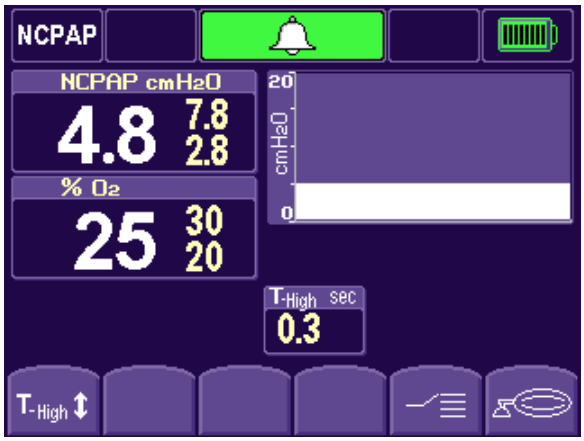


Figure 15 NCPAP

BiPhasic

The BiPhasic mode allows for time triggered pressure assists, with or without breath rate monitoring and adjustable low breath rate alarm, delivered based on clinician set Time High (T-High) criteria, rate and pressure settings.

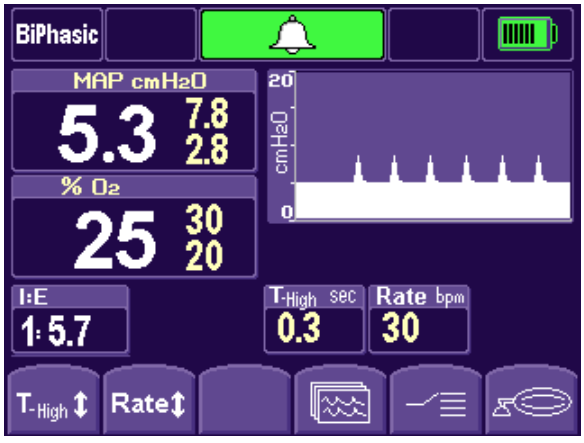


Figure 16 BiPhasic

BiPhasic tr*

The BiPhasic tr mode allows for patient triggered pressure assists with breath rate monitoring enabled, adjustable apnea time interval, apnea alarm and adjustable apnea back up rate. The upper level pressure is delivered based on operator set Time High (T-High) and pressure settings.

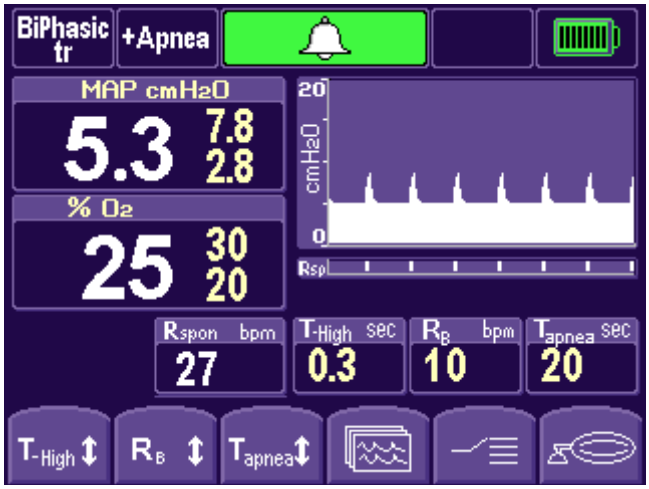


Figure 17 BiPhasic tr

* This mode available in Comprehensive configurations only.

Chapter 7 Alarms and Indicators

Audible and visual indications are given to alert the Operator to specified conditions that affect operation. The electronic alarm limits are automatically set after two minutes without the necessity of Operator inputs.

Alarms can be manually set at any time if required (i.e. after settings change or patient disconnect/ reconnect) by pressing the Alarm Mute / Reset button for 3 seconds.

Alarm Priority

On activation of a MEDIUM or HIGH priority alarm, a locked screen will automatically revert to the unlocked display. The alarm status indicator flashes intermittently based on the current highest alarm priority. Distinct audible alarms represent a HIGH, MEDIUM or LOW priority alarm.

Measured parameters and alarm limits associated with a high or medium priority alarm condition flash RED (HIGH priority) or YELLOW (MEDIUM priority) to denote alarm condition and priority.

Silencing audible alarms

Pressing the Alarm Mute / Reset button will silence active alarms for up to 30 seconds. If a new high priority alarm condition occurs during the alarm silence time period, the silence will be cancelled to alert the operator of the new alarm condition.

Resetting alarms

Press the Alarm Mute / Reset button for 3 seconds to clear resolved and LOW Priority alarms and to reset alarm limits (i.e. after a control setting change). Where the alarm cause remains, the appropriate alarm will immediately reoccur.

Audible alarm priority

High Priority – a series of 10 tones (2 groups of 3 tones followed by a pause and 2 more tones) every 10 seconds

Medium Priority – three audible tones every 15 seconds

Low Priority – two audible tones every 30 seconds

Alarm Types

The following alarm systems are provided with the Infant Flow SiPAP driver. Electronic alarms are set after 2 minutes of operation without operator intervention although the operator can manually set or reset them if required. Refer to Appendix C for information on troubleshooting alarms.

Supply Gases Failure

If the differential pressure between the two inlet gases falls outside of the limit of 30 PSI (2.0 bar) or one gas fails completely, an alarm will sound and the gas at the higher pressure only will be delivered to the patient.

High Airway Pressure

A HIGH priority audible and visual high pressure alarm activates when pressure reaches 3 cmH_2O above the measured airway pressure.

Airway Over-Pressure Limit Alarm

A HIGH priority audible and visual high pressure alarm activates at 11 cmH_2O during NCAP and time triggered BiPhasic modes and 15 cmH_2O in BiPhasic tr mode. Upon activation of this alarm, the patient circuit pressure drops to near zero. Pressure is restored after 3 seconds, and reduces to near zero again should the condition causing the alarm remain.

Low Airway Pressure

A HIGH priority audible and visual low pressure alarm activates if pressures fall to 2 cmH_2O below the measured airway pressure or at 1.5 cmH_2O, if this would otherwise be less than zero.

High and Low % O_2

HIGH priority audible and visual alarms are provided at ± 5% of the measured FiO_2 with an upper maximum limit of 104% and a lower minimum limit of 18%.

A low hazard warning occurs at 18% Oxygen or below.

Low Battery Charge

If the battery charge falls below 40% the battery charge indicator changes from green to red as a warning indicator. In this instance, plug the driver into an approved AC power source.

Low Battery Voltage

If the battery voltage falls to < 11.10 V for 5 seconds a MEDIUM priority audible and visual alarm is activated. In this instance, plug the driver into an approved AC power source.

Flat Battery

If the battery charge is too low to reliably power the analogue and valve driver circuits, the unit enters a safe 'flat battery' screen, until it is either switched off, or plugged into a suitable external power source. The screen display will go completely blank when the battery charge is too low to power it. While sufficient power is available, audible and visual indication of the high-priority alarm is maintained.

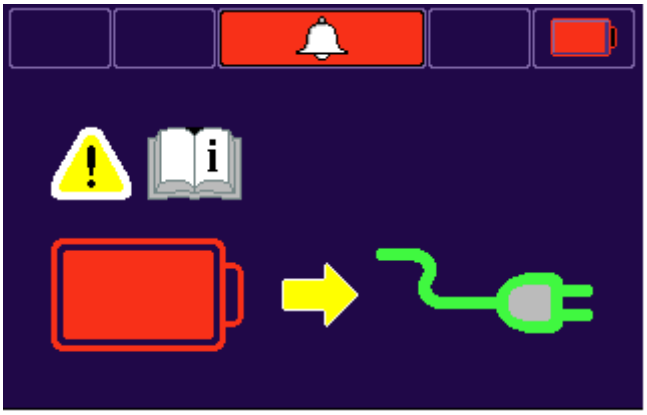


Figure 18 Flat Battery screen

Operation without Electrical Power (No AC or DC power)

The Infant Flow SiPAP will continue to deliver NCPAP flow only as set from the NCPAP / Pres Low flow meter and the set $\%O_2$ in the event of a total loss of AC and DC power. In this mode, visual indications and audible alarm warnings are not given except for the supply gases failure alarm.

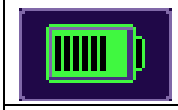
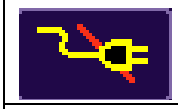
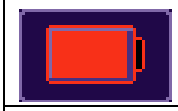
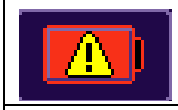
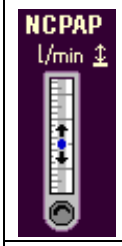
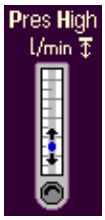
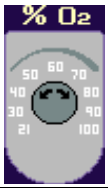
Error code indication

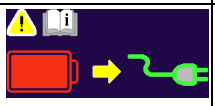
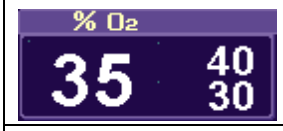
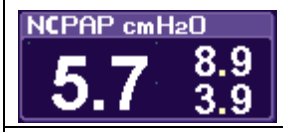
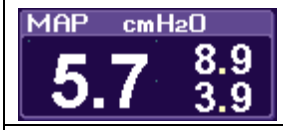
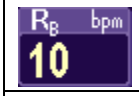
When a unit error is active, and this does not cause complete device failure, then a non-mutable HIGH priority alarm is activated with the error code displayed in flashing RED text in the upper right hand of the display screen, alternating with any currently displayed mode information. Refer to Appendix D for a listing of error codes. Remove driver from service and refer to a qualified service technician.

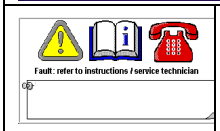
Alarm Symbols and Indicators

The following displays are shown within the graphical display. As needed displays in this table are shown separately as Domestic US configuration displays (left-hand column) and non-US configuration displays (right-hand column).

Table 1 Alarm Symbols and Indicators

Indicator	Meaning
	Battery status/charge level; Green indicates full charge; red indicates charge < 40%)
	External power source not connected
	Flat battery
	Battery fault (battery unable to hold charge) or supply fault
 	Respiratory transducer interface has become detached during breath monitoring
	Indication during pre-use checks that the NCPAP / Pres Low flow meter should be set as desired and pressure verified
	Indication during pre-use checks that the Pres High flow meter should be set as desired and pressure verified
	Indication during pre-use checks and/or calibration that % O_2 should be set and verified.

Indicator	Meaning
 	Indication during pre-use checks that operator should attach the respiratory sensor (cross indicates that transducer assembly is not connected)
 	Indication during pre-use checks that the operator should attach the respiratory sensor (indicates that transducer assembly is connected) Does not verify attachment of sensor to patient
 	Refer to manual
 	Power has failed; re-connect external power source
	Display of % O_2 measured value and associated alarms
	Display of NCPAP airway pressure measured value and alarms (NCPAP modes only)
	Display of mean airway pressure measured value and alarms (BiPhasic and BiPhasic tr* modes only)
	I:E ratio
	Spontaneous breathing rate
	Set parameter T-High
	Set parameter Rate (BiPhasic modes only; mandatory rate)
	Set parameter R_B (BiPhasic tr* mode only; backup rate)
 	Set parameter low breath rate or apnea alarm timeout

Indicator	Meaning
	Display of measured airway pressure graph. With breath monitoring active, spontaneous breaths are indicated in yellow, below delivered airway pressure graph.
 	Device fault (fault code will be indicated). Refer to manual. Contact qualified service technician.

Note

Provision of labeling in this manual for any function should not be taken as evidence that the function is available. For example parameter RB relates to BiPhasic tr mode, not currently approved for use in the US.*

Chapter 8 Maintenance and Cleaning

Cleaning

Examine the exterior of the case and the stand for damage and dirt. If necessary clean the unit and stand. If damage to either is apparent, always seek qualified Technical advice.

Clean the exterior surfaces of the driver, transducer assembly, and stand using a damp cloth or sponge with a mild soap or liquid disinfectant solution. Do not spray liquid onto the exterior surface of the SIPAP driver. Do not use cleaning agents that contain abrasives. Make sure that cleaning agents do not enter the driver through patient connections or other ports.

CAUTION

Do not immerse any part of the Infant Flow SiPAP driver in water or sterilize it with gas or steam. To prevent liquid from entering the unit, do not spray cleaning solution on the exterior surface of the unit.

Maintenance

No special maintenance is required by the operator other than that listed below. There are no operator serviceable parts. The unit must only be maintained and serviced by an approved service supplier or trained biomedical engineer. Only parts approved by CareFusion may be used in this unit. Refer to the Service Manual or your Service Supplier for an approved service parts list

WARNING

Oxygen vigorously accelerates combustion. To avoid explosion hazard, do not use any instrument or other equipment that may have been exposed to oil or grease contamination.

Calibrate the oxygen analyzer regularly. **Calibration of the oxygen analyzer must be done with the unit off patient.**

Check the water trap at least every 24 hours (more frequently if needed, depending on amount of water in the air supply).

The water trap is accessed from the rear panel of the driver enclosure. Push the button on the bottom of the water trap to release the water. Empty the water trap according to the approved, hospital procedures.

Disconnect the air and oxygen gas sources when the Infant Flow SiPAP driver is not in use.

Storage and Battery Care

Store the unit in a clean dry location. Make sure that all connections and ports are suitably covered to prevent the ingress of dirt, moisture and foreign objects. If the unit is not being used for a long period of time, remove the battery (refer to the Service Manual or your Service Technician).

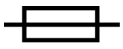
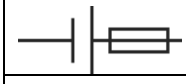
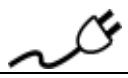
Dispose of scrap units in accordance with the local regulations. Refer to the Service Manual or your Service Supplier.

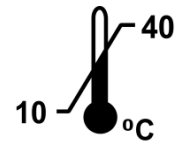
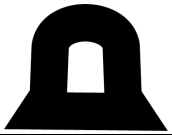
Chapter 9 Explanation of Symbols

Equipment Symbols

The following symbols may be referenced on the Infant Flow SiPAP driver or in accompanying documentation.

Table 1 Equipment Symbols

Symbol	Source / Compliance	Meaning
	Symbol #03-02 IEC 60878	I Indicates ATTENTION, consult ACCOMPANYING DOCUMENTS
	Symbol #5016 IEC 60417	This symbol indicates a FUSE.
	Symbol #5031 IEC 60417	This symbol indicates DIRECT CURRENT (DC)
	Symbol #5019 IEC 60417 Symbol #01-20 IEC 60878	This symbol indicates protective EARTH (ground).
	Symbol #5021 IEC 60417 Symbol # 01-24 IEC 60878	This symbol indicates the EQUIPOTENTIAL connection used to connect various parts of the equipment or of a system to the same potential, not necessarily being the earth (ground) potential (e.g., for local bonding).
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 30878	This symbol is located on the rating plate. It indicates the equipment is suitable for alternating current.
	Symbol #5007 IEC 60417 Symbol #01-01 IEC 60878	Indicates ON (Power)
	Symbol #5008 IEC 60417 Symbol #01-02 IEC 60878	Indicates OFF (Power)
	MDD Directive 93/42/EEC	CE Mark
	CareFusion Symbol	This symbol indicates an INTERNAL BATTERY FUSE
	ISO 7000:2004 (2616)	Electrical AC connection

Symbol	Source / Compliance	Meaning
	ISO 15223:2000 (3.11) EN 980:2003 (5.7.3)	Operating temperature range of unit
2.5A/T 250 V	N/A	Fuse holder and fuse rating
 XDCR	CareFusion Symbol	Transducer Assembly
	IEC 60878:1988 (01-41) ISO 7000:2004 (2301)	Alarm
	**IEC 60878:1988 (02-03)**	Type BF patient applied part
	Intertek Group	ETL Mark and Registration Number
	ISO 15223: 2000 (3.13) EN 980:2003 (4.4)	Year of Manufacture
	IEC 60878 (03-02)	Read Accompanying Documents
	ISO 15223:2000 (3.1.4) EN 980:2003 (4.4)	Unique Batch Number Identifier
	ISO 15223:2000 (3.12) EN 980:2003 (4.3)	Use Before Expiry Date shown Year-Month
	ISO 15223:2000 (3.2) EN 980:2003 (4.2)	Single Use Only - Do NOT Re-use
	ISO 15223:2000 (3.8)	Keep Dry

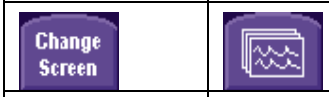
Symbol	Source / Compliance	Meaning
	ISO 15223:2000 (3.8)	Keep Away from Heat

Symbols used on buttons

The following symbols are used to label user input areas within the graphical display. As needed displays in this table are shown separately as Domestic US configuration displays (left-hand column) and non-US configuration displays (right-hand column).

Table 1 Button Symbols

Symbol		Description
		High Priority Alarm Active, red flashing
		Medium Priority Alarm Active, yellow flashing
		Low Priority Alarm Active, yellow, does not flash.
		No alarms are present, green, does not flash
		Active alarm silenced
		Adjust BiPhasic rate
		Adjust BiPhasic tr* backup rate
		Adjust apnea alarm timeout
		Adjust low breath rate alarm timeout
		Adjust BiPhasic, BiPhasic tr* on time, and NCPAP manual breath function
		Decrease / Increase currently selected parameter
		Go to mode select screen.

Symbol	Description
	Nasal CPAP mode
	Nasal CPAP mode with breath rate monitoring
	BiPhasic mode
	BiPhasic mode with breath rate monitoring
	BiPhasic tr* mode with breath rate monitoring
	Manual Breath. Single BiPhasic cycle at current settings for T-High, Pres High and % O_2. One BiPhasic cycle is delivered regardless of button press duration
	Toggle between Main Screen and Monitored Parameter Screen
	Go to user calibration screen
	Confirm
	Wait
	Completed
	Action has failed
	Press to un-lock keypad
	Warning message. To clear, press any of the three icons.
	Oxygen monitor and alarms disable

Note

Provision of labeling in this manual for any function should not be taken as evidence that the function is available. For example parameter R_B relates to BiPhasic tr mode, not currently approved for use in the US.*

Appendix A Product Configurations

Non-US Configuration Parameters

Table 2 Non-US Configuration Parameters

Parameter	Min	Max	Accuracy	Units	Default
Set Oxygen concentration, $\%O_2$	21	100	±3	%	N/A
NCPAP / Pres Low flow rate	0	15	±15%	L/min	N/A
Pres High flow rate	0	5	± 15%	L/min	N/A
BiPhasic / BiPhasic tr* on time, T-High	0.1	3.0	± 0.005	seconds	.3 sec
BiPhasic rate, R (mandatory rate)	1	120	± 0.5	bpm	30 bpm
BiPhasic tr* backup rate, Rb (apnea backup rate)	1	120	± 0.5	bpm	10 bpm
Apnea timeout, Tapnea	10	30	± 1	seconds	20 sec

Note

BiPhasic tr mode not currently available in the United States. In non-US configurations, T-High automatically reduces at higher R and Rb rate settings to maintain a minimum off time of 100 milliseconds.

US Configuration Parameters

Table 3 US Configuration Parameters

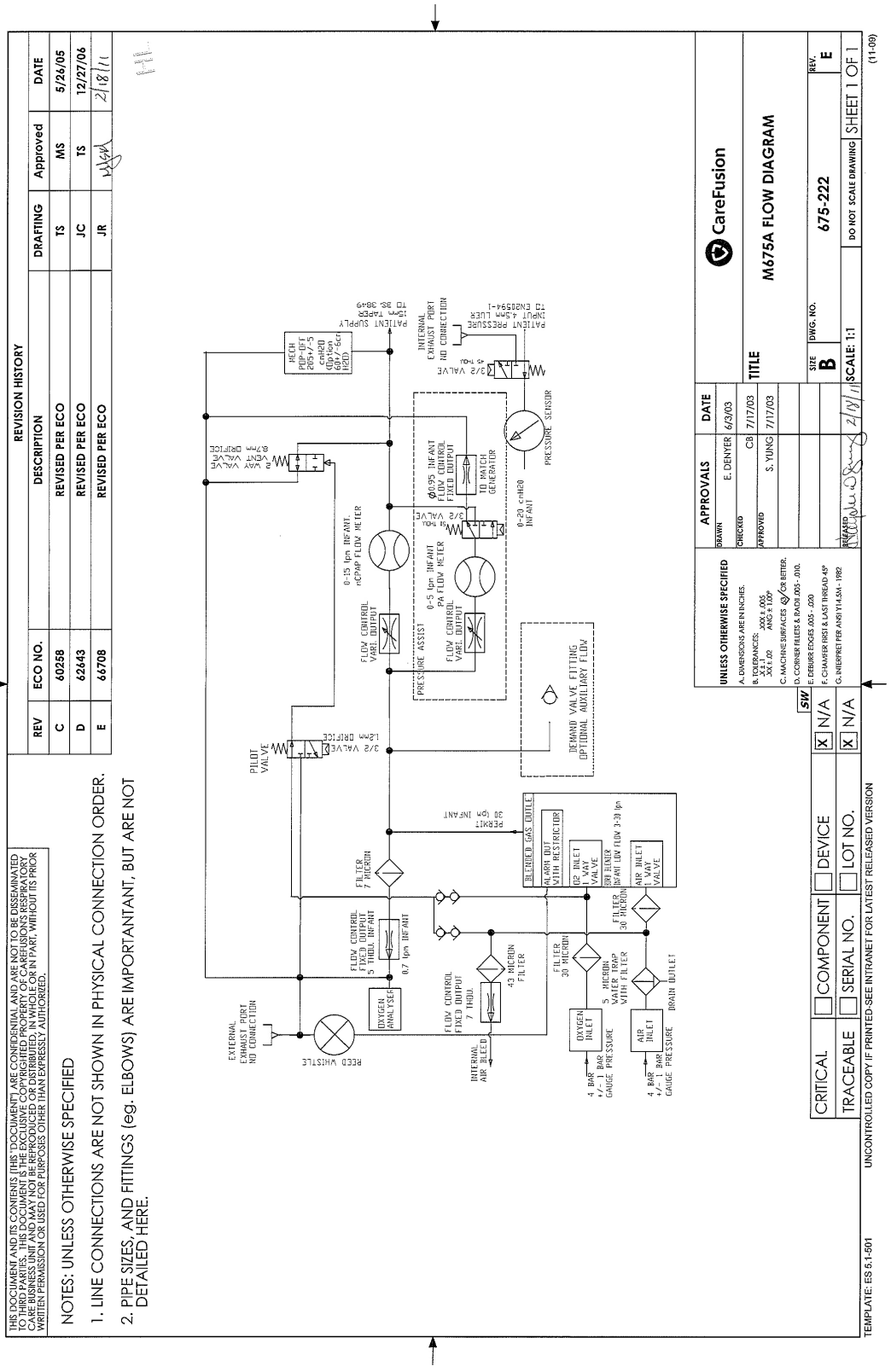
Parameter	Min	Max	Accuracy	Units	Default
Set Oxygen concentration, $\%O_2$	21	100	±3	%	N/A
NCPAP / Pres Low flow rate	0	15	±15%	L/min	N/A
Pres High flow rate	0	5	± 15%	L/min	N/A
BiPhasic on time, T-High	0.1	3.0 *	± 0.005	seconds	1.0 sec
BiPhasic rate, R (Mandatory rate)	1	54	± 0.5	bpm	10 bpm
Low Breath Rate timeout, T_{LBR}	10	30	± 1	Seconds	20 sec

Note

In US configurations, T-High automatically reduces at higher R and Rb rate settings to maintain a minimum off time of 1.0 seconds.

Infant Flow SiPAP

Appendix B Pneumatic Diagram



Infant Flow SiPAP

Appendix C Alarm Troubleshooting

Table 4 Alarm Troubleshooting

Alarm	Priority	Possible Cause	Actions
$\%O_2$ < 18%	High	• O_2 calibration required.	• Restore FiO_2 level to above the minimum limit • Press Alarm Reset for 3 seconds. • Recalibrate O_2 as soon as practicable.
$\%O_2$ > 104%	High	• O_2 calibration required.	• Restore FiO_2 level to below the maximum limit • Press Alarm Reset for 3 seconds. • Recalibrate O_2 as soon as practicable.
High $\%O_2$ (> 5% above setting for 15 seconds).	High	• Blender setting changed. • Supply gas failure • Water trap overflow	• Press Alarm Mute to silence the alarm • Correct delivered oxygen concentration • Press Alarm Reset for 3 seconds to set new limits
Low $\%O_2$ (> 5 % below setting for 15 seconds).	High	• Blender setting changed. • Supply gas failure • Water trap overflow	• Press Alarm Mute to silence the alarm • Correct delivered oxygen concentration • Press Alarm Reset for 3 seconds to set new limits
Over pressure (> 11 cmH_2O in NCPAP and BiPhasic modes)	High	• Flow rate set too high. • Occlusion of exhalation limb • Blocked silencer/bacteria filter	• Check exhaust tube / filter • Reduce flow rate to achieve pressure below high pressure limit • Press Alarm reset for 3 seconds to set new limits
Over pressure (> 15 cmH_2O in BiPhasic tr* mode)	High	• Flow rate set too high. • Occlusion of exhalation limb • Blocked silencer/bacteria filter	• Check exhaust tube / filter • Reduce flow rate to achieve pressure below high pressure limit • Press Alarm reset for 3 seconds to set new limits
Low battery charge (< 40%).	Medium/High	• Battery status indicator changes from green to red.	• Connect external power

Alarm	Priority	Possible Cause	Actions
Battery fault	High (Cannot be reset)	• Battery disconnected • Battery failing to hold charge	• Push Alarm Mute button for 3 seconds to silence alarm • Refer to Service Technician.
Low battery voltage < 11.10 V for 5 seconds).	Medium	• Battery disconnected • Battery failing to hold charge	• Push Alarm Mute button for 3 seconds to silence alarm • Connect AC power
AC power disconnected	Low	• AC power disconnected	• Push Alarm Mute button for 3 seconds to silence alarm • Reconnect the AC power.
High NCPAP / Pres Low (CPAP > 3 cmH_2O above set for 15 seconds).	High	• NCPAP / Pres Low setting change • Circuit disconnect / reconnect	• Push Alarm Mute button for 3 seconds to silence and reset alarm limits • Reset alarm limits after setting change and patient circuit disconnect / reconnect
Low NCPAP / Pres Low (CPAP < 2 cmH_2O below set for 15 seconds) or < 1.5 cmH_2O at any time).	High	• NCPAP / Pres Low setting change • Circuit disconnect / reconnect • Circuit leak	• Push Alarm Mute button for 3 seconds to silence and reset alarm limits • Reset alarm limits after setting change and patient circuit disconnect / reconnect • Check for leaks in patient circuit
High BiPhasic or BiPhasic tr* pressure (MAP > 3 cmH_2O above set for 15 seconds).	High	• Pres High setting change • Circuit disconnect / reconnect	• Push Alarm Mute button for 3 seconds to silence and reset alarm limits • Reset alarm limits after setting change and patient circuit disconnect / reconnect
BiPhasic or BiPhasic tr*) mode fails to operate as set.	High (Cannot be silenced)	• See description of error code displayed	• Revert to nCPAP mode • Refer to Service Technician

Alarm	Priority	Possible Cause	Actions
Low breath rate	High • Plus: audible / visual alarms only • Comprehensive : audible / visual alarms and backup rate	• Rr = 0 for > low breath (apnea) interval timeout	• Push Alarm Mute button once to silence alarm • Restore patient breathing. • Check placement / connection of abdominal Respiratory Sensor
Flow meter fault.	N/A	• No flow indications • Flow can't be adjusted.	• Refer to Service Technician.
Gas Supply failure	N/A Blender Alarm High	• Differential pressure between the two inlet gases falls outside of the limit of 30 PSI (2.0 bar) or one gas fails completely	• Check gas inlet supplies • Check inlet water trap • Refer blender to service technician
Oxygen cell calibration error.	High	• Oxygen cell incorrectly calibrated, damaged or depleted	• Calibrate or replace oxygen cell. • Refer to Service Manual.
Electrical fault.	High	• AC power LED does not match screen icon.	• Refer to Service Technician
Water trap blocked	High and Blender Alarm	• Full or leaking • Filter blocked • Loss of wall pressure • Imbalance in gas supply	• Refer to Service Technician
Software fault	High (Cannot be reset)	• See description of error code displayed	• Refer to Service Technician
Software not running with unit connected to power	High (Cannot be reset)	• See description of error code displayed	• Refer to Service Technician

***BiPhasic tr mode not currently available in the United States**

Infant Flow SiPAP

Appendix D Fault Management

The general philosophy when handling a software detectable *fault condition* is to still allow a basic level of treatment to be applied to the patient - with over pressure protection, oxygen alarms and apnea monitoring (where possible), but inhibiting the higher level features of the unit (such as BiPhasic modes).

Fault classification

Each fault condition is classified according to the severity ratings (where × means not available under software control, ✓ means available under software control, and **(✓)** means may or may not be available depending on other severity rating 3 and 4 conditions, which may occur individually or simultaneously):

Table 5 Fault Classification

Severity	Classification	Impact On Unit Functionality	Reporting Mechanism	Measurements		Control Modes and Features			
				O_2 %	CmH_2O	NCPAP	+apnea	Biphasic	tr biphasic
1 (major)	Un-usable	Unit is inoperable under software control, but can still be used in an un-powered pneumatic mode	A list of error codes are presented to the user via the "Fault lockout" display	×	×	×	×	×	×
2	Re-stricted	Unit functionality is restricted to NCPAP modes only	Where applicable, error codes listed on mode selection screen. Status bar mode alternates with worst error code	✓	✓	✓	✓	×	×
3	Un-trigger-able	Patient trigger functions not available (NCPAP and BiPhasic with breath monitoruing on and BiPhasic tr*)	Where applicable, error codes listed on mode selection screen. Status bar mode alternates with worst error code	✓	✓	✓	×	✓	×
4a (minor)	No backup	Unit will not operate on battery when the external power is removed	Battery status appears as if flat battery	✓	✓	✓	(✓)	(✓)	(✓)

Severity	Classification	Impact On Unit Functionality	Reporting Mechanism	Measurements		Control Modes and Features			
				O_2 %	CmH_2O	NCPAP	+apnea	Biphasic	tr biphasic
4b (minor)	Spurious	Spurious software exception trapped	Software restarts, and status bar extended mode alternates with worst error code	✓	✓	✓	(✓)	(✓)	(✓)
5 (minor)	Spurious	Non-fatal error trapped	High-priority alarm; status bar extended mode alternates with worst error code	✓	✓	✓	✓	✓	✓
6 (minor)	No oxygen monitor	Oxygen monitor and alarm functions are not available.	High priority alarm may be cleared by operator reset; status bar extended mode alternates with error code.		✓	✓	✓	✓	✓

Fault recovery / action

If a detectable fault condition occurs (either before treatment begins or while being applied) the software will respond in the following way:

Table 6 Fault Recovery

E##	Fault condition	Consequence	Clas-sification	Software Response	Corrective Action Required
-	Program memory checksum error	Software corrupt - execution inhibited	Unusable	Hardware held in permanent reset condition with alarm bar lit (status LED on)	Service: Reload software
-	Battery too flat (<6.5V) to operate LCD, analogue and valve driver circuits (no external power)	No user interface display	Unusable	Hardware held in reset condition with alarm bar lit (status LED off) until external power applied	User: Plug in external power
-	Battery too flat (<10.25V) to operate analogue and valve driver circuits but sufficient for LCD driver (no external power)	Sensor readings invalid	Unusable	User lockout: "Plug in external power" prompt	User: Plug in external power

E##	Fault condition	Consequence	Clas-sification	Software Response	Corrective Action Required
E10	Non-volatile memory fault	Unable to retrieve/set unit configuration and calibration data	Unusable	User lockout: Error "E##" prompt	Service: Fix or replace PCB
E11	Calibration data lost	Sensor readings invalid	Unusable	User lockout: Error "E##" prompt	Service: Low level calibration (O_2, Pressure and Flow)
E12	Configuration DIP settings and/or PT PRESENT different to non-volatile configuration record	Possible incomplete unit set-up performed	Unusable	User lockout: Error "E##" prompt	Service: Perform set-up procedure
E20	Charged battery voltage too low (<11V) when under test load	Battery capacity low	No backup	Battery fault icon flashes and "E##" alarm	Service: Fix Battery or charger
E21	External supply voltage too low (<14V) to charge battery (battery flat)	Battery will not charge	No backup	Battery low alarm continues even through external power applied - "E##" alarm	User: Plug in correct external supply Service: Fix PSU circuits
E22	Analogue supply rails out of limits	Unreliable sensor readings	Unusable	User lockout: Error "E##" prompt	Service: Fix circuits
E23	Valve driver supply rails out of limits	Valve operations unreliable	Unusable	User lockout: Error "E##" prompt	Service: Fix valve supply rail
E24	Hardware 'safe-start' watchdog disabled	Valves disabled	Unusable	User lockout: Error "E##" prompt	Service: Fix reset/safe-start circuits
E30	Pressure sensor fault (ADC hits rail)	Pressure sensor readings invalid	Unusable	User lockout: Error "E##" prompt	Service: Fix sensor/circuits
E31	Zero valve not connected (via sense)	Pressure sensor readings unreliable	Unusable	User lockout: Error "E##" prompt	Service: Fix valve/circuits
E32	Zero valve activation fault (via sense)	Pressure sensor readings unreliable	Unusable	User lockout: Error "E##" prompt	Service: Fix valve/circuits
E33	Unable to auto-zero pressure sensor	Pressure sensor readings unreliable	Unusable	User lockout: Error "E##" prompt	Service: Fix valve/sensor/circuits
E41	Dump valve not connected (via sense)	No over pressure protection	Restricted	Restricted mode: Error "E##" alarm	Service: Fix valve/circuits
E42	Dump valve activation fault (via sense)	No over pressure protection	Restricted	Restricted mode: Error "E##" alarm	Service: Fix valve/circuits

E##	Fault condition	Consequence	Clas-sification	Software Response	Corrective Action Required
E50	Oxygen sensor fault (ADC hits rail)	Oxygen sensor readings invalid	No oxygen monitor	High priority alarm; Error "E##" prompt	Service: Fix sensor/circuits.
E51	Oxygen sensor cannot be recalibrated by user (bad offset or high gain)	Possible fuel cell, electronic, blender or gas supply fault	No oxygen monitor	High priority alarm; Error "E##" prompt	User: Check gas supplies. Service: Fix sensor/circuits/ blender.
E52	Oxygen sensor calibrates but the fuel cell is worn-out (low gain)	Oxygen sensor readings unreliable	No oxygen monitor	High priority alarm; Error "E##" prompt	User: Check gas supplies. Service: Replace sensor.
E53	Oxygen sensor too noisy to calibrate (calibration timeout)	Oxygen sensor readings unreliable	No oxygen monitor	High priority alarm; Error "E##" prompt	User: Check gas supplies. Service: Fix sensor/circuits/ blender.
E54	Oxygen calibration may be invalid (O_2 reading below 17% or above 104% detected)	Oxygen sensor readings unreliable	No oxygen monitor	High priority alarm; Error "E##" prompt	User: recalibrate the oxygen cell.
E55	Oxygen sensor disabled by the operator	Oxygen sensor readings unreliable	No oxygen monitor	Error “E##” prompt	User: re-power the device to re-enable oxygen monitoring
E61	BiPhasic valve not connected (via sense)	BiPhasic modes unusable	Restricted	Restricted mode: Error "E##" alarm	Service: Fix valve/circuits
E62	BiPhasic valve activation fault (via sense)	BiPhasic modes unusable	Restricted	Restricted mode: Error "E##" alarm	Service: Fix valve/circuits
-	PT transducer disconnected	Apnea and/or patient trigger unusable/interrup ted	Un-triggerable	NCPAP and BiPhasic modes with breath monitoring on, inhibited (or low breath rate alarm given if treatment started)	User: Reconnect PT transducer
E70	PT module fault (PTRDY or CAN bus failure)	Apnea and patient trigger unusable	Un-triggerable	Reduced functionality - "E##" alarm	Service: Fix PT/circuits
E71	No breath signal from PT module although CAN data does not report Apnea	Patient may be in apnea but PT module dysfunctional?	Untriggera ble	Reduced functionality - "E##" alarm	Service: Fix PT/circuits
E72	No trigger signal from PT module	BiPhasic tr* mode inoperable.	Untriggera ble	Reduced functionality - "E##" alarm	Service: Fix PT/circuits

E##	Fault condition	Consequence	Clas-sification	Software Response	Corrective Action Required
(E90)	Spurious software interrupt, XTAL fails, stack overflow/underflow, CPU Class B exception	Software interrupted and restarts (possibly during treatment)	Spurious	Hardware reinitialized (disabled) with alarm bar lit and beeper sounding to identify root cause	Software: Fix persistent exceptions
E90	Abnormal hardware, software or watchdog reset	Software restarts possibly during treatment	Spurious	Software restarts - "E##" alarm	Software: Fix persistent exceptions Service: Fix abnormal reset
E91	Internal software error detected	Software unreliable	Unusable	User lockout: Error "E##" prompt	Software: Fix software error
E99	Unknown error detected	Software unreliable	Unusable	User lockout: Error "E##" prompt	Software: Fix software error

[1] Error codes in parentheses (brackets) are generated as an indirect consequence of the problem.

* Biphasic tr mode not currently available in the United States

Fault code display screen

The fault lockout screen shall incorporate item ref. (as appropriate to build) and shall display a list of all active fault codes. Faults not resulting in user lockout shall result in indication on the status bar.

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Glossary

Term	Meaning
Apnea	Temporary inability to breathe.
LBR	Low Breath Rate
Bpm	Breaths per minute (applies to each of spontaneous, triggered and mandatory)
CPAP	Continuous Positive Airway Pressure
Generator	Patient attachment for delivering CPAP, used with nasal prongs or mask
BiPhasic	Time triggered, time cycled pressure assists at two separate pressures levels.
BiPhasic+LBR	BiPhasic with Low Breath Rate monitoring (US labeling)
BiPhasic tr*	Patient triggered, time cycled pressure assists at two separate pressure levels. *This mode currently not available in the United States.
BiPhasic tr+Apnea*	BiPhasic tr* with Low Breath Rate monitoring (non-US labeling). *This mode currently not available in the United States.
NCPAP	Nasally applied CPAP
NCPAP+LBR	NCPAP with Low Breath Rate monitoring (US labeling)
NCPAP+Apnea	NCPAP with Low Breath Rate monitoring (non-US labeling)
Rate	Mandatory rate (per minute); active in BiPhasic mode
R_B	Backup ventilator rate (in BiPhasic mode during apnea alarm, per minute; non-US labeling)
R_{SP}	Patient's spontaneous respiratory rate (per minute)
s / sec	Seconds
T_{apnea} / T_{LBR}	Apnea Interval (non-US labeling) or Low Breath Rate (LBR) monitor alarm time (US-labeling); both in seconds This mnemonic may also be associated with an alarm icon
T-High	Length of time (in seconds) for a sigh or manual breath (Time High).
US labeling	Labeling using English text in place of symbols and/or icons
Non-US labeling	Labeling using non-linguistic symbols in place of English text wherever possible
PEEP	Positive End-Expiratory Pressure
PIP	Peak Inspiratory Pressure
Pres Low	Adjustable lower baseline pressure level control in BiPhasic and BiPhasic tr modes
Pres High	Adjustable upper pressure level control in BiPhasic and BiPhasic tr modes

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