Operator's Manual

Infant Flow Advance™ System

CE 0086

E.M.E. (Electro Medical Equipment) Ltd.
A subsidiary of VIASYS Healthcare inc.

Revision History

Date	Revision	Pages	Changes
December 2003	A	All	Release
June 2004	B	All	Release manual in VIASYS Healthcare template using VIASYS Healthcare Critical Care nomenclature. Add Appendix C, Abdominal Respiratory Sensor Placement. Revise part number list in Appendix B.

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CAUTION

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

CAUTION

Not suitable for use in the presence of flammable anesthetics.

CAUTION

Always read the Operator's Manual before applying treatment.

CAUTION

The Infant Flow Advance™ has been designed and tested as a complete system using Infant Flow™ accessories. Use only approved accessories (Refer to Appendix B for a list of approved accessories).

CAUTION

Service and/or repair of this instrument is restricted to VIASYS Healthcare authorized or VIASYS Healthcare Trained Personnel only.

Warranty

The Infant Flow Advance 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 VIASYS Healthcare, Critical Care Division, (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.

Contents

Chapter 1: Product Description

The Infant Flow Advance™ Driver is a combined Air/Oxygen Mixer, Oxygen Analyzer, Flow meter and Pressure Manometer with integral alarm systems designed specifically to be used in conjunction with the Infant Flow™ nasal CPAP circuits, generator, and patient interfaces consisting of a selection of masks and prongs. Together these products make up the Infant Flow Advance System.

The Infant Flow Advance Driver is assembled in a sheet metal enclosure from standard and commercial components. These are a Medical Air/Oxygen Blender, a Flow meter calibrated for mixed gas between 0 and 15 L/min, a galvanic Oxygen Fuel Cell with associated electronics, a self activating electronic pressure measuring and limiting system and a power supply.

The Infant Flow Advance Driver is supplied with a pole mount bracket to fit round or square section poles from 10 to 35 mm (0.4 to 1.4 in) diameter.

The Medical Air and Oxygen gas inlets are standard NIST, DISS or other appropriate inlets. High-pressure Medical Air and Oxygen hoses must be ordered separately.

The patient outlet is an ISO standard 15 mm female taper fitting and the pressure monitoring inlet is a standard Luer taper fitting. The Oxygen monitor is an integral part of the driver and does not require any additional external fittings.

The Oxygen monitor uses a galvanic fuel cell sensor which is fitted in a pressure controlled path to avoid variations in delivered gas pressure altering the measured value. The gas which is used for the Oxygen analyzer is subsequently vented from the rear of the Infant Flow Driver.

The Infant Flow Advance™ Driver is designed to supply a periodic or patient-triggered additional flow of oxygen-enriched air to the patient, and to provide an apnea monitoring and alarm facility when used in conjunction with the appropriate accessories.

The Infant Flow Advance™ Driver can be used in the following modes:

- Nasal CPAP, via the Infant Flow generator, with or without apnea monitoring using a respiration sensor that is attached to the patient's abdomen.
- Pressure Assist (PA), whereby an elevated pressure is intermittently delivered to the patient via the Infant Flow™ generator. This can be applied at a variable rate (R) and for varying lengths of time (Ti) and with or without apnea monitoring using a respiration sensor that is attached to the patient's abdomen.
- Triggered PA (trPA), whereby an elevated pressure is intermittently delivered to the patient via the Infant Flow™ generator. This is triggered by the patient's own respiratory effort by using a respiration sensor that is attached to the patient's abdomen and for varying lengths of time (Ti). Apnea monitoring is a feature of this mode and a back-up rate (Rb) is available.

Applications

Applications are prescribed by the clinician depending on the needs of the patient.

Intended Use

The Infant Flow Advance System consisting of a driver and generator plus nasal CPAP prongs and masks, is intended for the provision of periodic and patient triggered bi-Level CPAP. The system is for use in hospitals, hospital-type facilities and intra-hospital transport environments.

Chapter 2: Product Specification

This manual describes the operation and routine maintenance of the M674 models of the Infant Flow Advance™ Driver when fitted with Version 1.00 software and above. Identification of the particular version of software fitted in the equipment may be made at power-up. When the Infant Flow Advance Driver is turned on, the 7 segment displays show first three "8"s, then blanks, then the software version number as part of the start-up procedure.

- Gas supply - Nominal 50 PSI (3.5 bar) clean, dry Medical Air and Oxygen.
- Range - Minimum 30 psig (2.1 bar), maximum 80 psig (5.6 bar). Maximum differential pressure 30 psig (2.1 bar).
- Power Supply – 95-135 Vac, 0.30A, 50-60 Hz or 200-265 Vac, 0.15A, 50-60 Hz. Internal lead acid battery (2 hours running time when fully charged).

CAUTION

Equipment must be used with approved power supplies. Refer to Appendix B for a list of approved accessories.

- Power and Battery status indicators – indicates connection to an external power source and the battery status.
  - Top indicator shows green when an external 12V DC power source is connected and indicates the battery is being charged.
  - The full battery indicator shows green when the battery is fully charged.
  - The low battery indicator shows red when the battery is low. With this LED illuminated, approximately 15 minutes of power remain before a complete discharge of the battery occurs.
- Dimensions: 11in (27.5 cm) x 8.5 in (22.25 cm) x 5.5 in (13.75 cm) (excluding gas inlets, patient outlets and mounting bracket)
- Weight: 16 lbs (7.2 kg)
- Air/Oxygen Mixer - Range 21 to 100% Oxygen, accuracy ± 3% of selected output
- Flow meter - Range 0 to 15 L/min, accuracy ± 5% of selected output
- Pressure relief valve - 2 systems incorporated
  - Patient safety - automatic electronic valve system pre-set to vent to ambient at 11 cmH2O.
  - System and delivery circuit safety - mechanical internal relief valve pre-set at 205 cmH2O.
- Manometer - Range, 0 to 12 cmH_2O, accuracy ± 1 cmH_2O.
- Oxygen Monitor – Range, 0 to 100% Oxygen, accuracy ± 2% of span.

- Alarm System - Four separate alarm systems are provided all of which are automatic. The electronic alarms are set after 2 minutes of operation without operator intervention although the operator can manually set or reset them if required.

  1 **Supply gases failure**: If the differential pressure between the two inlet gases falls outside of the limit of 20 PSI (1.4 bar) or one gas fails completely, an alarm will sound and the gas at the higher pressure only will be delivered to the patient.

  2 **High patient pressure**: An audible and visual high pressure alarm is pre-set at 11 cmH_2O. This alarm automatically activates a pressure relieving solenoid which instantly reduces the pressure in the patient circuit to near zero. The pressure is restored after 3 seconds, but will be reduced to near zero should the cause of the alarm condition still exist. A second high pressure alarm with audible and visual indication is set 3 cmH_2O above the measured CPAP pressure.

  3 **Low patient pressure**: An audible and visual low pressure alarm is set at 2 cmH_2O below the measured CPAP pressure or at 0 cmH_2O if this would otherwise be negative.

  4 **Failure to deliver correct Oxygen concentration:** Audible and visual alarms are provided at ± 5% of the measured FiO_2 at the time of arming of the alarms with an upper maximum limit of 101% and a lower minimum limit of 20%. There is a low hazard warning at 18% Oxygen or below. Additionally, the Infant Flow Advance has the following characteristics:

     - Variable augmented flow: 0 to 5 L/min of the mixed gas
     - Pressure display with time: 0 to 10 cm H_2O; accuracy: 10% of full scale
     - Timing accuracy: 1% of setting
     - Input connection: 8-way self-locking socket for Transducer Interface
     - Apnea alarm indicator (red)
     - Breath indicator (yellow) – indicates inspiration when the Transducer Interface and abdominal respiratory sensor are properly fitted.

- Environment: Keep dry and do not expose to direct sunlight.

  - **Temperature**

    Operating: 50 to 104 ºF (10 to 40 ºC)
    Storage: 32 to 122 ºF (0 to 50 ºC)

  - **Humidity**

    Operating : <90% non condensing

    Storage: <90% non condensing

  - **Atmospheric Pressure**

    Storage: 8.7 to 20.3 PSI (0.6 to 1.4 bar)

ETL Classification

With respect to applicable requirements of Standard for Safety Medical Electrical Equipment, UL 60601-1 1st Ed. 04/25/03 and General Requirements for Safety General Instructions No. 1, CAN/CSA C22.2 No. 601.1-M90.

EN 60601-1 Classification

Equipment is Class 1 and internally powered, IPX0 Protected, and uses Type B and Type BF applied parts.

Equipment not suitable for use in presence of flammable anesthetics.

NOTE

For use of Model M674A in Australia and New Zealand, Power supply Part Number 777223 must be used. This replaces Power Supply 674-037. With Power Supply Part Number 777223 in use, M674A equipment is Class 2 and internally protected, and uses Type B applied parts.

NOTE

Although the Infant Flow™ Advance meets the requirements of current EMC/RFI legislation, this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause malfunction of the Infant Flow™ Advance and should not be used in the vicinity of the device.

Chapter 3: Summary of Warnings and Cautions

The Infant Flow Advance System consisting of a driver and generator plus nasal CPAP prongs and masks, is intended for the provision of periodic and triggered bi-Level CPAP. The system is for use in hospitals, hospital-type facilities and intra-hospital transport environments.

This equipment has been tested and found to comply with the limits for medical devices in IEC 601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. VIASYS Healthcare makes no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

The Infant Flow Advance Driver is a medical device intended for use only by or under the order of a physician.

Personnel operating this equipment are responsible for reading and thoroughly understanding all product documentation provided. The warning, caution and note statements listed below must be thoroughly read and understood prior to use of this device. These statements may be repeated throughout the product documentation as needed and have special significance as follows:

Terms

WARNING - Means there is a possibility of personal injury to the operator or patient.

CAUTION - Indicates there is a possibility of damage to the product or other equipment attached to it.

NOTE - Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment.

Warnings

- 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 form of malfunction that may occur with the system. In addition, some problems may require immediate attention.
- The abdominal respiratory sensor is used only to enable features associated with the Pressure Assist (PA) and Triggered PA (trPA) modes on the Advance 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 SaO_2 monitoring.
- Blender alarms must be corrected swiftly as the Oxygen concentration which was selected for the patient will not be delivered during an alarm/bypass situation.
- The gas blender incorporated in this product is designed to mix Air and Oxygen only. Do not modify the inlets to accommodate other source gases such as anesthesia gases.
- Liquid water or other contaminants in either gas supply, particularly the air supply, will cause malfunction of this equipment and equipment connected to it.
- 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.
- The gas failure alarm will not function if both supply gases are below 30 psig (2.1 bar).
- Leaving the humidifier refill bag above the height of the Infant Flow™ Advance Driver can cause the pole and stand assembly to be mechanically unstable. Always place the water refill bag at a lower level than the chamber after filling of the chamber has been completed. The shut off clamp must be fully closed at all times other than when filling the chamber.
- Nasal CPAP treatment in general can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to the recommended usage instructions for the Infant Flow Advance accessories may reduce the incidence of these complications.
- Do not overload the pole and stand. The stand's maximum net load is approx. 22 lbs (10 kg); including the 4.4 lb (2 kg) humidifier mounted on the supplied bracket, the 15.9 (7.2 kg) Infant Flow Advance Driver mounted at a maximum of 10.2 in (260) mm above the stand handle, two bags of water (4.4 lb / 2 kg) in the basket, associated gas hoses, and patient breathing circuit.
- Do not use conductive patient circuits with the Infant Flow Advance.
- The Infant Flow Advance™ must only be operated with the supplied approved AC adaptor (refer to appendix B for a list of approved accessories).

- When filling the humidifier, do not move the stand; moving or transporting the stand while re-filling may cause the whole assembly to over-balance.
- Disconnect power supply before servicing.

Cautions

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Not suitable for use in the presence of flammable anesthetics.
- Always read the Operator's Manual before applying treatment.
- The Infant Flow Advance™ has been designed and tested as a complete system using Infant Flow™ accessories. Use only approved accessories (Refer to Appendix B for a list of approved accessories).
- Service and/or repair of this instrument is restricted to VIASYS Healthcare authorized or VIASYS Healthcare Trained Personnel only.
- The precision gas blender incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.
- Always reset the alarms after changing patient settings.
- Remove any liquid in the manometer line; any obstruction leads to inaccurate readings of pressure.
- The ☑ mark indicates the connection between the Transducer Interface and the Driver only. It does not indicate correct positioning of the abdominal respiratory sensor.
- The power switch on this unit does not isolate the unit from the external power supply. Disconnect the external power supply to ensure isolation.
- Remove primary battery if equipment is to be stored without use for long periods of time.
- Equipment must be used with approved power supplies. Refer to Appendix B for a list of approved accessories.
- Verify that this device has been authorized for use by qualified personnel.
- Disconnect the mains power supply before removing covers.
- Do not immerse any part of this device or gas or steam sterilize it. Damage will result.

Notes

- For use of Model M674A in Australia and New Zealand, Power supply Part Number 777223 must be used. This replaces Power Supply 674-037. With Power Supply Part Number 777223 in use, M674A equipment is Class 2 and internally protected, and uses Type B applied parts.

- VIASYS Healthcare recommends the use of a heated humidifier which utilizes a heater wire in the inspiratory limb for enhanced patient safety.
- The gas failure alarm/bypass will activate when the first gas is connected and will reset upon connection of the second supply gas.
- We recommend that the temperature be set between 36 °C (96.8 °F) and 37 °C (98.6 °F) but never higher than 37 °C (98.6 °F) for inspired gases.
- Due to local regulations these options are not available in all markets.
- It is recommended that hospital personnel responsible for the Performance Verification Test maintain records of their activities and identify equipment authorized for use.
- Although the Infant Flow™ Advance meets the requirements of current EMC/RFI legislation this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause malfunction of the Infant Flow™ Advance and should not be used in the vicinity of the device.
- The Infant Flow Advance is an integral system consisting of the Driver (including air-oxygen blender, monitor and oxygen analyzer), electronics module with screen display and the Infant Flow nasal CPAP Generator. These components can only be used as a system. The Infant Flow Advance should not be used for any other type CPAP or ventilation system. The Infant Flow nasal CPAP Generator should not be used with any other delivery system.
- It is advisable to leave the Infant Flow Advance connected to a power source whenever possible. This will ensure maximum battery life for transport applications. (It may take up to 16 hours to charge a fully discharged battery).
- The additional flow available through the Infant Flow Advance module should be turned to zero prior to set-up.
- Certain modes are not available unless the Transducer Interface is attached to the unit and will not operate unless an abdominal respiratory sensor is attached to the patient.
- The graphics displayed on the screen are a representation of the manometer LED's on the front of the Infant Flow Driver.
- 'Pressure Assist' can work with or without the Transducer Interface fitted (ie with and without Apnea monitoring).
- The 'bell symbol'  will not be shown on the screen if the Transducer Interface is not attached to the Infant Flow Advance.
- During set-up of any mode the user can return to the Treatment Selection Screen by selecting '↰' key.
- The over and under pressure alarms are set and detect pressure over a period of time. In the Pressure Assist modes, the mean pressure over the timed period will be higher than just CPAP. The alarms should therefore be set around this average.

- The duration of the single Pressure Assist will be the default value of Ti unless changed through the PA Set-Up screen.
- The LED on the Transducer Interface and the Infant Flow Advance™ will flash simultaneously when a patient breath is detected. If either LED does not illuminate, fit an alternative Transducer Interface, or contact your local VIASYS Healthcare representative.
- The ball in the Flowmeter will 'bounce' during operation in the PA and trPA modes. This is a normal occurrence during these modes. For pressure reading see the LED display.
- Battery Maintenance for extended storage: remove the battery from the equipment and charge to 100%. Charge the battery every month if stored at temperatures below 60 °F (15.5 °C). If stored in an area above 60 °F (15.5 °C), charge every two weeks.
- All of the functional accessories supplied by VIASYS Healthcare for use with the Infant Flow™ driver are for single patient use only. These accessories include the Infant Flow™ generator, delivery breathing circuits, humidification chambers, silencer/bacteria filters and fixation bonnets. Under no circumstances should sterilization or re-use of these products be attempted.
- A complete list of service parts can be found in the Service Manual.

Chapter 4: Operating Instructions

The Infant Flow Advance provides a virtually constant CPAP pressure irrespective of patient demand or expiratory flows via the specially designed driver, generator, and nasal interface. The Infant Flow generator is subject to a direct relationship between controlled enriched gas flow and Nasal CPAP pressure.

A nomogram illustrating the general relationship between constant airway pressure and flow settings is shown below. Example: 8 L/min will provide in the order of 5 cmH_2O Nasal CPAP. Please note that actual devices may demonstrate tolerances of more than 10% from that illustrated in the nomogram and, in particular, at pressures below 2 cmH_2O.

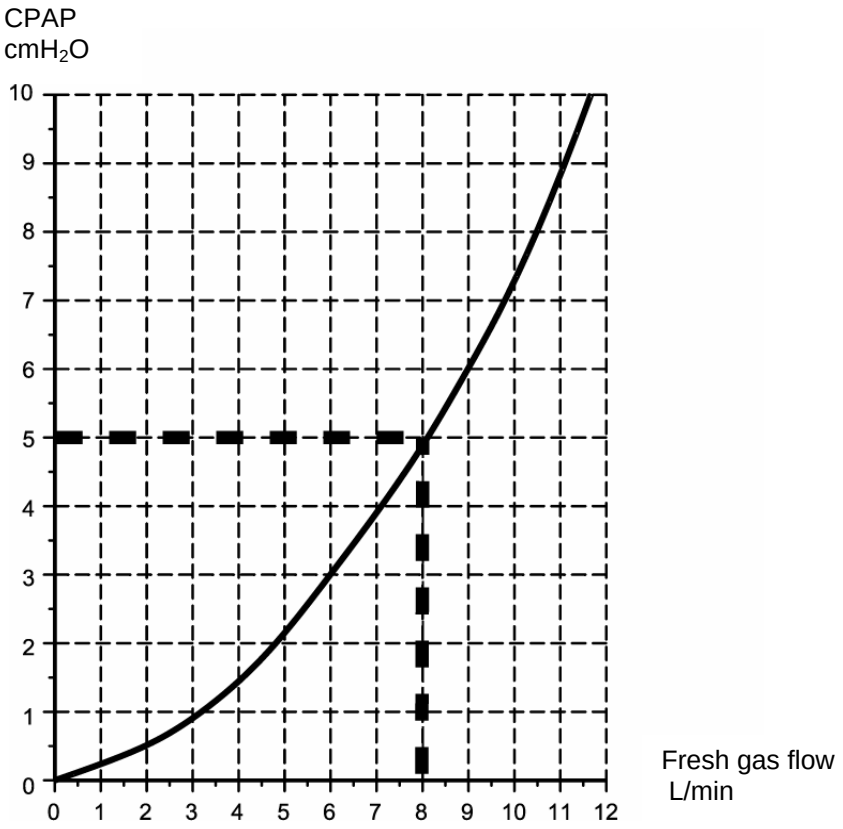

Figure 1 - Flow Pressure Nomogram for the Infant Flow Advance

CAUTION

Verify that this device has been authorized for use by qualified personnel.

CAUTION

Remove any liquid in the manometer line; any obstruction leads to inaccurate readings of pressure.

Step by Step Instructions

1 Firmly mount the Infant Flow Advance™ on either the pole and stand or the rail system with all of the ancillary equipment such as the heated humidifier. Check the integrity of the driver, the Transducer Interface and all ancillary equipment prior to operation.

NOTE

VIASYS Healthcare recommends the use of a heated humidifier which utilizes a heater wire in the inspiratory limb for enhanced patient safety.

2 Connect the medical air and oxygen hoses to the driver and then to the high pressure source.

NOTE

The gas failure alarm/bypass will activate when the first gas is connected and will reset upon connection of the second supply gas.

3 Connect the power cord for the Infant Flow Advance Driver to a suitable outlet. **Do not** switch on the driver at this point.

4 Connect the patient circuit and Infant Flow Generator as shown in Figure 2.

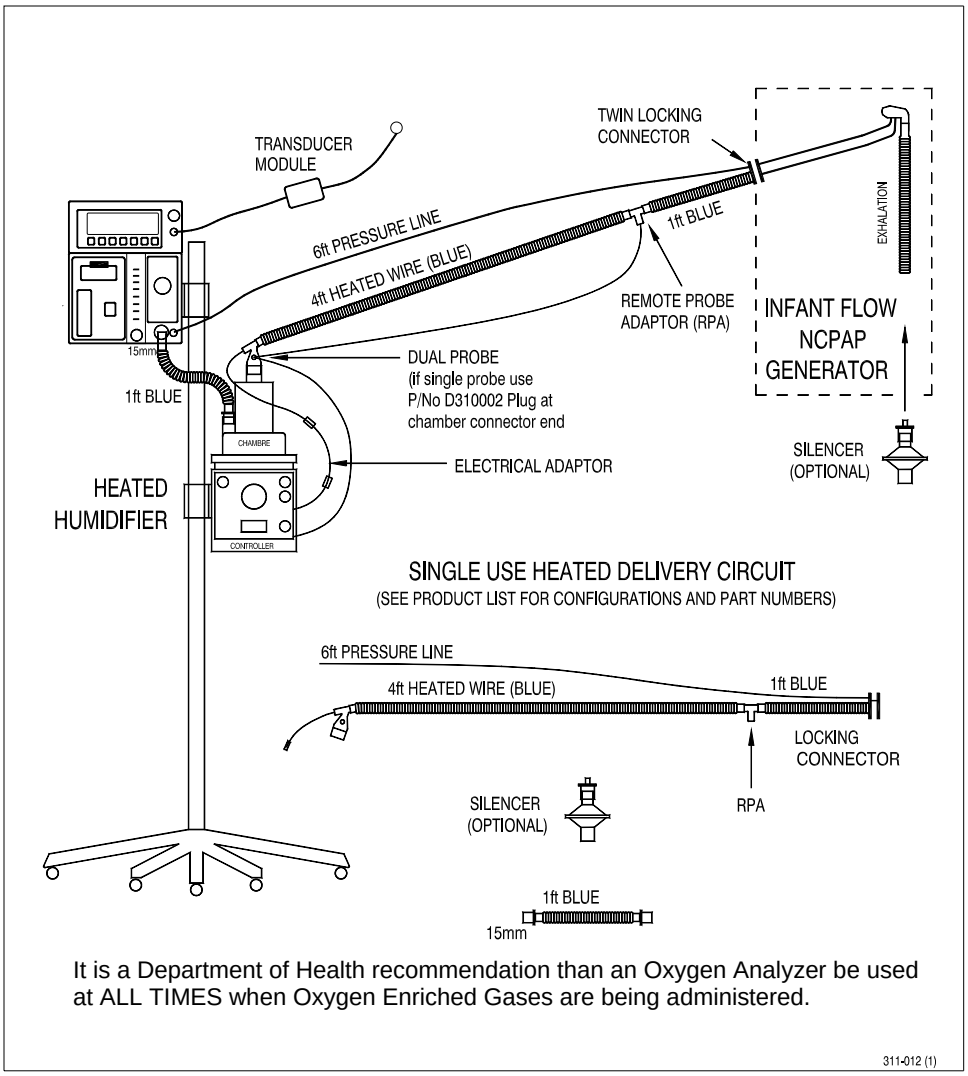

Figure 2 - Set Up Infant Flow Advance System

This figure is a general indication of how the various devices would be interconnected in a typical setup. The actual configuration will vary dependent on the type of ancillary equipment used.

WARNING

Liquid water or other contaminants in either gas supply, particularly the air supply, will cause malfunction of this equipment and equipment connected to it.

5 Set the desired delivery temperature on the heated humidifier and switch it on.

NOTE

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

6 Select the appropriate sized bonnet. Full instructions on placement of the bonnet and fixation may be found on the instruction leaflet included with the bonnets and generator.

- Use the forehead and the nape of the neck as reference points when measuring the infant's head to determine the proper bonnet size.
- Too small a bonnet may cause it to ride up, putting tension on the patient interface, distorting the infant's nose.
- Too large a bonnet may allow it to slide down over the infant's eyes and release the interface from the infant's nose.

7 Open a Generator set and attach it to the circuit. Select the largest size interface that will fit the infant's nares (for prongs) or around the nose (for masks). When fitted correctly, nasal prongs should be inside the nares with some space existing between the prong and the nose. The generator assembly should not be pulling up on or causing distortion to the infant's nose.

8 Attach the prongs or mask interface to the Generator.

9 Switch on the Infant Flow Advance™ using the on/off switch at the rear of the Infant Flow™ driver.

- The Breath and Apnea alarm indicator lamps are illuminated briefly when the equipment is first powered. If either lamp is not working, do not use the equipment.
- All the elements of the display are exercised at switch-on so that the operation of the display can be checked, and the software version can be viewed.
- The display presents the Pre-treatment Set-up screen after two seconds (see Appendix for typical screen displays).

10 Occlude the patient interface.

11 Turn the gas flow to 8 L/min using the knob under the flow meter and verify that the pressure reads 5 cmH_2O. Check breathing circuit and connections for leaks if 5 cmH_2O is not achieved. The flow meter indicator may take up to 3 seconds to settle after a step change in flow has occurred.

12 Once the CPAP pressure is set, the button under the CPAP icon should be pressed. The flashing '?' will change to a '✓'

13 Set the required FiO_2 using the O_2% graduated control.

14 Set the Pressure Assist characteristics by:

- Adjusting the flow by using the knob above the transducer connection to the right of LED display. Check the additional pressure on the graphic display.
- Once set to the desired level, the button under the PA icon should be pressed and the flashing '?' will change to a '✓'.

15 The button under the patient icon should be pressed when the Interface and sensor have been properly attached or when the user has decided that this option is not required. The flashing '?' will change to a '✓'.

CAUTION

The ☑ mark indicates the connection between the Transducer Interface and the Driver only. It does not indicate correct positioning of the abdominal respiratory sensor.

16 Fit the generator to the patient and bonnet. Ensure that the correct size interface is selected and that the entire assembly is properly fitted to the infant. Use the largest size interface that fits the infant's nares or around the infant's nose to form a seal.

17 When properly set, the prongs should be inside the nares. There should be some space between the prong set and the infant's nose. The prongs should not be pulling up on the infant's nose. Alternatively, the mask should be snugly fitted around the nose. The mask should not press down on the infant's face or come into contact with the infant's eyes or mouth. Refer to the instruction insert found with the bonnet or generator packaging for a diagram of final fixation position.

18 Small adjustments to the nasal CPAP flow rate may be required until the display reads the prescribed CPAP level. The relationship between the flow setting and CPAP pressure should be compared with Figure 1 as a reference. If outside the suggested range, check with the troubleshooting section of the manual.

19 If Apnea monitoring or trPA is required, attach the abdominal respiratory sensor to the patient and to the Transducer Interface, and the Transducer Interface to the Infant Flow Advance Driver. Refer to Appendix C for placement instructions. At this point a ☑ will appear on the screen to identify the Transducer Interface is connected and remain on the screen until the Transducer Interface is disconnected.

WARNING

The abdominal respiratory sensor is used only to enable features associated with the Pressure Assist (PA) and Triggered PA (trPA) modes on the Advance 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 SaO_2 monitoring.

CAUTION

The ☑ mark indicates the connection between the Transducer Interface and the Driver only. It does not indicate correct positioning of the abdominal respiratory sensor.

NOTE

The LED on the Transducer Interface and the Infant Flow Advance™ will flash simultaneously when a patient breath is detected. If either LED does not illuminate fit an alternative Transducer Interface, or contact your local VIASYS Healthcare representative.

20 Using the Treatment Set-up screens;

- Set the duration of the Pressure Assist by adjusting Ti↑ and Ti↓. The default setting is 0.3 seconds.
- Set the rate in Pressure Assist mode by adjusting R↑ and R↓. The default is 30 per minute.
- In Triggered Pressure Assist, the rate is the back-up rate should the patient become apneic. In this mode the default setting is 10 per minute.
- Set the Apnea alarm period by pressing the Alarm bell button. The alarm period can be set at 10, 15, 20, 25 and 30 seconds. The default setting is 20 seconds.

NOTE

During set-up of any mode the user can return to the Treatment Selection screen by selecting '↩' key.

21 Set the pressure and FiO_2 alarms by pressing and holding the Alarm Silence button for three seconds.

NOTE

The over and under pressure alarms are set and detect pressure over a period of time. In the Pressure Assist modes, the mean pressure over the timed period will be higher than just CPAP. The alarms should therefore be set around this average.

22 Ensure that the nasal CPAP pressure is that which is prescribed. The "Target Range" section of the bar graph indicates the most commonly used pressures with the Infant Flow Generator. However, the actual pressures used for the treatment of individual patients must be prescribed by the clinician.

Minor variations between devices occur but the pressure delivered should always be within ± 10% of those shown on the Nomogram (Figure 1). If they are out of specification check that there are no leaks in the patient circuit.

23 The electronic alarms for FiO_2 and pressure will automatically set after a 2 minute stabilization period. Should you wish to set them earlier, simply hold the Arm/Mute button in for three seconds. The alarm will bleep to indicate that

your command has been accepted and the Alarms Armed indicator will illuminate.

24 Should you change the nasal CPAP treatment pressure or the Oxygen concentration, it is necessary to reset the alarm levels by holding the Arm/Mute button in for three seconds.

25 In order to change treatments at anytime, first unlock the screen by pressing the 'key strike-thru' button. Then, press the 'treatment strike-thru' button to end the current treatment and return to the treatment selection screen. CPAP will always be applied.

26 A single Pressure Assist may be delivered at any time. This can be applied to the patient by first unlocking the screen by pressing the 'key strike-thru' button, and then pressing the button.

NOTE

The duration of the single Pressure Assist will be the default value of Ti unless changed through the PA Set-Up screen.

NOTE

The ball in the Flow meter will 'bounce' during operation in the PA and trPA modes. This is a normal occurrence during these modes. For pressure reading see the LED display.

27 Should Apnea monitoring be required, the Transducer Interface must first be attached to the Infant Flow Advance Driver, then an Abdominal Respiratory Sensor should be attached to the patient and the Transducer Interface. The apnea monitoring period may be adjusted between 10 and 30 seconds in 5 second interval by pressing the button beneath the bell symbol.

WARNING

The abdominal respiratory sensor is used only to enable features associated with the Pressure Assist (PA) and Triggered PA (trPA) modes on the Advance 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 SaO_2 monitoring.

28 What to do if an alarm occurs - Always attend alarm conditions immediately as the patient may not be receiving the prescribed FiO_2 or nasal CPAP or may have become apneic. Check all connections between the device and the patient.

29 There are two distinct alarm types built in the Infant Flow Advance. The Air/Oxygen Mixer has a mechanical bypass and alarm system which will sound if one of the supply gases is below or above the range of pressure which can be handled satisfactorily.

30 The second alarm system consists of an electronic system built into the pressure and Oxygen monitoring module. This has several functions as shown in Table 1 in this chapter. All electronic alarms with the exception of the

overpressure alarm are self re-setting. In the event of an overpressure being detected (> 11 cmH_2O), the Driver activates a vent-to-ambient solenoid valve which removes gas flow from the patient circuit.

WARNING

Nasal CPAP treatment in general can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to the recommended usage instructions for the Infant Flow Advance accessories may reduce the incidence of these complications.

31 Nasal CPAP is not a benign procedure, all operators must be aware of the possible hazards and complications associated with this treatment. Operators must apply all necessary precautions to ensure safe and effective application and treatment.

32 Do not over-tighten the generator straps. There is a risk of tissue damage.

33 Always choose the correct interface size.

34 Check the infant at least every 3-4 hours for the following:

- nasal irritation and septal distortion;
- skin irritation and pressure necrosis;
- nasal mucosal damage due to lack of humidification;
- gastric insufflation;
- abdominal distention.

TABLE 1 - Infant Flow Advance Driver Alarm Systems

Alarm function	Device Action	Operator Action
Oxygen supply failure	Audible alarm.	Check and restore oxygen supply.
Air supply failure	Audible alarm.	Check and restore air supply.
High oxygen concentration	Audible alarm & high oxygen indicator illuminated.	Check supply gases and/or galvanic fuel cell. Press the Arm/Mute button to silence the audible alarm.
Low oxygen concentration	Audible alarm & low oxygen indicator illuminated.	Check supply gases and/or the galvanic fuel cell. Press the Arm/Mute button to silence the audible alarm.
High pressure	Audible alarm & high pressure indicator illuminated.	Check the flow rate and check for occluded tubes. Press the Arm/Mute button to cancel the alarm or restore pressure in the circuit.
Low pressure	Audible alarm & low pressure indicator illuminated.	Check the flow rate and check for occluded or disconnected tubes or nasal interface. Press the Arm/Mute button to silence the audible alarm.
Apnea timeout period	Audible alarm & LED illuminated	Check patient to determine breathing. Check position of abdominal respiratory sensor. Check connections between the sensor, the Transducer Interface and the Driver. Replace Transducer Interface and sensor as appropriate. The alarm will self cancel if the cause is removed within the first timeout period. If it is not removed, then the Arm/Mute button must be pressed to silence the audible alarm.

TABLE 2 – Default Settings and Set Ranges

DEFAULT SETTINGS	
Inspiration Time	Ti: 0.3 seconds (+/- 1%)
Breath rate - detected Breaths Per Minute	bpm +/- 1
PA Rate (During Pressure Assist)	R: 30 / minute
Back Up Rate (During Triggered Pressure Assist)	Rb: 10 / minute
Apnea Alarm Delay	20 seconds (+/- 1%)
SET RANGES	
Inspiration Time	Ti: 0.1s to 1.0s
PA Rate (During Pressure Assist)	R: 1 – 120 / minute
Back Up Rate (During Triggered Pressure Assist)	Rb: 1 – 30 / minute
Apnea Alarm Delay	10, 15, 20, 25, 30 seconds
Variable Additional Flow	0 – 5 L/min

Chapter 5: Clinical References

1 Klausner J, Lee AY, Hutchison AA. Decreased imposed work with a new nasal continuous positive airway pressure device. Pediatr Pulmonology 22:188-194, 1996.

2 Moa G, Nilsson K, Zetterstrom H, Jonsson LO. A new device for administration of nasal continuous positive airway pressure in the newborn: an experimental study. Crit Care Med 16:1238-1242, 1988.

3 Rasanen J, Leijala M. Breathing circuit respiratory work in infants recovering from respiratory failure. Crit Care Med 19:31-35, 1991.

4 Guilleminault C, et al. Upper airway resistance in infants at risk for sudden infant death syndrome. J Pediatr, Volume 122, Number 6, June 1993.

5 Moa G, Nilsson K. Nasal continuous positive airway pressure: experience with a new technical approach. Acta Pediatr 82: 210-11, 1993

6 Avery ME, et al. Is chronic lung disease in low birth weight infants preventable? A survey of eight centers. Pediatrics 79:26-30 1987.

7 Higgins RD, Richter SE, Davis JM. Nasal continuous positive airway pressure facilitates extubation of very low birth weight neonates. Pediatrics 88:999-1003, 1991.

8 Locke RG, et al. Inadvertent Administration of Positive End-Distending Pressure During Nasal Cannula Flow. Pediatrics (ISSN 0031 4005) 1993.

9 Stocks J. Effect of nasogastric tubes on nasal resistance during infancy. Archives of Diseases in Childhood, 55:17-21, 1980.

10 Courtney, SE, et al. Lung volume changes during nasal continuous positive airway pressure (nasal CPAP) in preterm infants: comparison of a variable vs a continuous flow device. The American Pediatric Society and The Society for Pediatric Research Abstract, #989, May 1998.

Chapter 6: Routine Maintenance

WARNING

Disconnect power supply before servicing.

Routine maintenance of the Infant Flow Advance is limited to regular checking of the oxygen analyzer calibration and periodic (every 4 months) checking of the Air/Oxygen Mixer and Electronic Pressure Manometer, status of the gas inlet filters, integrity of the alarm system and cleaning of exterior surfaces.

An Infant Flow Advance in need of recalibration, service or repair must not be used until the necessary procedures are performed and the equipment has been tested to ascertain that it is functioning correctly.

Ensure pole clamp screws and clamp are securely fastened.

The Infant Flow Advance Service Manual is available to qualified technicians to effect calibration, service and repair. If this is not feasible, contact VIASYS Healthcare to insure full reliability and safety as special tools and equipment are required.

Service and/or repair of this instrument is restricted to VIASYS Healthcare authorized or VIASYS Healthcare Trained Personnel only. Parts designated in this manual should be replaced only with parts manufactured or sold by VIASYS Healthcare.

Gas Inlet Filters – The exterior air filter can be observed through the polycarbonate bowl. If it is discolored or wet it should be replaced.

CAUTION

The precision gas blender incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.

Oxygen Analyzer Calibration

The integral oxygen analyzer is of the fuel cell type and as such requires regular calibration. To perform this check, set up the Infant Flow Driver as for use and allow 2 minutes for stabilization of the electronic measuring circuits.

Select an oxygen concentration of 21%, wait 2 minutes and verify that the display indicates 21. If not, remove the small white plug adjacent to the 21% mark on the side of the device and adjust the potentiometer to give a reading of 21.

Set the mixer to 100%, wait 2 minutes and verify that the display indicates 100. If not, remove the small white plug adjacent to the 100% mark on the side of the device and adjust the potentiometer to give a reading of 100.

Return the mixer to the 21% position and verify that the display reads 21. There may be some small interaction between the set point controls if a gross adjustment is required and the process may need to be repeated two or three times. If this is the case, it is indicative that the fuel cell is wearing out and should be replaced. Refer

the Infant Flow Advance Driver to a competent service department for replacement of the fuel cell. Once calibration is completed, please replace the white plugs.

Cleaning

The exterior surfaces of the Infant Flow Advance Driver and Transducer Interface can be cleaned with a mild soap or liquid disinfectant solution. Do not use cleaning agents that contain abrasives. Care should be taken to ensure that cleaning solutions do not enter the unit via any patient connection ports.

CAUTION

Do not immerse any part of this device or gas or steam sterilize it. Damage will result.

Single Use devices should be disposed of in accordance with local regulations for bio-hazardous materials after use.

Battery Maintenance

The Infant Flow Advance™ incorporates a sealed lead acid battery. There is no routine maintenance to be carried out on this battery which has an expected useful life of five years. The Infant Flow Advance™ has a built in charger which will safely charge the battery and keep it in the best possible condition. It is recommended that the driver is connected to an external power source via the approved AC adaptor whenever possible to ensure that the battery is fully charged should it be required for transport or in the event of a power failure.

NOTE

Due to local regulations these options are not available in all markets.

WARNING

The Infant Flow Advance™ must only be operated with the supplied approved AC adaptor (refer to appendix B for a list of approved accessories).

NOTE

All of the functional accessories supplied by VIASYS Healthcare for use with the Infant Flow™ driver are for single patient use only. These accessories include the Infant Flow™ generator, delivery breathing circuits, humidification chambers, silencer/bacteria filters and fixation bonnets. Under no circumstances should sterilization or re-use of these products be attempted.

Exhausted batteries and oxygen fuel cells both contain lead and must be disposed of according to local regulations.

Chapter 7: Summary of Symbols

The following international standard symbols may appear on the Infant Flow Advance and in this manual. It is essential that all users of the equipment have a firm understanding of the symbols.

	EN60601 Type B Patient Applied Part.		Internal Battery Fully Charged
	AC Alternating Current		Internal Battery Low
	DC Direct Current		Year of Manufacture
	Fuse		Read the Accompanying Documents
	Activate / Reset Alarm		Electric Shock Hazard
	Silence Alarm		Unique Batch Number Identifier
	Patient Circuit Connections		Use Before Expiry Date Shown Year-Month
	Respiratory Sensor Connections		Single Use Only Do NOT Re-use
	High Alarm		External Power Source Connected

	Low Alarm		Keep Away From Heat
	Power on		Keep Dry
	Power Off	CE 0086	CE Mark and Notified Body Number.
	Application of a single Pressure Assist cycle.		Please read the Operator's Manual.
	EN60601 Type BF Patient Applied Part.	INTERTEK ETL LISTED C US 78425	ETL mark and registration number.

Appendix A: Screen Flow Diagrams

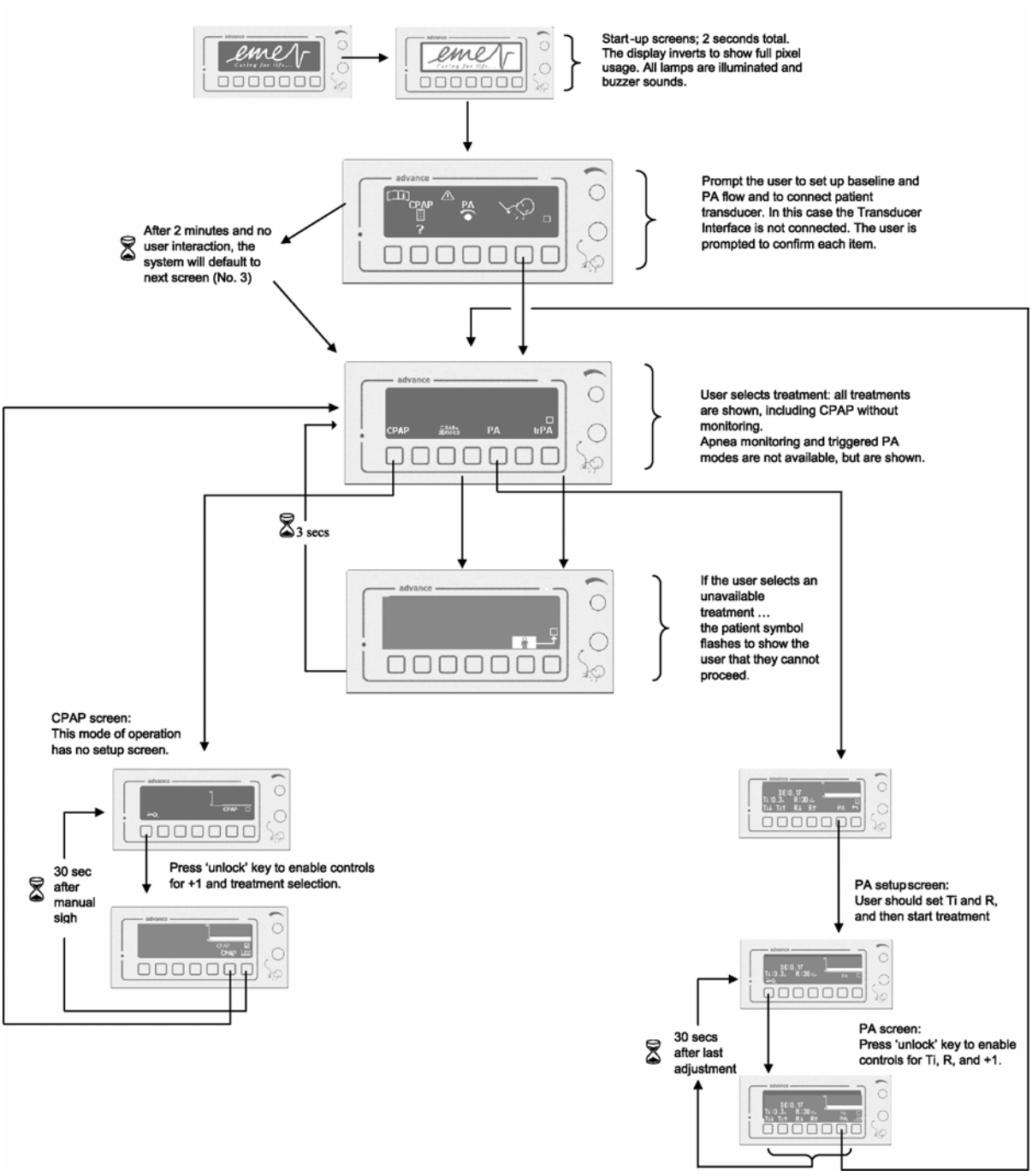

Figure 3 – Setup Scenario I

In this scenario, the Transducer Interface is not present and therefore not all modes are available.

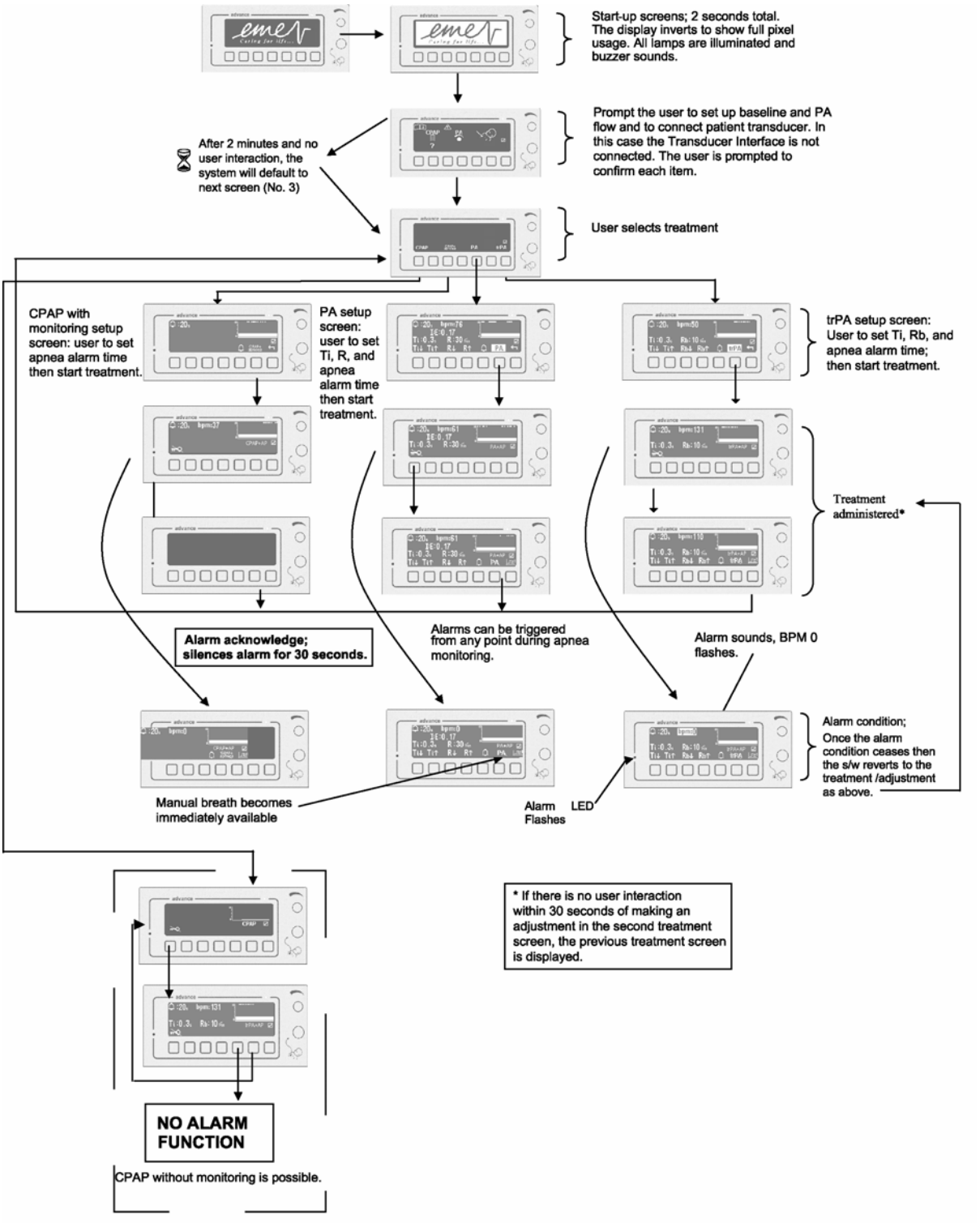

Figure 4 - Setup Scenario II

Patient Abdominal Respiratory Sensor is present and the Transducer Interface is connected; all modes are available. If the Transducer Interface is disconnected, the device reverts to the treatment selection screen (see Figure 3) unless non-triggered PA therapy is being delivered (in which case it switches to un-monitored PA).

Appendix B: Approved Accessories

VIASYS P/N	EME P/N Ref.	Description
Infant Flow Advance Generators		
777085-102	D350T	Infant Flow nasal CPAP Generator (Box of 20)
777085-101	D350T/10	Infant Flow nasal CPAP Generator (Box of 10)
Infant Flow Advance Bonnets		
777084-101	DBWH000	Infant Flow Bonnet – Size 000 (White)
777084-102	DBGY00	Infant Flow Bonnet – Size 00 (Grey)
777084-103	DBPK0	Infant Flow Bonnet – Size 0 (Pink)
777084-104	DBBR1	Infant Flow Bonnet – Size 1 (Light Brown)
777084-105	DBYE2	Infant Flow Bonnet – Size 2 (Yellow)
777084-106	DBBL3	Infant Flow Bonnet – Size 3 (Light Blue)
777084-107	DBGO4	Infant Flow Bonnet – Size 4 (Gold)
777084-108	DBGR5	Infant Flow Bonnet – Size 5 (Green)
777084-109	DBBU6	Infant Flow Bonnet – Size 6 (Light Burgundy)
777084-110	DBOR7	Infant Flow Bonnet – Size 7 (Orange)
777084-111	DBDG8	Infant Flow Bonnet – Size 8 (Dark Green)
777084-112	DBNA9	Infant Flow Bonnet – Size 9 (Navy)
Infant Flow Advance Mask/Prong Patient Interfaces		
777086-101	D360XS	Nasal Mask Extra Small
777086-102	D360XL	Nasal Mask Extra Large
777086-103	N/A	Nasal Mask Extra-Extra Large
777087-101	D360S	Nasal Prong Small
777087-102	D360M	Nasal Prong Medium
777087-103	D360L	Nasal Prong Large
Infant Flow Advance Standard Circuits		
773386	C8112E	Patient Circuit IF, F&P 730 (Box 20)
773387	N/A	Patient Circuit IF, F&P 850 (Box 20)
773388	N/A	Patient Circuit IF, RCI 380-90 16V (Box 20)
773389	N/A	Patient Circuit IF, RCI 380-88/Concha IV 21V (Box 20)
Infant Flow Advance Miscellaneous Parts and Accessories		
D1420/100	Same	Infant Flow Silencer/Bacteria Filter (Box 20)
M674-920	Same	Infant Flow Advance Service Manual (English)
673-055-A	M673055A	Infant Flow Pole and Stand complete with IV extension pole
772-235-A	M772235A	Infant Flow Pole and Stand without IV extension pole
772236	M772236	Infant Flow extension pole alone
674-037	MW160MA	AC Adaptor (MW160) ⚠
777223	N/A	AC Adapter Australia and New Zealand, M674A only
M674ARC	same	Abdominal Respiratory Sensor (Box 25)
M677-1	same	Infant Flow Advance Transducer Interface

Note

A complete list of service parts can be found in the Service Manual.

Appendix C: Abdominal Respiratory Sensor Placement

1. Connect the Abdominal Respiratory Sensor (A.R.S.) to the Infant Flow Advance™ transducer interface.
2. Switch on the Infant Flow Advance (refer to Chapter 4, Operating Instructions). Light compression of the respiratory sensor causes the LED on the transducer interface to illuminate, indicating that the sensor and transducer interface are functioning.
3. Site the A.R.S., taking the following into account:
   - Ensure that the abdomen exhibits consistent outward movement during each spontaneous **inspiratory** effort.
   - Place the sensor in a position where no retractions are present. Avoid areas just below the rib margin and in proximity to an active pericardium.
   - Ensure that the patient does not lie on the A.R.S. Considering periodic body position changes, a lateral abdominal site may be preferred for this reason.
4. Select a fixation tape that is suitable for the patient.
5. Place the A.R.S. in the center of the tape with the pressure line perpendicular to the tape.
6. Place the A.R.S. between the umbilicus and the xiphisternum (refer to Figure 5).

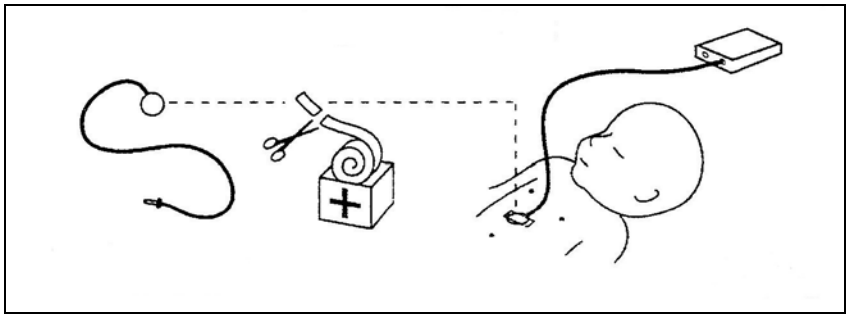

Figure 5 - A.R.S. Placement

7. Stretch the tape as you apply the A.R.S. to the patient, providing a taught profile.
8. Verify correct A.R.S. placement by observing spontaneous breathing. The onset of inspiration for each spontaneous breath (abdomen moving outward) must be accompanied by the LED flashing.

Glossary of Terms

CPAP	Continuous Positive Airway Pressure
Nasal CPAP	Nasal Continuous Positive Airway Pressure.
PA	Pressure Assist – extra flow is delivered causing an increase in pressure through the generator. This is in addition to current CPAP
trPA	Triggered Pressure Assist gives the same effect as PA but only when the baby's inspiratory effort is detected
CDP	Continuous Distending Pressure
FRC	Functional Residual Capacity
L/min	Liters per minute
cmH_2O	Centimeters water pressure
PSI	Pounds per Square Inch
Bar	A pressure of one atmosphere
Ti	Period of time that the additional pressure is available to the patient during Pressure Assist modes
R	Rate - number of times the additional pressure will be applied during the PA
Rb	Back-Up Rate - number of times the additional pressure will be applied during detected periods of apnea in trPA
bpm	Breaths Per Minute – as detected by the Abdominal Respiratory Sensor
I:E	The ratio between the length of time that the additional pressure is available to the patient (Ti) and the length of time that the CPAP pressure is available to the patient