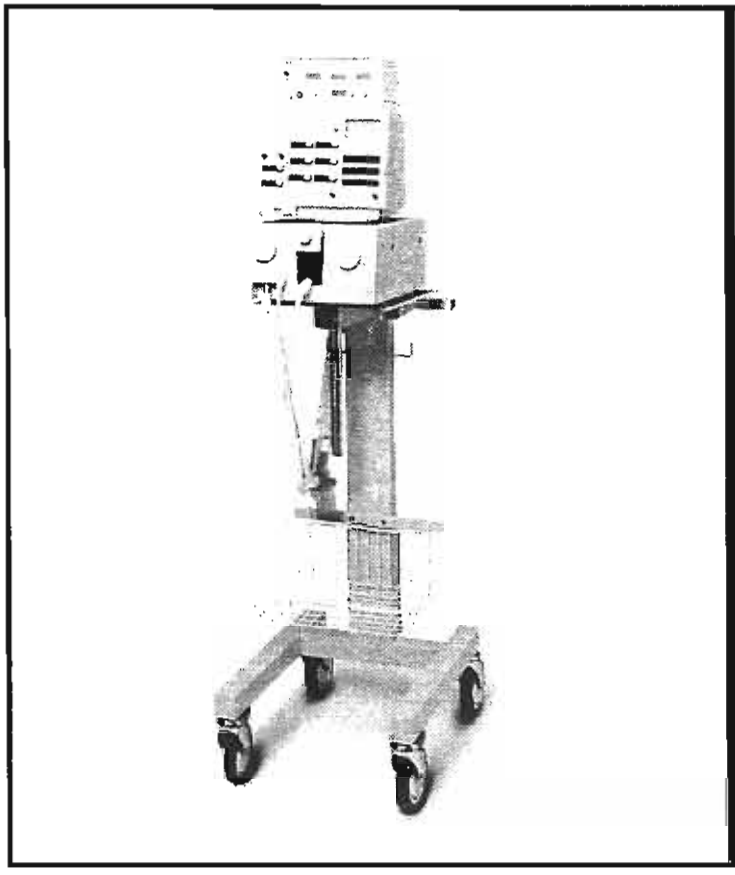
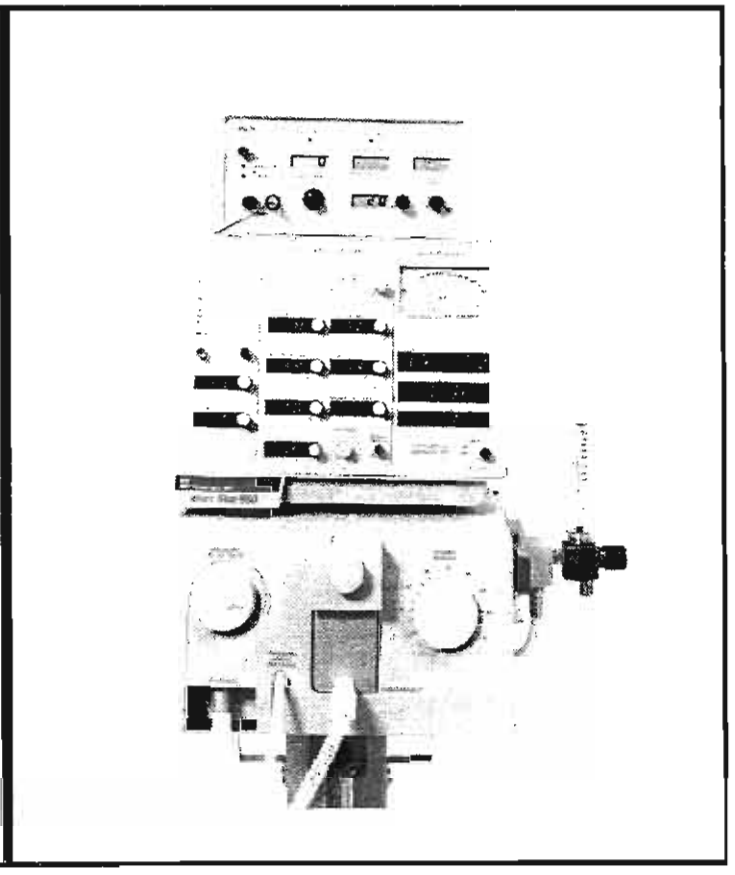
Infant Star® 500/950

Ventilators

OPERATING INSTRUCTIONS





NELLCOR PURITAN BENNETT™

Star® Series

Re: Ballard Sx:

Blue = 6 french - 28 wks & below
2.5 & under (ETT)

Pink = 8 french - 29 wks & above
≥ 3.0 ETT

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LIST OF ILLUSTRATIONS

DEFINITION OF WARNINGS, CAUTIONS AND NOTES

Statements in the Operating Instructions preceded by the words "**WARNING**", "**CAUTION**" and "**NOTE**" carry special significance. The definitions of these words are as follows:

WARNING

Means there is a possibility of injury to oneself or others.

CAUTION

Means there is a possibility of damage to the instrument or other property.

NOTE: Indicates points of particular interest for more efficient and convenient operation.

SUMMARY OF WARNINGS, CAUTIONS AND NOTES

The following must be read before using the Infant *Star* 500 and 950 Ventilators. When using the Infant *Star* 950 in either the **HFV ONLY** or **HFV + IMV** mode, refer to the Operating Instructions HFV Addendum in the back of this manual.

WARNING

Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons:

a. Some malfunctions require immediate corrective action.
b. An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.

WARNING

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

WARNING

Adjustment of the **PEAK INSP PRESSURE**, **INSPIRATORY TIME** and **FLOW RATE** affects the volume delivered to the patient. Carefully monitor this interrelationship.

WARNING

While running the Quick Checkout Procedure or operating the ventilator, if a mechanical or electrical problem is recognized, the ventilator must be removed from use and referred to qualified personnel for servicing. Using a malfunctioning ventilator may result in patient injury.

WARNING

Do Not use in the presence of flammable anesthetics. An explosion or fire may result.

WARNING

Whenever a humidifier is placed inline with the patient breathing circuit, water traps or heated wires should be used in the inspiratory and expiratory limbs of the patient breathing circuit to prevent water accumulation in the tubing from being inadvertently drained toward the airway.

WARNING

Never use the **PRESSURE RELIEF VALVE** to establish the **PEEP/CPAP** level. Always adjust the **PRESSURE RELIEF VALVE** to a pressure setting in excess of 6 cm H_2O above the **PEEP/CPAP** level to assure that fresh gas reaches the patients' airway.

WARNING

The **ALARM SILENCE** is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

WARNING

When using the ventilator with low **BACKGROUND FLOW**, major changes in the **OXYGEN PERCENT** may require 30 to 45 seconds before the new concentration reaches the airway.

WARNING

To verify accuracy of the oxygen delivery system and ensure patient safety at all times, an oxygen monitor should be connected in the tubing between the ventilator and the humidifier. Incorrect FiO2 may result in patient injury.

WARNING

Failure to properly set the **LOW INSP PRESSURE** alarm may result in failure to detect an inadequate mandatory breath or a leak in the breathing circuit.

WARNING

The **LOW PEEP/CPAP** alarm does not detect all tubing disconnections or changes in the **PEEP/CPAP** level. Although the **LOW PEEP/CPAP** alarm will detect a breathing circuit disconnection or wye to endotracheal tube adapter disconnection, when set at 2 cm H_2O **PEEP/CPAP** or greater, it may not alarm in the presence of a patient extubation. The endotracheal tube or nasal CPAP prongs may produce sufficient back pressure so that the alarm threshold is not reached.

WARNING

If the **VENTILATOR INOP** alarm activates, gas flow to the patient is stopped and the patient airway is vented to the room air. An alternate source of patient ventilation must be immediately provided.

WARNING

Ventilator components should be well aerated before use following ethylene oxide sterilization. Aeration time will vary depending on temperature used during processing and type of aerator. Follow the sterilizer manufacturer's recommendation regarding aeration time.

WARNING

Turn humidifier to OFF or PAUSE during suctioning procedure to avoid the possibility of the humidifier chamber overheating. Chamber overheating may result in gas temperature overshoot at the airway during reconnection.

WARNING

Do Not tee accessory monitoring devices into the **PROXIMAL PRESSURE** line. Adding additional tubing volume will delay demand flow response and may cause activation of the **OBSTRUCTED TUBE** alarm. If necessary, tee into the inspiratory or expiratory limbs of the breathing circuit.

WARNING

Connect the **PROXIMAL AIRWAY PRESSURE** tube to the patient wye before attaching the inspiratory and expiratory limbs. A **PROXIMAL AIRWAY PRESSURE** tube disconnect will result in one or more alarms, including an **OBSTRUCTED TUBE** alarm (A05) and **LOW PEEP/CPAP**. All alarm situations must be corrected to ensure adequate ventilation.

WARNING

When using the **CPAP MODE** of ventilation, the **FLOW RATE**, **PEAK INSP PRESSURE** and **INSPIRATORY TIME** should be adjusted to appropriate values. When the **MANUAL BREATH** button is engaged, the magnitude and duration of the mandatory breath are based on these settings.

WARNING

To verify that the audible/visual alarms for low oxygen and low air pressure operate, momentarily disconnect the gas sources. The alarms should activate and the alarm should silence when source pressure is reconnected. Failure to detect a source gas failure will change the FiO2 and may result in patient injury.

WARNING

An electric shock hazard exists when performing cleaning and maintenance procedures. Make sure the **VENTILATOR POWER** switch and the **CIRCUIT BREAKER** (MAINS/Battery Charger) are in the **OFF** position. If maintenance is required, refer the ventilator to qualified personnel for servicing.

WARNING

The use of some brands of breathing circuits and humidifier reservoirs may result in excessive resistance and an increase in inadvertent PEEP. Flow resistance and inadvertent PEEP are factors of the humidifier reservoir design, the internal diameter of the breathing circuit, length of the expiratory tubing, as well as the small internal orifice of the breathing circuit tubing connection at the patient wye. The supplied breathing circuit is designed to minimize flow resistance and inadvertent PEEP. Care must be taken when using other brands of breathing circuits.

WARNING

When operating the ventilator, the gas hoses should be connected directly to the hospital piping system or to a regulator attached to a high pressure cylinder. Do Not attach to a flowmeter or any other type of device that may restrict the gas flow to the ventilator. The restricted delivery system may activate **LOW AIR PRESSURE** and **LOW O_2 PRESSURE** alarms due to the drop in pressure below 45 psig (310 kPa) model 950 and pre 1996 model 500 or 35 psig (241 kPa) later model 500. Air and oxygen hoses are not interchangeable. Connections are Diameter Indexed Safety System (DISS) coded.

WARNING

The **REMOTE ALARM** connection provides an electrical contact to an external remote alarm. The adequacy and function of the **REMOTE ALARM** is not monitored by the ventilator. Malfunction or disconnection of the **REMOTE ALARM** does not activate the ventilator's **ALARM STATUS**.

WARNING

(220-240 volt units only)
This equipment should only be connected to an earth grounded outlet.

WARNING

(220-240 volt units only)
Anti-Static or electrically conductive hoses or tubing should not be used.

WARNING

Ventilator malfunction may occur when operated in the close vicinity to high frequency surgical (diathermy) equipment, defibrillators or short-wave therapy equipment.

CAUTION

Use only dry and clean compressed air. Water or debris in the air or oxygen supply can cause equipment malfunction.

CAUTION

Do Not spray any solutions directly on the ventilator. Do Not allow any liquid agent to penetrate to the inside of the ventilator.

CAUTION

If an external battery is being used and the voltage drops below 11.8 VDC, the internal battery will not recharge. Both the internal and external batteries will discharge simultaneously. The **EXT POWER LOSS** and **LOW BATTERY** alarms will activate when both batteries are near depletion.

CAUTION

Do Not gas or steam sterilize the ventilator. Damage to internal components could result.

NOTE: When the **PRESSURE RELIEF VALVE** is set at a pressure below the PIP setting, the **OBSTRUCTED TUBE** alarm may detect only situations resulting in elevated **PEEP/CPAP** or impeded exhalation following a mandatory breath. Refer to **OBSTRUCTED TUBE** alarm section for a more detailed explanation of HI CPP, A04 or HI PIP, A03.

NOTE: When storing the ventilator for prolonged periods of time, it is recommended that the unit be connected to an electrical outlet and the **CIRCUIT BREAKER** (MAINS/Battery Charger) be left in the **ON** (I) position in order to maintain the internal battery at peak charge. If the **CIRCUIT BREAKER** (MAINS/Battery Charger) switch is left in the **OFF** (O) position, the battery will not be charged even if the electrical cord is connected to an A/C power source. The **EXT POWER LOSS** LED will illuminate in the **ALARM STATUS** section of the front control panel only when the **VENTILATOR ON/OFF** switch is in the **ON** position.

NOTE: For convenience and safety, a minimum of two complete exhalation diaphragms and exhalation blocks per ventilator is recommended, so that one assembly may be in use while the second is being cleaned.

NOTE: Should a **VENTILATOR INOP** occur, an error message will appear in the **SELECTED DATA** display. Record the error code and all ventilator settings prior to turning the ventilator off. If the **VENTILATOR INOP** alarm activates again, the ventilator and current settings information should be referred to qualified personnel for servicing.

NOTE: When using extreme **PEAK INSP PRESSURE**, **INSPIRATORY TIME** or other control combinations, the **PROXIMAL AIRWAY PRESSURE** meter may not provide a precise measurement of pressure. Under these circumstances, the digital **PIP** display should be used exclusively.

NOTE: If the **ALARM SILENCE** is not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists. All alarms may be silenced with the exception of **VENTILATOR INOP** and **LOW BATTERY**.

NOTE: When removing and replacing the exhalation diaphragm, the ventilator should be turned off. If the ventilator is left on, gas flow to the diaphragm may hamper realignment.

NOTE: If the **LOW INSP PRESSURE** setting is fully counter-clockwise (3 cm H_2O) and **PEEP/CPAP** is higher, the alarm threshold will automatically track the **PEEP/CPAP**, using **PEEP/CPAP** as the minimum alarm set point.

NOTE: Each ventilator goes through an extensive run-in cycle, followed by calibration and a final performance check. It is normal for a new ventilator to have 100 or more hours on the **HOURS** meter.

NOTE: The **VENTILATOR RATE** display will flash if set rate is not being delivered. (see **INSUFFICIENT EXP TIME** alarm section).

NOTE: If during start up any number under 103 appears in the **SELECTED DATA** display, the software level should be updated. Call 1-800-NELLCOR.

NOTE: Changes in either **VENTILATOR RATE** or **INSPIRATORY TIME** will affect the **EXPIRATORY TIME**.

NOTE: P/N 4402024, 15 mm to 10 mm Adapter, may be used to connect the breathing circuit to the inlet ports on the humidifier chamber if the internal diameter of the inlet is a standard15 mm taper.

NOTE: For breath rates less than 100 BPM, minimum **EXPIRATORY TIME** is 0.3 seconds. For breath rates of 100 BPM and greater, minimum **EXPIRATORY TIME** is 0.2 seconds. These limits allow for inverse I:E ratios while maintaining sufficient expiratory times.

NOTE: The **LOW INSP PRESSURE** alarm setting must be adjusted to a setting below the **PEAK INSP PRESSURE** and **PRESSURE RELIEF VALVE** settings. Set the **LOW INSP PRESSURE** alarm to 3 to 5 cm H_2O below **PEAK INSP PRESSURE**, or as determined by hospital protocol.

NOTE: **PEAK INSP PRESSURE** should always be adjusted to a pressure at least 5 cm H_2O above the **PEEP/CPAP** setting. If the **PEAK INSP PRESSURE** is set to less than 5 cm H_2O above **PEEP/CPAP**, the **PIP** display will flash, informing the operator that the set PIP has been automatically adjusted to 5 cm H_2O above the set **PEEP/CPAP** to ensure minimum ventilation.

NOTE: The **DUR POS PRESS** display will flash when an incorrect measurement is recorded.

NOTE: During spontaneous ventilation, a low **BACKGROUND FLOW** may reduce inspiratory/expiratory work of breathing while minimizing inadvertent PEEP. With high mandatory breath rates, a **BACKGROUND FLOW** of 2 to 4 LPM provides a stable baseline without inadvertent **PEEP/CPAP**.

NOTE: The **REMOTE ALARM** connection is factory set in the "NORMALLY OPEN" position. If the **REMOTE ALARM** module used requires a "NORMALLY CLOSED position, please refer the ventilator to qualified personnel for servicing.

NOTE: In order to ensure patient safety, the maximum **HIGH INSP PRESSURE** alarm is 15 cm H_2O above **PEAK INSP PRESSURE**. Should the operator set the **HIGH INSP PRESSURE** alarm more than 15 cm H_2O above the **PEAK INSP PRESSURE**, the alarm display will flash and the microprocessor will automatically set the **HIGH INSP PRESSURE** alarm at **PIP** + 15 cm H_2O.

NOTE: **BACKGROUND FLOW** can not be set higher than **FLOW RATE**. However, if the **BACKGROUND FLOW** is set beyond this limit, an increase in **FLOW RATE** may result in an increase in the **BACKGROUND FLOW**. Subsequently, a decrease in **FLOW RATE** may result in a decrease in the **BACKGROUND FLOW**, because the **BACKGROUND FLOW** can not be set higher than the **FLOW RATE**.

NOTE: The exhalation diaphragm is manufactured with a small nipple in the center on one side of the diaphragm. This nipple must be facing out to ensure proper ventilator operation.

NOTE: The use of heating wires does not ensure water condensation will not occur. There are many factors which will influence humidity delivered to the patient as well as water condensation within the inspiratory/expiratory limbs of the patient circuit, and exhalation valve. Some of these factors are:

The humidifier used; adjustment of humidifier temperature and relative humidity settings; usage of single wire, dual wire or no-wire patient circuits; ventilator **FLOW RATE** and tubing length; external environmental conditions such as room temperature, direct sunlight and cold drafts of air, etc.

The clinician should closely monitor the interrelationship between the humidifier, ventilator and patient circuit to ensure adequate humidification with minimum condensation.

NOTE: Leave the **HFV ON/OFF** key switch in the **OFF** position for conventional ventlation to avoid inadvertent activation of HFV modes.

SECTION 1

UNPACKING / ASSEMBLY INSTRUCTIONS

Unpacking

Before unpacking the Infant *Star* inspect the shipping container for any signs of damage.

Remove the ventilator and pedestal stand, or *Star* Cart, from the shipping containers. Inspect for damage that may have occurred during shipment.

Assembly

The Infant *Star* 500 and 950 are designed to be mounted on either a pedestal stand or the *Star* Cart. If the unit requires frequent moving, it is highly recommended that a *Star* Cart be the preferred stand. Follow the appropriate assembly instructions below for the specific product.

NOTE: Each ventilator goes through an extensive run-in cycle, followed by calibration and a final performance check. It is normal for a new ventilator to have 100 or more hours on the **HOURS** meter.

PEDESTAL

1. Insert the pole with the bolt end of the column passing through bottom of the pedestal. Position washer and nut, tightening securely (see Illustration 1).
2. Place the stand assembly upright on a flat area.
3. Carefully align the ventilator recess with the top of the pole.
4. Tighten the anti-swivel device to prevent uncontrolled rotation of the ventilator on the pedestal.
5. Mount an appropriate neonatal/pediatric humidifier to the pedestal directly below the ventilator.
6. Connect the patient breathing circuit.
7. Attach the high pressure hoses to the air and oxygen inlets. Tighten securely to prevent leakage.

WARNING

When operating the ventilator, the gas hoses should be connected directly to the hospital piping system or to a regulator attached to a high pressure cylinder. Do Not attach to a flowmeter or any other type of device that may restrict the gas flow to the ventilator. The restricted delivery system may activate **LOW AIR PRESSURE** and **LOW O_2 PRESSURE** alarms due to the drop in pressure below 45 psig (310 kPa) model 950 and pre 1996 model 500 or 35 psig (241 kPa) later model 500. Air and oxygen hoses are not interchangeable. Connections are Diameter Indexed Safety System (DISS) coded.

STAR CART

1. Lock the two front wheels to prevent the *Star* Cart from moving.
2. Insert the 6.5 inch pole into the hole on the top of the *Star* Cart with the threaded hole down. Insert the supplied bolt through the platform into the pole and tighten securely.
3. Install the Infant *Star* on top of the *Star* Cart by sliding the socket on the bottom of the ventilator onto the top pole.
4. Place the supplied basket on the cross bar.
5. Mount an appropriate neonatal/pediatric humidifier to the pole below the platform.
6. Connect the patient breathing circuit.
7. Attach the high pressure hoses to the air and oxygen inlets. Tighten securely to prevent leakage.

WARNING

When operating the ventilator, the gas hoses should be connected directly to the hospital piping system or to a regulator attached to a high pressure cylinder. Do Not attach to a flowmeter or any other type of device that may restrict the gas flow to the ventilator. The restricted delivery system may activate **LOW AIR PRESSURE** and **LOW O_2 PRESSURE** alarms due to the drop in pressure below 45 psig (310 kPa) model 950 and pre 1996 model 500 or 35 psig (241 kPa) later model 500. Air and oxygen hoses are not interchangeable. Connections are Diameter Indexed Safety System (DISS) coded.

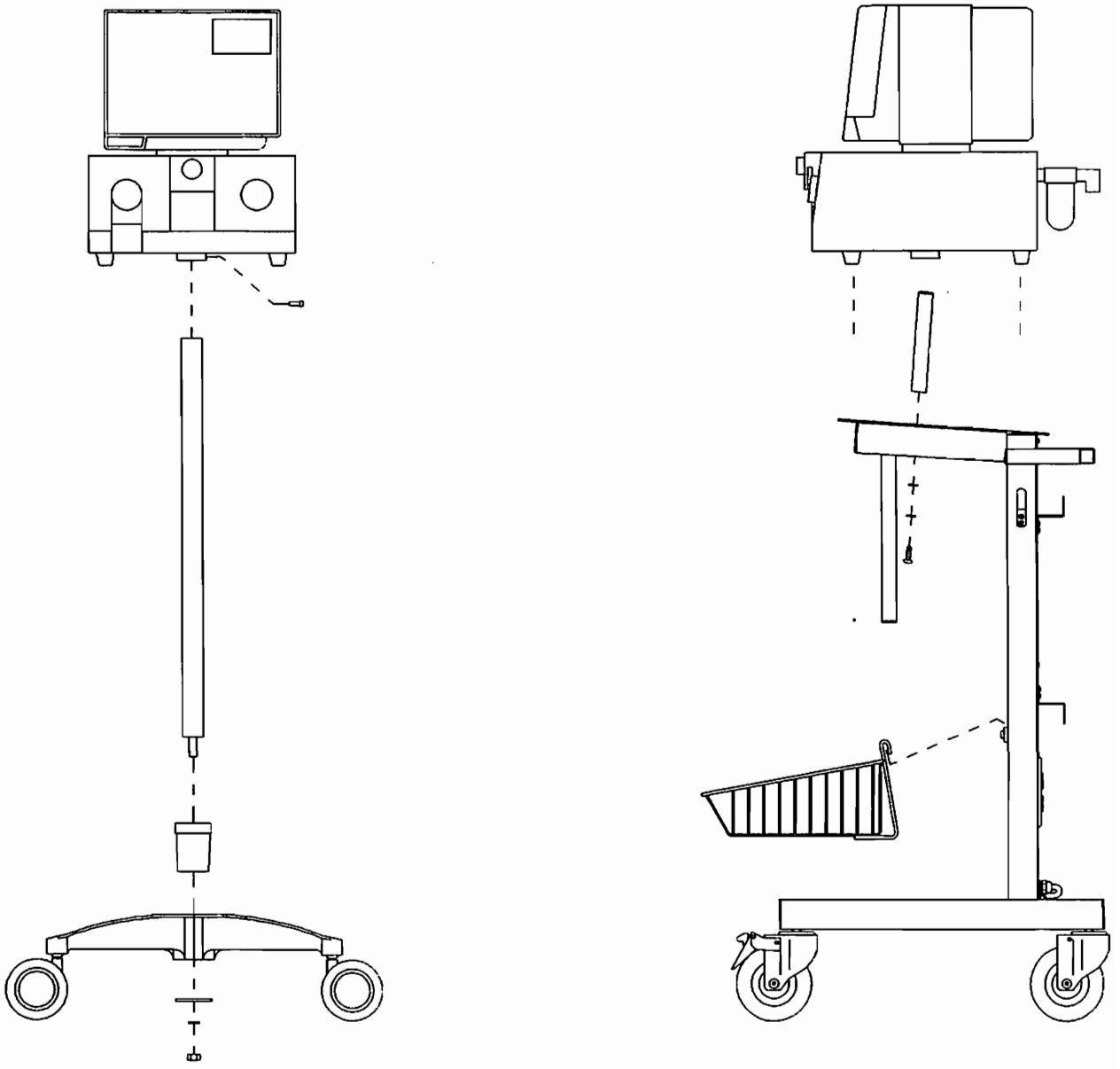


Illustration 1 - Pedestal/*Star* Cart Assembly

SECTION 2

INTRODUCTION AND SYSTEM DESCRIPTION

The Infant *Star* 500 and 950 are time cycled, pressure limited, continuous flow ventilators, offering adjustable **BACKGROUND FLOW** in the **CPAP** and **IMV** modes. Operation in the **CPAP** and **IMV** modes is identical in the 500 and 950. Operational instructions specific to the high frequency modes of the 950 (**HFV ONLY** and **HFV + IMV**) are contained in the latter sections of this manual. The Infant *Star* is designed to provide continuous ventilatory support for neonatal and pediatric patients less than 40 lbs. (18 kg), with an adjustable **FLOW RATE** range of 4 to 40 liters per minute (LPM), and **BACKGROUND FLOW** range of 2 to 30 LPM (2 to 32 LPM software versions 107 and above).

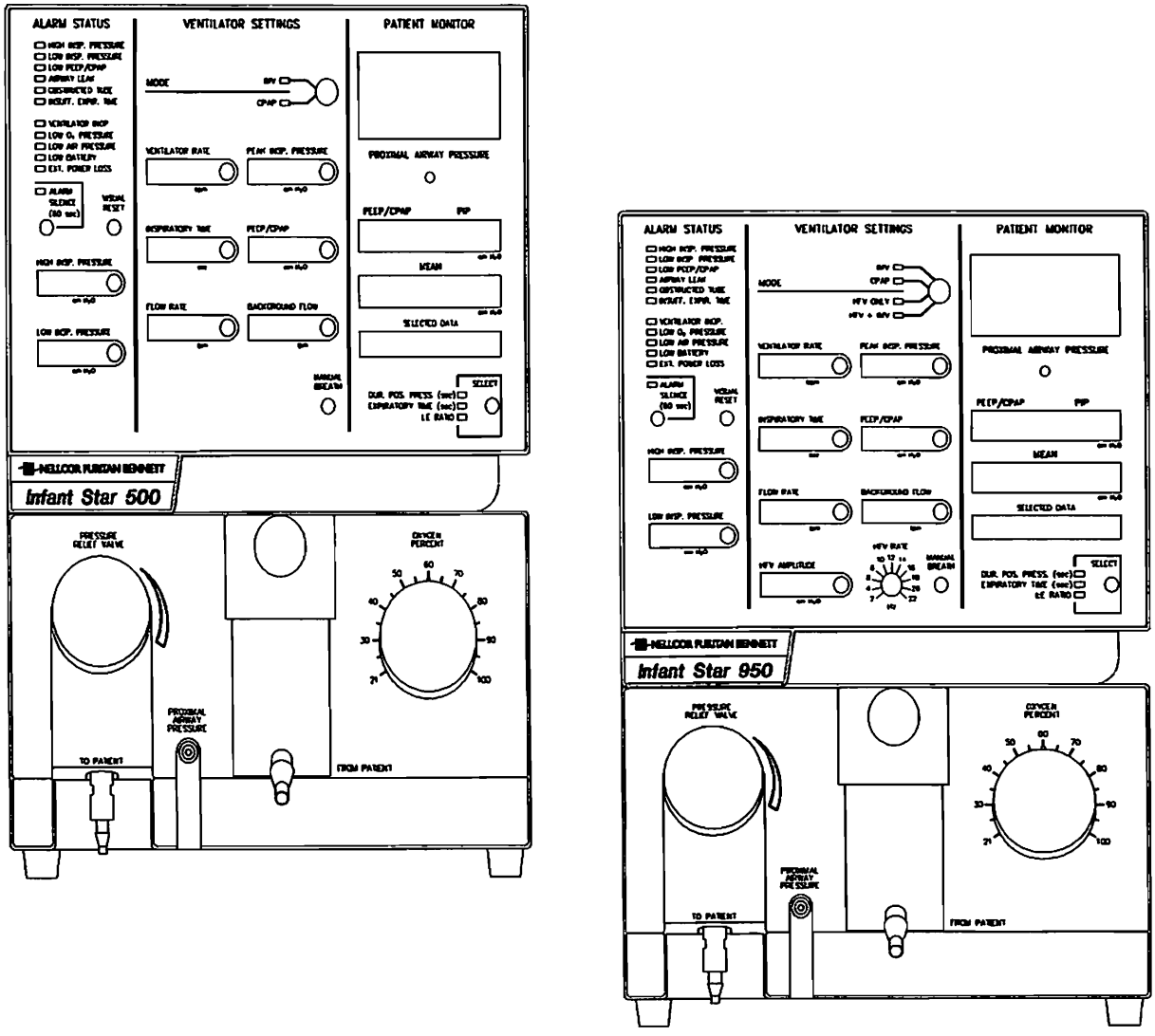


Illustration 2 - Infant *Star* Ventilators 500 and 950

Dual microprocessors are used to control ventilator functions. The first microprocessor controls the ventilator operation, while the second provides display information. The use of two microprocessors provides an additional margin of operational safety since continual operational checks are being run between the two microprocessors. If during one of these checks either microprocessor detects a malfunction, the **VENTILATOR INOP** alarm activates an audible, visual alarm and vents the breathing circuit to atmosphere.

Comprehensive monitoring and alarm systems alert the operator to problems and patient ventilation changes as they occur.

WARNING

Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons:

a. Some malfunctions require immediate corrective action.

b. An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.

To facilitate patient connection while maximizing visibility of displays, the upper and lower portions of the ventilator rotate 270 degrees independently.

The front panel layout is grouped into three logical use sections to minimize confusion and simplify operator training. (1) the **ALARM STATUS** section with individual red LEDs to show specific alarm conditions; (2) **VENTILATOR SETTINGS** with numerical displays in green; and (3) **PATIENT MONITORING** parameters with displays in amber.

The microprocessors continually monitor the operator set **PEEP/CPAP** level and activate a jet venturi in the exhalation block to automatically compensate for inadvertent **PEEP/CPAP**. The **PEEP/CPAP** level remains constant, regardless of changes made in other ventilator parameters.

To reduce unnecessary waste of oxygen and air, a unique blender calibrated from 21 to 100% reduces gas waste. The Infant *Star* directs high flows of mixed gas into a storage system and an electronic snap-acting regulator turns the blender on and off, ensuring accuracy without waste. Air and oxygen water trap filters, with 5 micron elements, are provided to prevent water and debris from entering the ventilator.

To ensure uninterrupted ventilation during periods of brownout or electrical failure, as well as to facilitate transport, the ventilator includes an automatic recharging, self-contained battery. The internal gel cell battery powers the electronics at all times, while the electrical connection at the wall recharges the battery during ventilator operation or storage.

NOTE: When storing the ventilator for prolonged periods of time, it is recommended that the unit be connected to an electrical outlet and the **CIRCUIT BREAKER** (MAINS/Battery Charger) be left in the **ON** (I) position in order to maintain the internal battery at peak charge. If the **CIRCUIT BREAKER** (MAINS/Battery Charger) switch is left in the **OFF** (O) position, the battery will not be charged even if the electrical cord is connected to an A/C power source. The **EXT POWER LOSS** LED will illuminate in the **ALARM STATUS** section of the front control panel only when the **VENTILATOR ON/OFF** switch is in the **ON** position.

The ventilator includes an RS-232 computer interface or cardiac monitor connection. When connected to a personal computer, it can allow ventilator information to be collected, reviewed and displayed in trend or numerical form. By attaching a printer, written records can be output.

A second output connection allows a strip chart recorder to produce analog pressure waveforms. Both monitoring outputs increase clinician information, as well as providing permanent records.

During clinical use, a variety of conditions may be experienced. Refer to the Clinical Trouble-shooting Chart, Section 8.

An important aspect of the microprocessor controlled design is to not only ensure meeting today's clinical requirements, but also to allow quick installation of future enhancements. Microprocessor software is contained in erasable, programmable read-only-memory ICs (EPROMs). As new features are proven to be desirable, they will be offered as software updates and the revised EPROMs easily installed in the hospital, thus expanding versatility while reducing premature clinical obsolescence.

Upon power up, the Infant *Star* briefly displays the software level in the **SELECTED DATA** display on the lower right side of the front panel.

NOTE: If during start up any number under 103 appears in the **SELECTED DATA** display, the software level should be updated. Call 1-800-NELLCOR.

SYSTEM SPECIFICATIONS

CONTROL OR PARAMETER	RANGE
Front Control Panel	
ALARMS	
High Insp Pressure	5 to 105 cm H_2O
Low Insp Pressure	3 to 60 cm H_2O
Low PEEP/CPAP	This alarm activates when the 25 second average proximal pressure drops below the
For PEEP/CPAP setting (cm H_2O)	PEEP/CPAP settings by
0 to 5	2
6 to 8	3
9 to 12	4
13 to 24	5
Airway Leak	Leak makeup flow exceeds BACKGROUND FLOW by 13 LPM for 4 seconds
Obstructed Tube	Detects any problems that cause: PROXIMAL PRESSURE to rise above set HIP by 5 cm H_2O Prolonged or impeded exhalation PEEP/CPAP pressure risen above the set point by 6 cm H_2O in 5 second average Intenal pressure above set HIP by 10 cm H_2O
Insufficient Exp. Time	0.3 secs at rates < 100 breaths/min 0.2 secs. At rates $\geq$ 100 breaths/min
Ventilator Inop	System malfunction or fully depleted internal battery
Low O_2 Pressure	ISV 950 & pre-1996 ISV 500 < 45 psig (310 kPa) ISV 500 (after 1/96) < 35 psig (241 kPa)
Low Air Pressure	ISV 950 & pre-1996 ISV 500 < 45 psig (310 kPa) ISV 500 (after 1/96) < 35 psig (241 kPa)
Low Battery	Activates 5 to 10 minutes prior to full battery discharge

CONTROL OR PARAMETER (cont.)	RANGE (cont.)
ALARMS cont.	
Ext Power Loss	A/C power source disconnection. Battery life of 30 minutes minimum (assuming reasonable battery condition and charge)
Alarm Silence	60 seconds
Visual Reset	Push to clear alarm indicators (except EXT POWER LOSS, LOW BATTERY and VENTILATOR INOP)
VENTILATOR SETTINGS	
Mode	IMV and CPAP
	(950 only) HFV ONLY and HFV + IMV
Ventilator Rate	1 to 150 per minute
Peak Insp Pressure	5 to 90 cm H_2O
Inspiratory Time	0.1 to 3.0 secs.
PEEP/CPAP	0 to 24 cm H_2O
Flow Rate	4 to 40 LPM
Background Flow	2 to 30 LPM 2 to 32 LPM- Software version 107 and above
High Insp Pressure Alarm	5 to 105 cm H_2O
Low Insp Pressure Alarm	3 to 60 cm H_2O
Manual Breath	Delivers single controlled mandatory breath
HFV Rate (950 only)	2 to 22 Hz
HFV Amplitude (950 only)	Varies pulse flow from 12 to 120 LPM
PATIENT MONITOR	
Proximal Airway Pressure	-10 to 120 cm H_2O
Proximal PEEP/CPAP	-9 to 99 cm H_2O

CONTROL OR PARAMETER (cont.)	RANGE (cont.)
Peak Insp Pressure (PIP)	0 to 110 cm H_2O
Proximal Mean	-9.9 to 99.9 cm H_2O
Selected Data	Push button control allows a single display to be used for multiple measurements
Dur Pos Press	0.02 to 5.0 secs.
Expiration Time	0.2 to 59.9 secs.
I:E Ratio	1:0.1 to 1:99.9
HFV Amplitude (950 only)	0 to 160 cm H_2O - Maximum amplitude will vary based on ventilator settings, infant's size and compliance, breathing circuit configuration, humidifier chamber resistance and compressible volume, endotracheal tube diameter etc.
Lower Section	
PRESSURE RELIEF VALVE	5 to 120 cm H_2O
Exhalation Block	Houses exhalation valve diaphragm and jet venturi
OXYGEN PERCENT	21 to 100%
Rear Control Panel	
Alarm	72 to 88 decibels
Hours (elapsed hours meter)	0.0 to 99999.9 hours
To *Star* Sync	9-pin DIN connector
A/C Circuit Breaker	100V - 2.0 amps
MAINS/Battery Charger	115V - 1.2 amps 220V - 0.6 amps
D/C Circuit Breaker	12V - 8.0 amps
12 VDC Input	11.8V to 18 volt @ 5 amp battery power source
ON/OFF Switch	Turns ventilator ON and OFF
RS-232 Serial Output Connection	Baud rate: 1200
Analog Pressure Output	10 millivolts/cm H_2O - 0.1 to 1.2 volts
Remote Alarm Connection	30V - 0.5 amps
HFV ON/OFF (950 only)	Switch (keyed) disables HFV mode when OFF

CONTROL OR PARAMETER (cont.)	RANGE (cont.)
Inputs	
Electrical - Nominal	
100V	90 - 105 VAC, 50/60 Hz, 100 watts
115V	105 - 123 VAC, 50/60 Hz, 100 watts
220-240V	198 - 264 VAC, 50/60 Hz, 100 watts (as specified on electrical label attached to ventilator)
Pneumatic - Air and Oxygen	ISV 950 & pre-1996 ISV 500, 45 to 90 psig (310 to 621 kPa) ISV 500 (after 1/96) 35 to 90 psig (241 to 621 kPa)
Physical Characteristics	
Ventilator	16.25" high x 11.25" wide x 19.25" deep (41 cm x 29 cm x 49 cm)
Weight	50 lbs. (23 kg.) (does not include pedestal stand or cart)
Star Cart	39" high (99 cm) x 17" wide (64 cm)
Temperature	Storage: 0 to 150° F (-17 to 66° C)
	Operating: 55 to 90° F (13 to 32° C)
Shipping Characteristics	
Ventilator	20.25" high x 24.25" wide x 19.25" deep (51 cm x 62 cm x 49 cm)
Weight	61.5 lbs. (28 kg.)
Star Cart	44" high x 24" wide x 20" deep (112 cm x 61 cm x 51 cm)
Weight	50 lbs. (23 kg.)

Specifications are subject to change without notice.

SECTION 3

FUNCTIONAL DESCRIPTION

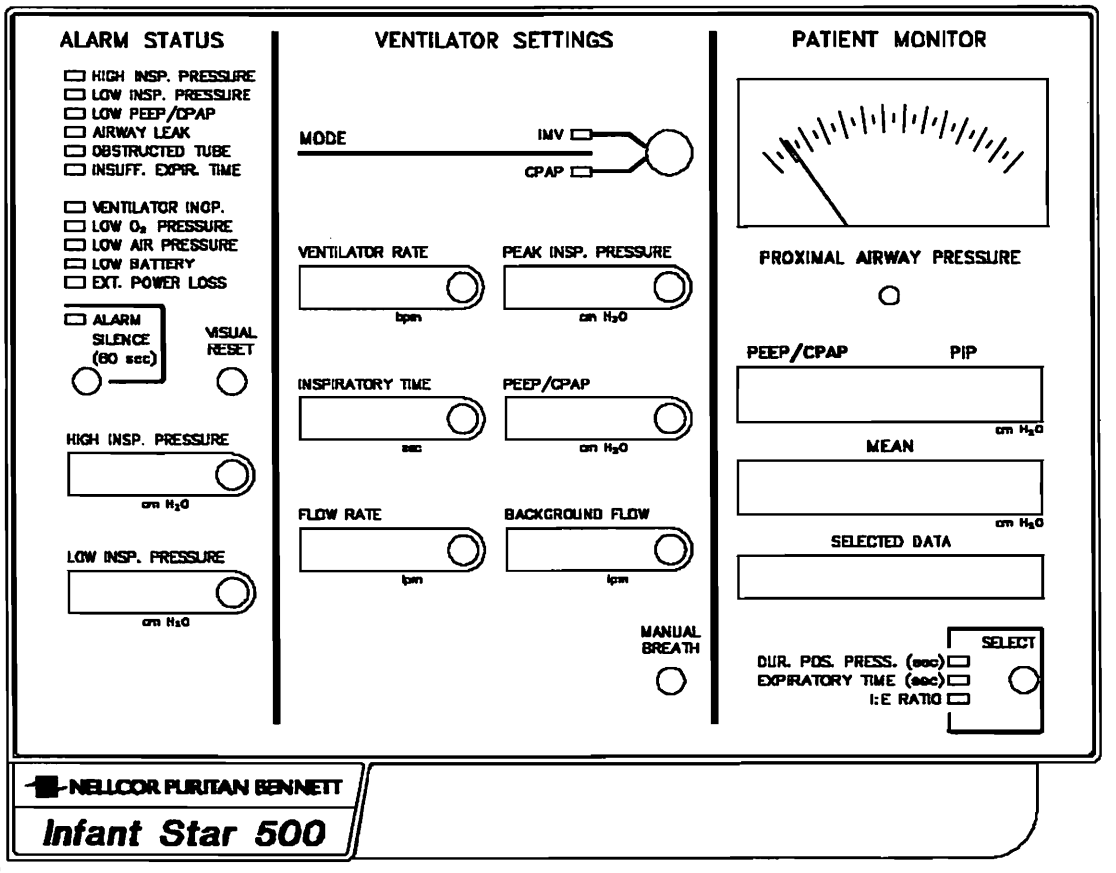


Illustration 3 - Front of Electronic Module

ALARMS

HIGH INSP PRESSURE (High Inspiratory Pressure)

Adjustable Range 5 to 105 cm H_2O

Establishes the amount the **PIP** may be exceeded before producing an alarm condition. If the established pressure limit is exceeded, the ventilator will immediately open the exhalation valve, stop the flow delivery, activate the audible alarm, illuminate the **HIGH INSP PRESSURE** LED and display HI PIP, A01 in the **PEEP/CPAP**, **PIP** and **SELECTED DATA** displays.

NOTE: In order to ensure patient safety, the maximum **HIGH INSP PRESSURE** alarm is 15 cm H_2O above **PEAK INSP PRESSURE**. Should the operator set the **HIGH INSP PRESSURE** alarm more than 15 cm H_2O above the **PEAK INSP PRESSURE**, the alarm display will flash and the microprocessor will automatically set the **HIGH INSP PRESSURE** alarm at **PIP** + 15 cm H_2O.

LOW INSP PRESSURE (Low Inspiratory Pressure)

Adjustable range above baseline 3 to 60 cm H_2O, but not lower than **PEEP/CPAP**.

Establishes the minimum pressure that must be reached during the inspiratory portion of the mandatory breath. If the minimum pressure is not achieved, the **LOW INSP PRESSURE** alarm is activated. Activation may be caused by a breathing circuit leak, inappropriate control settings, or an incorrect **PRESSURE RELIEF VALVE** setting.

Major changes in the **FLOW RATE** and **INSPIRATORY TIME** may affect **PIP** and may cause the **LOW INSP PRESSURE** alarm to activate.

WARNING

Failure to properly set the LOW INSP PRESSURE alarm may result in failure to detect an inadequate mandatory breath or a leak in the breathing circuit.

NOTE: If the **LOW INSP PRESSURE** setting is fully counter-clockwise (3 cm H_2O) and **PEEP/CPAP** is higher, the alarm threshold will automatically track the **PEEP/CPAP**, using **PEEP/CPAP** as the minimum alarm set point.

NOTE: The **LOW INSP PRESSURE** alarm setting must be adjusted to a setting below the **PEAK INSP PRESSURE** and **PRESSURE RELIEF VALVE** settings. Set the **LOW INSP PRESSURE** alarm to 3 to 5 cm H_2O below **PEAK INSP PRESSURE**, or as determined by hospital protocol.

LOW PEEP/CPAP

Automatic adjustment of the alarm threshold is done by the microprocessor, based on the operator adjusted **PEEP/CPAP** setting. The relationship is as follows:

PEEP/CPAP setting display (cm H_2O)	Pressure difference between setting and actual required to activate alarm (cm H_2O)
0 to 5	2
6 to 8	3
9 to 12	4
13 to 24	5

The alarm activates if actual (25 second average) **PEEP/CPAP** drops below the threshold. A "LO CPP" message appears in the **PEEP/CPAP** and **PIP** display windows.

WARNING

The **LOW PEEP/CPAP** alarm does not detect all tubing disconnections or changes in the **PEEP/CPAP** level. Although the **LOW PEEP/CPAP** alarm will detect a breathing circuit disconnection or wye to endotracheal tube adapter disconnection, when set at 2 cm H_2O **PEEP/CPAP** or greater, it may not alarm in the presence of a patient extubation. The endotracheal tube or nasal CPAP prongs may produce sufficient back pressure so that the alarm threshold is not reached.

AIRWAY LEAK

The alarm detects gross leaks in the patient circuit connections for **PEEP/CPAP** settings of 3 cm H_2O or greater. This alarm is most likely to occur when low **BACKGROUND FLOW** rates are used and is activated when leak makeup exceeds **BACKGROUND FLOW** by 13 LPM for 4 seconds or longer.

OBSTRUCTED TUBE

Detects any problems that cause:

1. Pressure at the airway to rise 5 cm H_2O above the set **HIGH INSP PRESSURE** setting.
2. **PEEP/CPAP** pressure to rise above the set point.
3. Interference with exhalation.
4. Pressure reading inside the ventilator to rise 10 cm H_2O higher than the **HIGH INSP PRESSURE** setting.

These alarms are automatically established by the microprocessor based on the **HIGH INSP PRESSURE** (HIP) alarm setting. An audible and visual alarm activates and a message is displayed in the **SELECTED DATA** display identifying the problem. To ensure patient protection against excessive pressure, two pressure transducers detect pressure while the exhalation valve and/or the internal safety valve are used to relieve airway pressure when excessive pressure is detected.

The following table describes the four **OBSTRUCTED TUBE** alarms:

DISPLAY	MEANING	ALARMS
1. HI PIP, A02	HIP + 5 cm H_2O	Audible/Visual
2. HI PIP, A03	Less than a 50% pressure drop from **PIP** to **PEEP** in the minimum **EXPIRATORY TIME**	Audible/Visual
3. HI CPP, A04	**PEEP/CPAP** + 6 cm H_2O for 5 second average	Audible/Visual
4. HI PIP, A05	HIP + 10 cm H_2O detected at **TO PATIENT** outlet	Audible/Visual

INSUFFICIENT EXP TIME (Insufficient Expiratory Time)

The alarm activates when the **VENTILATOR RATE** and **INSPIRATORY TIME** settings are incompatible and result in an **EXPIRATORY TIME** shorter than the minimum allowed.

The minimum **EXPIRATORY TIME** for breath rates up to 100 BPM is 0.3 seconds and for breath rates of 100 BPM and greater, is 0.2 seconds.

Should an **INSUFFICIENT EXP TIME** alarm occur, the ventilator automatically decreases the **VENTILATOR RATE** to ensure that the minimum **EXPIRATORY TIME** is maintained, and the **VENTILATOR RATE** display will flash, indicating the set rate is not being delivered.

VENTILATOR INOP (Ventilator Inoperative)

Activates when the microprocessor detects an error in the electronics. The ventilator stops mandatory breath delivery, stops gas flow, and opens the internal safety valve, venting **PROXIMAL AIRWAY PRESSURE** to ambient, and allowing the patient to breathe spontaneously. This alarm can not be silenced by the **ALARM SILENCE**.

Specific error codes will be displayed in the **SELECTED DATA** display assisting the operator in diagnosing the problem.

A complete listing of error codes may be found in the Infant *Star* 500/950 Service Manual, P/N 9910913.

WARNING

If the **VENTILATOR INOP** alarm activates, gas flow to the patient is stopped and the patient airway is vented to the room air. An alternate source of patient ventilation must be immediately provided.

NOTE: Should a **VENTILATOR INOP** occur, an error message will appear in the **SELECTED DATA** display. Record the error code and all ventilator settings prior to turning the ventilator off. If the **VENTILATOR INOP** alarm activates again, the ventilator and current settings information should be referred to qualified personnel for servicing.

LOW O_2 PRESSURE

Activation of this alarm occurs when the oxygen gas source drops below 35 psig (241 kPa) or 45 psig (310 kPa) depending on the model (see system specifications page 15).

If O_2 inlet pressure drops, the ventilator will continue operating with 21% O_2. For set **OXYGEN PERCENT** greater than 80, the ventilator performance may be compromised.

LOW AIR PRESSURE

Activation of this alarm occurs when the oxygen gas source drops below 35 psig (241 kPa) or 45 psig (310 kPa) depending on the model (see system specifications page 15). If air inlet pressure drops, the ventilator will continue operating at 100% O_2. For set **OXYGEN PERCENT** less than 30, the ventilator performance may be compromised.

WARNING

To verify accuracy of the oxygen delivery system and ensure patient safety at all times, an oxygen monitor should be connected in the tubing between the ventilator and the humidifier. Incorrect FiO2 may result in patient injury.

LOW BATTERY

During interruption of electrical wall power or when operating on internal battery power, the ventilator warns the operator 5 to 10 minutes prior to full battery discharge by alternately flashing the **EXT POWER LOSS** and **LOW BATTERY** indicators and activating the audible alarm. This alarm <u>can not</u> be silenced by the **ALARM SILENCE**.

When the battery becomes fully discharged, the **VENTILATOR INOP** and **LOW BATTERY** indicators activate and an audible alarm sounds. The ventilator stops mandatory breath delivery, stops gas flow, and opens the internal safety valve, venting **PROXIMAL AIRWAY PRESSURE** to ambient, allowing the patient to breathe spontaneously.

EXT POWER LOSS (External Power Loss)

Illuminates whenever electrical power is interrupted. The unit will continue to operate on the internal battery and will provide, at a minimum, thirty minutes of continued operation. The internal battery, when fully discharged, can be fully recharged in about 1 hour with the ventilator **OFF** and in 1-1/2 hours with the ventilator **ON**.

ALARM SILENCE

Silences the audible portion of alarm for 60 seconds. The LED above the **ALARM SILENCE** will be illuminated when active. If **ALARM SILENCE** is depressed a second time and the alarm is still active, the audible alarm will sound immediately. After 24 hours of continuous use of the ventilator, the activation of the **ALARM SILENCE** initiates the pressure transducer to re-zero.

WARNING

The **ALARM SILENCE** is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

NOTE: If the **ALARM SILENCE** is not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists. All alarms may be silenced with the exception of **VENTILATOR INOP** and **LOW BATTERY**.

VISUAL RESET

If an alarm condition self-corrects, the audible portion of the alarm system automatically silences, but the visual alarm remains illuminated to identify the alarm. Depress the **VISUAL RESET** to reset the LEDs.

VENTILATOR SETTINGS

Modes of Ventilation:

IMV (Intermittent Mandatory Ventilation)

The **VENTILATOR RATE** establishes the number of mandatory breaths to be initiated. The **INSPIRATORY TIME** sets the duration of the breath, and the **FLOW RATE** establishes the inspiratory pressure slope of the mandatory breath. The **BACKGROUND FLOW** establishes the initial flow occurring during exhalation, as well as the flow available for spontaneous breathing. If the patient's spontaneous breathing exceeds the available flow and the baseline pressure is decreased by 1 cm H_2O, the demand system will automatically supply additional flow up to 40 LPM. The **PEEP/CPAP** setting adjusts the baseline pressure.

CPAP (Continuous Positive Airway Pressure)

The **BACKGROUND FLOW** establishes the background continuous flow available for spontaneous breathing, while the **PEEP/CPAP** adjusts the baseline pressure. If the patient's spontaneous breathing exceeds the available flow and the baseline pressure is decreased by 1 cm H_2O, the demand system will automatically supply additional flow up to 40 LPM.

HFV ONLY and HFV + IMV (950 only)

Refer to sections 10-17 of this manual for HFV Operating Instructions.

VENTILATOR RATE

Adjustable Range 1 to 150 BPM

Establishes and adjusts the mandatory breath rates in:

One breath increments from 1 to 60
Two breath increments from 60 to 130
Five breath increments from 130 to 150

NOTE: The **VENTILATOR RATE** display will flash if set rate is not being delivered. (see **INSUFFICIENT EXP TIME** alarm section).

PEAK INSP PRESSURE (Peak Inspiratory Pressure)

Adjustable Range 5 to 90 cm H_2O

Establishes the maximum pressure to be delivered during the mandatory breath. As the pressure approaches the **PEAK INSP PRESSURE**, gas flow is slowed and then stopped. During pressure plateau, the ventilator adds intermittent flow as needed to compensate for leaks around the endotracheal tube or for spontaneous breathing.

NOTE: **PEAK INSP PRESSURE** should always be adjusted to a pressure at least 5 cm H_2O above the **PEEP/CPAP** setting. If the **PEAK INSP PRESSURE** is set to less than 5 cm H_2O above **PEEP/CPAP**, the **PIP** display will flash, informing the operator that the set PIP has been automatically adjusted to 5 cm H_2O above the set **PEEP/CPAP** to ensure minimum ventilation.

INSPIRATORY TIME

Adjustable Range 0.1 to 3.0 seconds

Establishes the time duration of the inspiratory portion of the mandatory breath. Setting increments are:

0.01 secs. for settings from 0.10 to 0.60 secs.
0.02 secs. for settings from 0.60 to 1.0 secs.
0.1 secs. for settings from 1.0 to 3.0 secs.

WARNING

Adjustment of the **PEAK INSP PRESSURE**, **INSPIRATORY TIME** and **FLOW RATE** affects the volume delivered to the patient. Carefully monitor this interrelationship.

NOTE: When using extreme **PEAK INSP PRESSURE**, **INSPIRATORY TIME** or other control combinations, the **PROXIMAL AIRWAY PRESSURE** meter may not provide a precise measurement of pressure. Under these circumstances, the digital **PIP** display should be used exclusively.

PEEP/CPAP

Adjustable Range 0 to 24 cm H_2O

Establishes the baseline pressure. Once the **PEEP/CPAP** pressure has been set, the proximal pressure transducer monitors the pressure and provides information to the microprocessor to increase or decrease pressure in the breathing circuit. Following a suction procedure, or after

extreme changes in control settings, the stabilization of **PEEP/CPAP** pressure is normally accomplished within 30 seconds. During this brief interval, it is not uncommon to see pressures 2 to 3 cm H_2O above or below the **PEEP/CPAP** setting.

WARNING

When using the **CPAP MODE** of ventilation, the **FLOW RATE**, **PEAK INSP PRESSURE** and **INSPIRATORY TIME** should be adjusted to appropriate values. When the **MANUAL BREATH** button is engaged, the magnitude and duration of the mandatory breath are based on these settings.

WARNING

Never use the **PRESSURE RELIEF VALVE** to establish the **PEEP/CPAP** level. Always adjust the **PRESSURE RELIEF VALVE** to a pressure setting in excess of 6 cm H_2O above the **PEEP/CPAP** level to assure that fresh gas reaches the patients' airway.

FLOW RATE

Adjustable Range 4 to 40 LPM

Adjustable in 2 LPM increments in both the **CPAP MODE** and the **IMV MODE**. Shapes the inspiratory pressure slope of the mandatory breath.

BACKGROUND FLOW

Adjustable Range 2 to 30 LPM - software version 107 and above 2 to 32 LPM.

Adjustable in 2 LPM increments in both the **CPAP MODE** and the **IMV MODE**. This flow provides the initial **BACKGROUND FLOW** available for spontaneous breathing. If the patient's spontaneous breathing exceeds the available flow and the baseline pressure is decreased by 1 cm H_2O, the demand system will automatically supply additional flow up to 40 LPM.

NOTE: During spontaneous ventilation, a low **BACKGROUND FLOW** may reduce inspiratory/expiratory work of breathing while minimizing inadvertent PEEP. With high mandatory breath rates, a **BACKGROUND FLOW** of 2 to 4 LPM provides a stable baseline without inadvertent **PEEP/CPAP**.

NOTE: **BACKGROUND FLOW** can not be set higher than **FLOW RATE**. However, if the **BACKGROUND FLOW** is set beyond this limit, an increase in **FLOW RATE** may result in an increase in the **BACKGROUND FLOW**. Subsequently, a decrease in **FLOW RATE** may result in a decrease in the **BACKGROUND FLOW**, because the **BACKGROUND FLOW** can not be set higher than the **FLOW RATE**.

MANUAL BREATH

Delivers one controlled mandatory breath in both modes of ventilation. Push and release the button for each additional breath.

WARNING

When using the CPAP MODE of ventilation, the FLOW RATE, PEAK INSP PRESSURE and INSPIRATORY TIME should be adjusted to appropriate values. When the MANUAL BREATH button is engaged, the magnitude and duration of the mandatory breath are based on these settings.

PATIENT MONITOR

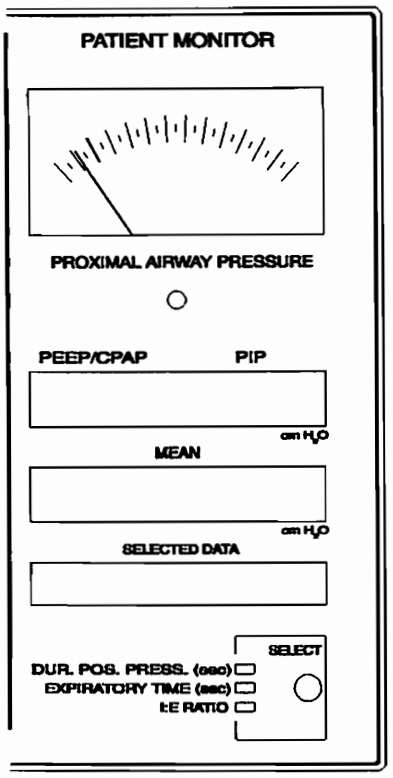


Illustration 4 - Patient Monitor Section

All pressures are measured at the patient airway through the proximal pressure tube. Actual values are displayed on the **PROXIMAL AIRWAY PRESSURE** meter as well as in their respective digital pressure displays.

PEEP/CPAP

Range 0 to 24 cm H_2O

This display shows digital values of the monitored **PEEP/CPAP** pressure. A five second moving average is used to calculate **PEEP/CPAP**. The **PEEP/CPAP** airway pressure is sampled every 10 milliseconds and updated every 200 milliseconds.

PIP (Peak Inspiratory Pressure)

Range 0 to 110 cm H_2O

The display shows the maximum pressure reached during each mandatory breath and is updated breath-by-breath.

MEAN (Mean Airway Pressure)

Range -9.9 to 99.9 cm H_2O

The display provides an average of proximal pressures for the past 30 seconds. Airway pressure is sampled every 5 milliseconds and the display is updated every 200 milliseconds.

SELECTED DATA

Pressing the **SELECT** button allows display of:

DUR POS PRESS (Duration of Positive Pressure)

Range 0.02 to 5.0 seconds

DUR POS PRESS measures the time duration that the **PROXIMAL AIRWAY PRESSURE** exceeds 1 cm H_2O above proximal baseline pressure during a mandatory breath.

NOTE: The **DUR POS PRESS** display will flash when an incorrect measurement is recorded.

EXPIRATION TIME

Range 0.2 to 59.9 seconds

This display shows the time period in seconds for expiration during mandatory breaths.

NOTE: Changes in either **VENTILATOR RATE** or **INSPIRATORY TIME** will affect the **EXPIRATORY TIME**.

I:E RATIO

Range 1:0.1 to 1:99.9

This display provides the calculated relationship of the duration of inspiration to the duration of expiration during a mandatory breath.

$$1 : \frac{\text{EXPIRATORY TIME}}{\text{INSPIRATORY TIME}}$$

Inspiration is always expressed as 1.

Expiration is shown as a whole number or with a decimal, followed by tenths. For inverse I:E ratios, expiration will be displayed as a decimal number less than 1.0.

SELECTED DATA scan feature is initiated by depressing the **SELECT** button and holding for at least 3 seconds and releasing. The **SELECTED DATA** display will show each of the three parameters for two seconds. To stop the scan feature depress the **SELECT** button once.

Lower Section

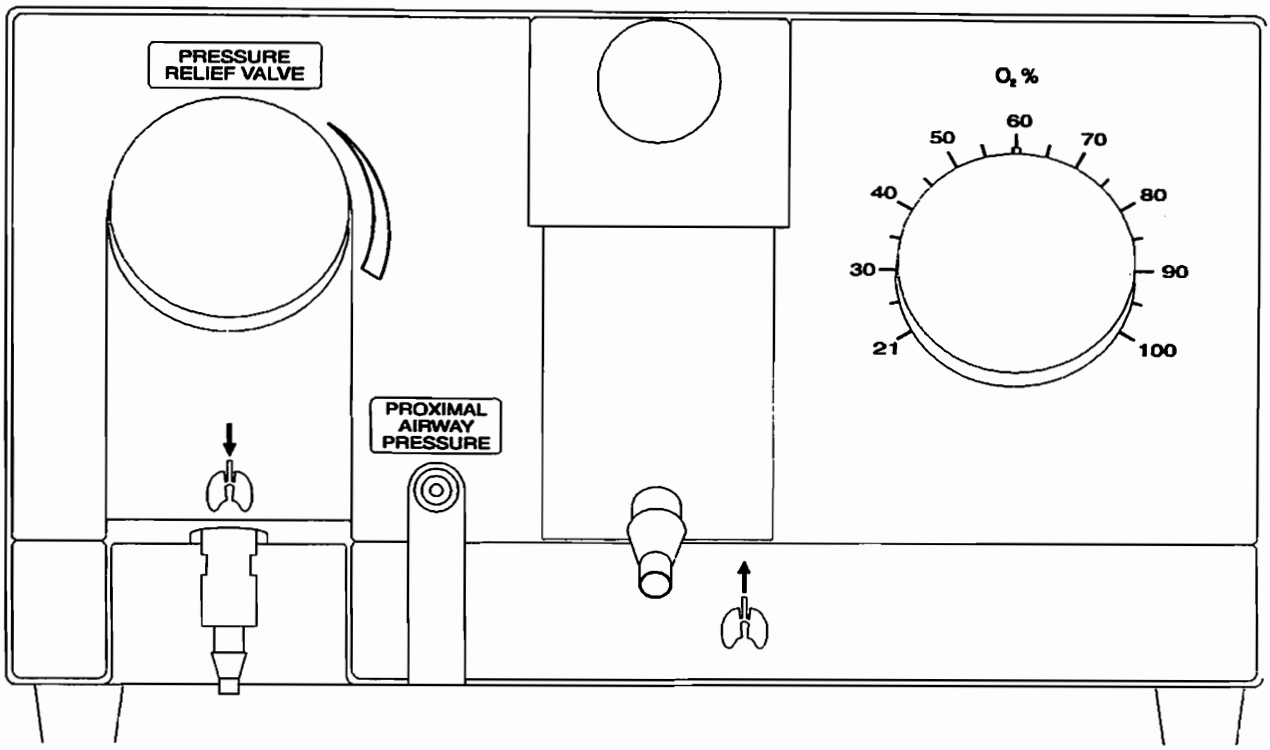


Illustration 5 - Front of Pneumatics Module

PRESSURE RELIEF VALVE

Adjustable Range 5 to 120 cm H_2O

EXHALATION BLOCK

The exhalation block is heated to minimize condensation. The surface temperature of the exhalation block varies depending on the **FLOW RATE** and **VENTILATOR SETTINGS**. The maximum surface temperature is 60° C. Care must be taken when removing the exhalation block. The exhalation diaphragm is seated behind the exhalation block (see Illustration 6).

NOTE: The exhalation diaphragm is manufactured with a small nipple in the center on one side of the diaphragm. This nipple must be facing out to ensure proper ventilator operation.

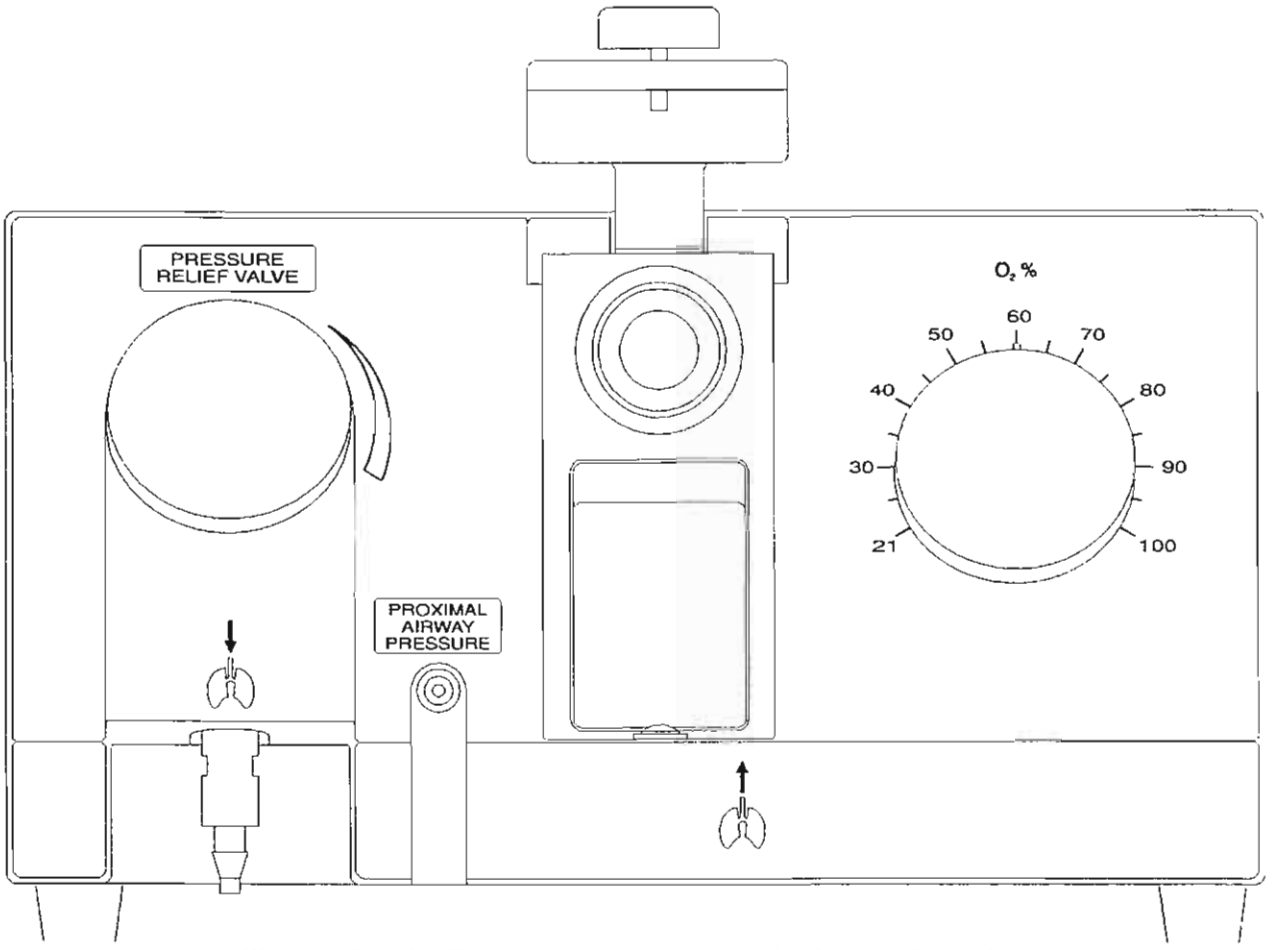


Illustration 6 - Exhalation Block and Diaphragm Housing

OXYGEN PERCENT

Adjustable Range 21% to 100%

The internal blender provides a variable oxygen concentration from 21 to 100%.

WARNING

To verify accuracy of the oxygen delivery system and ensure patient safety at all times, an oxygen monitor should be connected in the tubing between the ventilator and the humidifier. Incorrect FiO2 may result in patient injury.

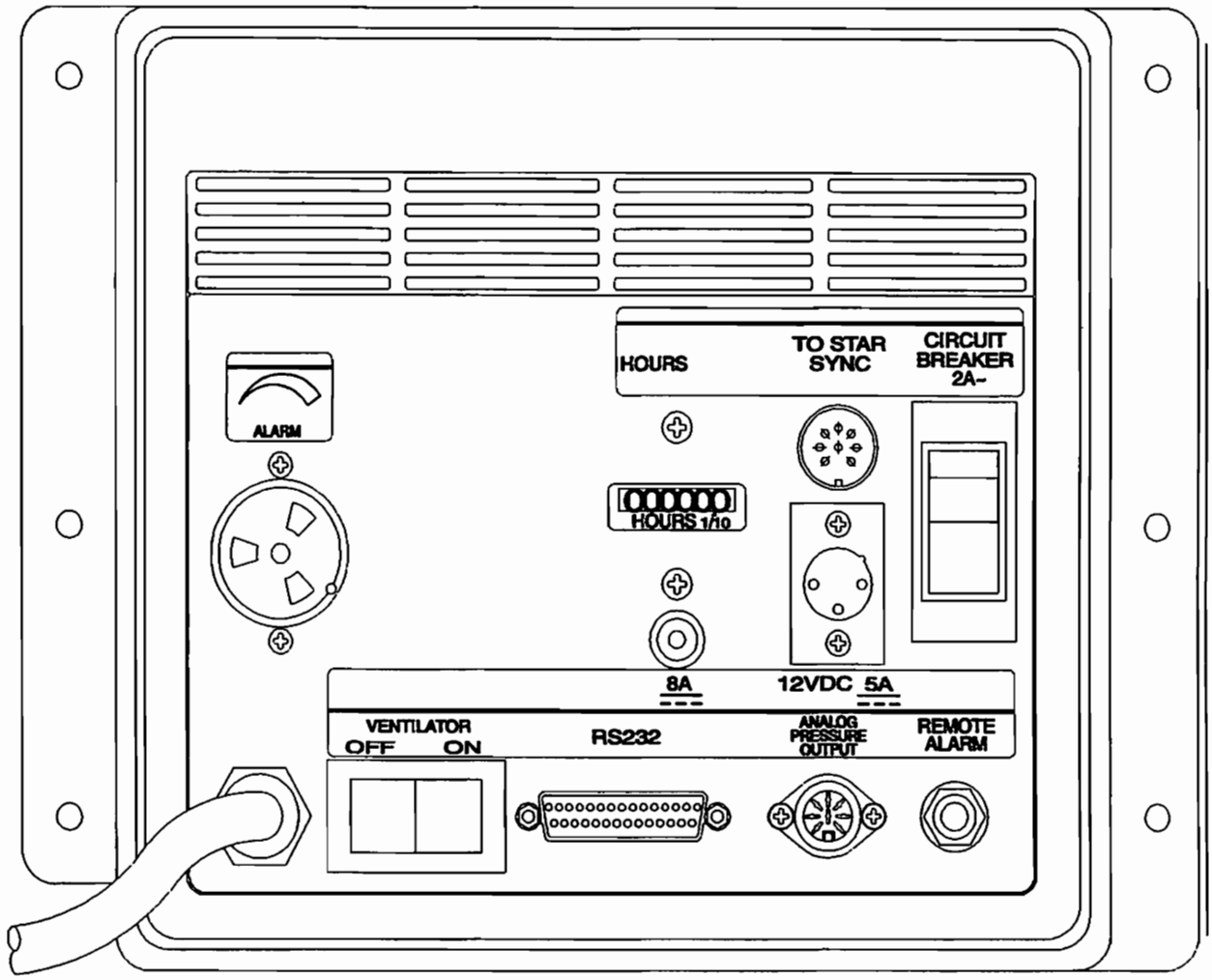


Illustration 7 - Back of Electronic Module

ALARM (Alarm Loudness)

Approximately 72 to 88 decibels

A rotary baffle is used to adjust the audible alarm intensity. To increase intensity rotate clockwise, to decrease rotate counter-clockwise.

HOURS (Elapsed Hours Meter)

Measures the total hours of operation. Activated when the **ON/OFF** switch is in the **ON** position.

NOTE: Each ventilator goes through an extensive run-in cycle, followed by calibration and a final performance check. It is normal for a new ventilator to have 100 or more hours on the **HOURS** meter.

A/C **CIRCUIT BREAKER** (MAINS/Battery Charger)

This illuminated rocker switch is located on the rear of the ventilator and is recessed. When connected to a power source and the switch is **ON**, it will illuminate green and allow the battery to charge. This switch also incorporates an A/C **CIRCUIT BREAKER**, protecting the ventilator against possible shorts or line surges. The breaker is rated at 1.2 amps for 115V or 0.6 amps for 220V units. If the circuit trips, the switch will automatically move to the **OFF** (O) position, interrupting A/C power to the ventilator. The breaker can be reset by rocking the switch back to the **ON** (I) position.

If the A/C **CIRCUIT BREAKER** (MAINS/Battery Charger) is in the **OFF** (O) position, the ventilator can be operated by turning the **VENTILATOR ON/OFF** (I-O)switch to **ON** (I). In this state, the battery will not be charged as power is consumed. After approximately 30 minutes of battery operation, the **LOW BATTERY** alarm will illuminate and an audible alarm will sound. If use continues without connecting to an active power source, following 5 to 10 minutes of additional usage the ventilator will stop operating and declare **VENTILATOR INOP**. Alternative power or alternative ventilation must be provided immediately.

NOTE: When storing the ventilator for prolonged periods of time, it is recommended that the unit be connected to an electrical outlet and the **CIRCUIT BREAKER** (MAINS/Battery Charger) be left in the **ON** (I) position in order to maintain the internal battery at peak charge. If the **CIRCUIT BREAKER** (MAINS/Battery Charger) switch is left in the **OFF** (O) position, the battery will not be charged even if the electrical cord is connected to an A/C power source. The **EXT POWER LOSS** LED will illuminate in the **ALARM STATUS** section of the front control panel only when the **VENTILATOR ON/OFF** switch is in the **ON** position.

D/C **CIRCUIT BREAKER**

D/C - 8.0 amps

Protects against possible shorts or line surges. The circuit breaker may be reset by pushing in and holding momentarily. If the circuit breaker continues to trip the circuit, the ventilator should be removed from use and referred to qualified personnel for servicing.

EXTERNAL POWER SOURCE

11.8 VDC - 18 VDC
5 amps MAX.

Allows connection of an external battery power source. The minimum battery voltage must be 11.8 volts D/C or the internal battery charge will be depleted simultaneously with the external battery.

VENTILATOR ON/OFF (I-O)
Recessed, rocker-type switch, turns the **VENTILATOR ON** and **OFF**. The internal battery will automatically recharge even though the switch is in the **OFF** position when ventilator is connected to a power source and the **CIRCUIT BREAKER** (MAINS/Battery Charger) is **ON**.

RS-232

Baud Rate 1200

The standard RS-232 serial output connector provides digital output of parameter settings and monitored pressures for data transmission to a computer or cardiac monitor.

ANALOG PRESSURE OUTPUT

Output: 10 mv/cm H_2O
Range: -0.1 V to 1.2 V

The 3-pin DIN connector allows for connection to a strip chart recorder or oscilloscope to provide graphic tracings of pressure waveforms. The output is calibrated to 10 millivolts per cm H_2O from -0.10 volts to 1.2 volts.

REMOTE ALARM

Allows for connection to a remote alarm. When an alarm condition is detected, this switch will close, causing the **REMOTE ALARM** to activate.

To ensure proper function of the **REMOTE ALARM**, connect a remote alarm and create an alarm condition. This should activate the **REMOTE ALARM**; if no alarm activates, refer the ventilator to qualified personnel for servicing.

WARNING

The **REMOTE ALARM** connection provides an electrical contact to an external remote alarm. The adequacy and function of the **REMOTE ALARM** is not monitored by the ventilator. Malfunction or disconnection of the **REMOTE ALARM** does not activate the ventilator's **ALARM STATUS**.

NOTE: The **REMOTE ALARM** connection is factory set in the "NORMALLY OPEN" position. If the **REMOTE ALARM** module used requires a "NORMALLY CLOSED position, please refer the ventilator to qualified personnel for servicing.

TO *STAR* SYNC

The 9-pin DIN connector allows the Infant *Star* 500 and 950 to communicate with the *Star* Sync Patient Triggered Interface. For additional information on *Star* Sync, please refer to the *Star* Sync Operating Instructions, P/N 9910325.

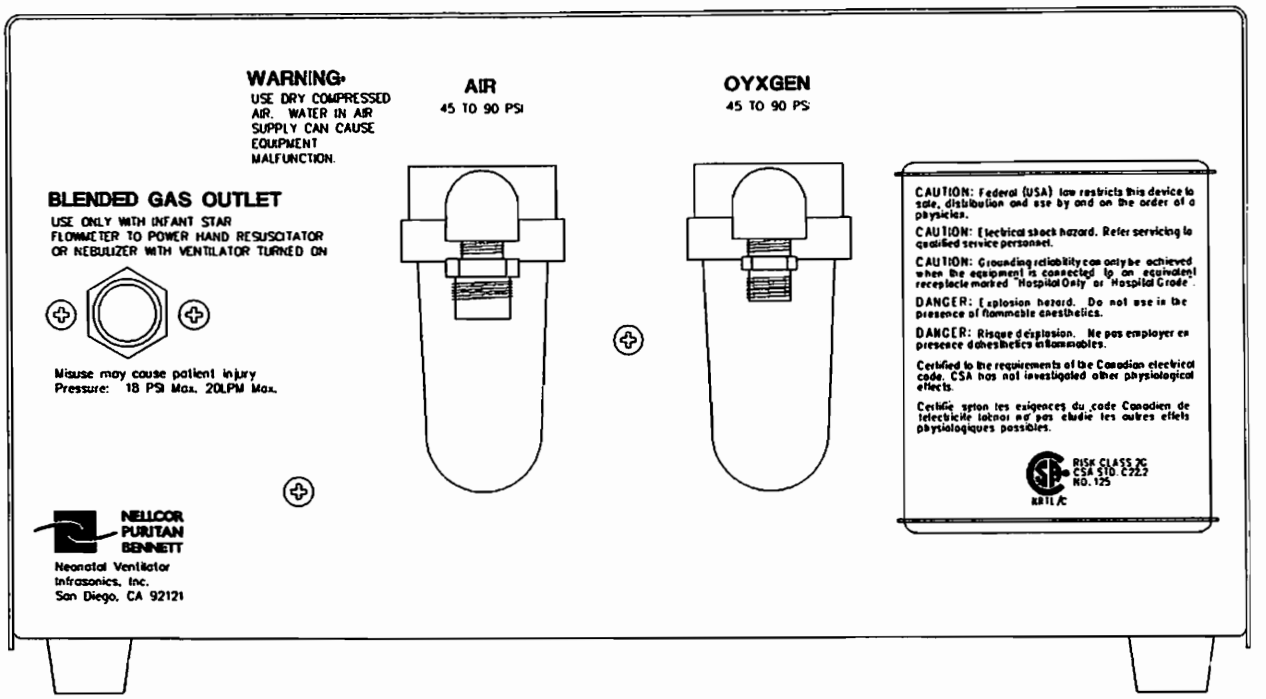


Illustration 8 - Back of Pneumatics Module

BLENDED GAS OUTLET

The 18 psi outlet is fitted with a DISS oxygen fitting, and provides blended gas for use with a small volume nebulizer or manual resuscitation bag.

WATER TRAPS / FILTERS

Allows for connection of high pressure oxygen and air gas sources while offering filtration of particles as small as 5 microns. The trap will also collect liquid contamination from the supply gas source. Check the traps routinely and empty as necessary by depressing the spring-loaded valve on the bottom of each jar.

HIGH FREQUENCY VENTILATION

Ventilators equipped with HFV (Infant *Star* 950) refer to Sections 10-17 of this manual for HFV Operating Instructions.

SECTION 4

OPERATING INSTRUCTIONS

WARNING

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

WARNING

Do Not use in the presence of flammable anesthetics. An explosion or fire may result.

WARNING

While running the Quick Checkout Procedure or operating the ventilator, if a mechanical or electrical problem is recognized, the ventilator must be removed from use and referred to qualified personnel for servicing. Using a malfunctioning ventilator may result in patient injury.

CAUTION

Use only dry and clean compressed air. Water or debris in the air or oxygen supply can cause equipment malfunction.

NOTE: When storing the ventilator for prolonged periods of time, it is recommended that the unit be connected to an electrical outlet and the **CIRCUIT BREAKER** (MAINS/Battery Charger) be left in the **ON** (I) position in order to maintain the internal battery at peak charge. If the **CIRCUIT BREAKER** (MAINS/Battery Charger) switch is left in the **OFF** (O) position, the battery will not be charged even if the electrical cord is connected to an A/C power source. The **EXT POWER LOSS** LED will illuminate in the **ALARM STATUS** section of the front control panel only when the **VENTILATOR ON/OFF** switch is in the **ON** position.

1. Attach the appropriate high pressure hose to the water traps/filters on the back panel and connect to a 35 to 90 psig (241 to 621 kPa) source outlet (see system specifications).

   Periodically inspect O_2 and air inlet water traps/filters. When necessary, drain the water from the bowl by depressing the stem on the bottom of the bowl. Inspect the filter and replace when it appears dirty. Clean internal components with a warm detergent solution. (See Infant *Star* 500/950 Service Manual, P/N 9910913)

2. Attach the patient breathing circuit. (See Illustration 9).

   a. Connect a 10 mm I.D. x 18 inch Tube, P/N 4401003, from the **TO PATIENT** port beneath the **PRESSURE RELIEF VALVE** to the inlet port on the humidifier.

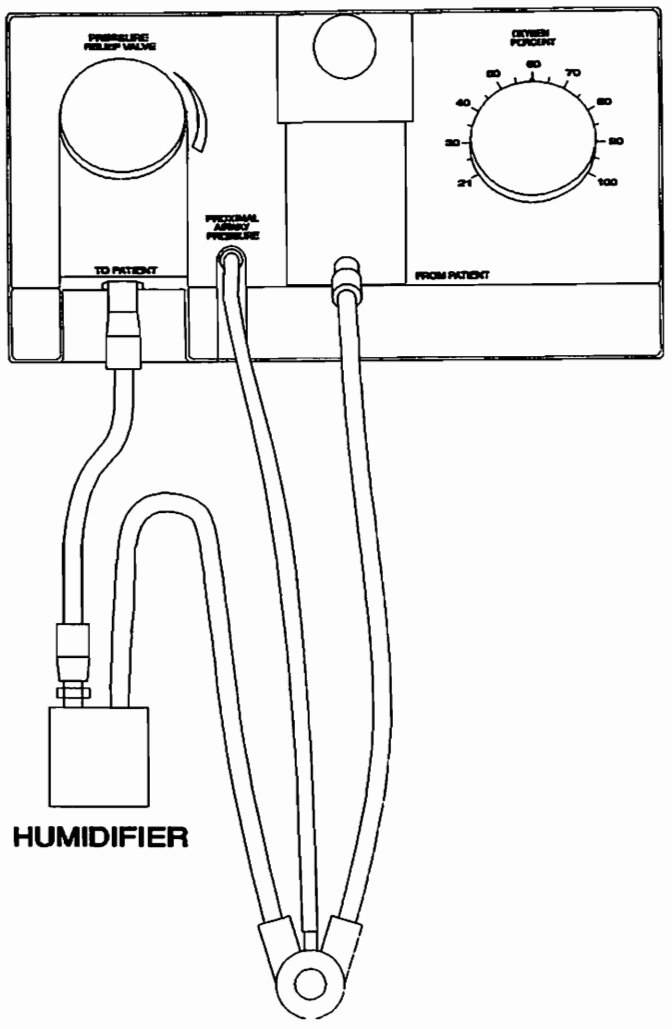


Illustration 9 - Breathing Circuit Set-up for Infant *Star* 500/950

Optional

Connect an In-line Bacteria Filter, P/N 501021, between ventilator and humidifier. This part number includes two 10 mm x 9 inch tubes and a filter. To replace the Filter Assembly only, order P/N4403008.

b. Connect the inspiratory limb of the patient breathing circuit to the humidifier outlet port.

NOTE: P/N 4402024, 15 mm to 10 mm Adapter, may be used to connect the breathing circuit to the inlet ports on the humidifier chamber if the internal diameter of the inlet is a standard 15 mm taper.

c. Connect the expiratory limb of the circuit to the **FROM PATIENT** port on the ventilator exhalation block.

d. Connect the **PROXIMAL AIRWAY PRESSURE** tube to the **PROXIMAL AIRWAY PRESSURE** barb fitting.

WARNING

Do Not tee accessory monitoring devices into the **PROXIMAL PRESSURE** line. Adding additional tubing volume will delay demand flow response and may cause activation of the **OBSTRUCTED TUBE** alarm. If necessary, tee into the inspiratory or expiratory limbs of the breathing circuit.

WARNING

Connect the **PROXIMAL AIRWAY PRESSURE** tube to the patient wye before attaching the inspiratory and expiratory limbs. A **PROXIMAL AIRWAY PRESSURE** tube disconnect will result in one or more alarms, including an **OBSTRUCTED TUBE** alarm (A05) and **LOW PEEP/CPAP**. All alarm situations must be corrected to ensure adequate ventilation.

WARNING

Whenever a humidifier is placed inline with the patient breathing circuit, water traps or heated wires should be used in the inspiratory and expiratory limbs of the patient breathing circuit to prevent water accumulation in the tubing from being inadvertently drained toward the airway.

NOTE: The use of heating wires does not ensure water condensation will not occur. There are many factors which will influence humidity delivered to the patient as well as water condensation within the inspiratory/expiratory limbs of the patient circuit, and exhalation valve. Some of these factors are:

The humidifier used; adjustment of humidifier temperature and relative humidity settings; usage of single wire, dual wire or no-wire patient circuits; ventilator **FLOW RATE** and tubing length; external environmental conditions such as room temperature, direct sunlight and cold drafts of air, etc.

The clinician should closely monitor the interrelationship between the humidifier, ventilator and patient circuit to ensure adequate humidification with minimum condensation.

e. Attach a *Star* Test Lung, P/N 1101262, to the patient wye.

f. Turn the ventilator **ON** using the **VENTILATOR ON/OFF** (I-O) switch located on the rear of the ventilator. Be certain the **CIRCUIT BREAKER** (MAINS /Battery Charger) switch is in the **ON** (I) position. A brief audible alarm will be heard and a software version number is displayed momentarily in the **SELECTED DATA** display.

All displays and indicators will illuminate as the switch is turned on, with the exception of **EXT POWER LOSS**, **LOW BATTERY** and **VENTILATOR INOP**.

NOTE: If during start up any number under 103 appears in the **SELECTED DATA** display, the software level should be updated. Call 1-800-NELLCOR.

3. Complete the Quick Checkout Procedure, Section 5.
4. Adjust the following ventilator controls, per physician's order, before connecting the ventilator to a patient.

   a. Mode of Ventilation

   CPAP (Continuous Positive Airway Pressure)

   The **BACKGROUND FLOW** establishes the continuous flow available for spontaneous breathing while the **PEEP/CPAP** adjusts the baseline pressure. If the patient's spontaneous breathing exceeds the available flow and a negative pressure of 1 cm H_2O or more below baseline results, the demand system will automatically supply additional flow up to 40 LPM.

   Adjust the **PEEP/CPAP** to the desired level of CPAP.

   The blender establishes the desired oxygen concentration. Adjust the humidifier to the proper setting. See the specific Humidifier Operation Manual supplied with the humidifier for further instructions.

WARNING

To verify accuracy of the oxygen delivery system and ensure patient safety at all times, an oxygen monitor should be connected in the tubing between the ventilator and the humidifier. Incorrect FiO2 may result in patient injury.

WARNING

When using the ventilator with low **BACKGROUND FLOW**, major changes in the **OXYGEN PERCENT** may require 30 to 45 seconds before the new concentration reaches the airway.

WARNING

Never use the **PRESSURE RELIEF VALVE** to establish the **PEEP/CPAP** level. Always adjust the **PRESSURE RELIEF VALVE** to a pressure setting in excess of 6 cm H_2O above the **PEEP/CPAP** level to assure that fresh gas reaches the patients' airway.

WARNING

When using the **CPAP MODE** of ventilation, the **FLOW RATE**, **PEAK INSP PRESSURE** and **INSPIRATORY TIME** should be adjusted to appropriate values. When the **MANUAL BREATH** button is engaged, the magnitude and duration of the mandatory breath are based on these settings.

IMV (Intermittent Mandatory Ventilation)

The **VENTILATOR RATE** establishes the number of mandatory breaths to be initiated. The **INSPIRATORY TIME** sets the duration of the breath and the **FLOW RATE** establishes the inspiratory pressure slope of the mandatory breath. The **BACKGROUND FLOW** establishes the background flow occurring during exhalation, as well as the flow available for spontaneous breathing. If the patient's spontaneous breathing exceeds the available flow and a negative pressure of 1 cm H_2O or more below baseline results, the demand system will automatically supply additional flow. The **PEEP/CPAP** adjusts the baseline pressure.

The blender establishes the desired oxygen concentration. Adjust the humidifier to the proper setting. See the specific Humidifier Operation Manual supplied with the humidifier for further instructions.

WARNING

To verify accuracy of the oxygen delivery system and ensure patient safety at all times, an oxygen monitor should be connected in the tubing between the ventilator and the humidifier. Incorrect FiO2 may result in patient injury.

WARNING

When using the ventilator with low **BACKGROUND FLOW**, major changes in the **OXYGEN PERCENT** may require 30 to 45 seconds before the new concentration reaches the airway.

b. Adjust the following controls to the appropriate setting displayed to the left of each control:

VENTILATOR RATE
PEAK INSP PRESSURE
INSPIRATORY TIME
PEEP/CPAP
FLOW RATE
BACKGROUND FLOW

Set the **HIGH INSP PRESSURE** alarm 5 to 15 cm H_2O above the **PEAK INSP PRESSURE** setting to establish the alarm point as well as a secondary maximum pressure limit during a mandatory or manual breath.

Set the **LOW INSP PRESSURE** alarm 3 to 5 cm H_2O below **PEAK INSP PRESSURE** setting to establish the alarm point of pressure to be reached during inspiration of a mandatory or manual breath.

Set the **PRESSURE RELIEF VALVE** to the appropriate setting, based on the desired **PIP**. See Adjusting the **PRESSURE RELIEF VALVE** section.

NOTE: If the **LOW INSP PRESSURE** setting is fully counter-clockwise (3 cm H_2O) and **PEEP/CPAP** is higher, the alarm threshold will automatically track the **PEEP/CPAP**, using **PEEP/CPAP** as the minimum alarm set point.

NOTE: Changes in either **VENTILATOR RATE** or **INSPIRATORY TIME** will affect the **EXPIRATORY TIME**.

Adjusting the **PRESSURE RELIEF VALVE**

The **PEAK INSP PRESSURE** establishes the maximum pressure to be applied at the airway. The **HIGH INSP PRESSURE** alarm establishes the three levels of over-pressure protection (A01, A02, A05). By setting the **PRESSURE RELIEF VALVE** as a backup, a further redundancy of pressure protection is added.

To properly set the **PRESSURE RELIEF VALVE**, remove the patient from the ventilator and attach an Infant *Star* Test Lung. Rotate the **PRESSURE RELIEF VALVE** knob fully clockwise. Adjust the **HIGH INSP PRESSURE** and the **PEAK INSP PRESSURE** to 30 cm H_2O above the desired **PIP**. To set the **PRESSURE RELIEF VALVE**, **PIP** must be set and mandatory breaths occurring. Slowly rotate the knob counter-clockwise until the pressure relief limits the **PEAK INSP PRESSURE** at 25 cm H_2O above the desired setting. Adjust the **PEAK INSP PRESSURE** to the desired setting. This procedure will result in the mechanical **PRESSURE RELIEF VALVE** limiting pressure approximately 25 cm H_2O above the desired **PIP** setting.

WARNING

Never use the PRESSURE RELIEF VALVE to establish the PEEP/CPAP level. Always adjust the PRESSURE RELIEF VALVE to a pressure setting in excess of 6 cm H_2O above the PEEP/CPAP level to assure that fresh gas reaches the patients' airway.

NOTE: When the **PRESSURE RELIEF VALVE** is set at a pressure below the PIP setting, the **OBSTRUCTED TUBE** alarm may detect only situations resulting in elevated **PEEP/CPAP** or impeded exhalation following a mandatory breath. Refer to **OBSTRUCTED TUBE** alarm section for a more detailed explanation of HI CPP, A04 or HI PIP, A03.

To set inverse I:E RATIO

For specific Ventilator Rates:

Select the **I:E RATIO** in the **SELECTED DATA** display. Select the mandatory breath rate and adjust the **INSPIRATORY TIME** until desired inverse **I:E RATIO** appears in the **SELECTED DATA** display. The resulting display will be an **I:E RATIO** less than 1:1.0.

For specific Inspiratory Times:

Select the **I:E RATIO** in the **SELECTED DATA** display. Select the desired **INSPIRATORY TIME** and decrease the **VENTILATOR RATE** until the desired **I:E RATIO** appears in the **SELECTED DATA** display. The resulting display will be an **I:E RATIO** less than 1:1.0.

NOTE: For breath rates less than 100 BPM, minimum **EXPIRATORY TIME** is 0.3 seconds. For breath rates of 100 BPM and greater, minimum **EXPIRATORY TIME** is 0.2 seconds. These limits allow for inverse I:E ratios while maintaining sufficient expiratory times.

NOTE: The **VENTILATOR RATE** display will flash if set rate is not being delivered. (see **INSUFFICIENT EXP TIME** alarm section).

Monitoring

Observe monitored parameters, all pressure readings are in cm H_2O or millibars and are based on pressure measured proximally at the patient wye.

The **PROXIMAL AIRWAY PRESSURE** meter continuously shows the actual pressure measured at the patient wye.

NOTE: When using extreme **PEAK INSP PRESSURE**, **INSPIRATORY TIME** or other control combinations, the **PROXIMAL AIRWAY PRESSURE** meter may not provide a precise measurement of pressure. Under these circumstances, the digital **PIP** display should be used exclusively.

PEEP/CPAP

This is the average **PEEP/CPAP** pressure measured at the patient wye during the last 5 seconds.

PEAK INSP PRESSURE

This is the highest airway pressure measured at the patient wye during the last mandatory breath.

MEAN

This is the average airway pressure measured at the patient wye during the last 30 seconds.

Miscellaneous

Administration of Small Volume Nebulizer Therapy

Use the **BLENDED GAS OUTLET** on the back panel and the 18 psi calibrated Flowmeter, P/N 4403004, to dispense the same FiO2 as selected on the front of the ventilator. Since extra flow is being added, which is not controlled by the microprocessor, the ventilator will react by producing a **HIGH INSP PRESSURE** alarm and terminating the breath. In this case, the **PRESSURE RELIEF VALVE** must be used as the primary **PIP** control.

To set the **PRESSURE RELIEF VALVE** as the primary **PIP** (**PIP** must be set and mandatory breaths occurring):

1. Rotate the **PRESSURE RELIEF VALVE** knob counter-clockwise until the digital **PIP** display drops 1 cmH_20.
2. Decrease the **BACKGROUND FLOW** 2 to 4 LPM to reduce potential inadvertent PEEP.
3. Perform small volume nebulizer therapy.
4. Upon completion of small volume nebulizer therapy, return the **PRESSURE RELIEF VALVE** to the original backup setting.
5. Return **BACKGROUND FLOW** to the previous setting.

The RELIEF VALVE pressure limit procedure may also be used when the patient is fighting the ventilator and when increasing the **HIP** alarm to **PIP** + 15 cm H_2O will not eliminate the alarm condition. If ignored, the resulting **HIGH INSP PRESSURE** alarm (**HI PIP**, A01) terminates the breath, shortening the **INSPIRATORY TIME** and reducing minute ventilation. Return the **PRESSURE RELIEF VALVE** to normal settings when the patient is sedated or agitation has diminished. The addition of Patient Triggered or Synchronized Ventilation using the *Star* Sync Interface can also address the patient who is fighting the ventilator.

Suction Procedure

1. Turn humidifier to OFF or PAUSE.

WARNING

Turn humidifier to OFF or PAUSE during suctioning procedure to avoid the possibility of the humidifier chamber overheating. Chamber overheating may result in gas temperature overshoot at the airway during reconnection.

2. Disconnect patient from the breathing circuit.
3. Perform suctioning procedure per hospital protocol.
4. If in the **IMV MODE**, the **LOW INSP PRESSURE** alarm sounds immediately after a mandatory breath since the pressure did not reach the **LOW INSP PRESSURE** alarm setting.

5. If the **EXPIRATORY TIME** is greater than 5 seconds, and the set **PEEP/CPAP** is above 3 cm H_2O, the **AIRWAY LEAK** alarm will activate after 4 seconds of disconnect. This occurs because the leak makeup system will try to compensate for loss of **PEEP/CPAP** by increasing flow in excess of 13 LPM above **BACKGROUND FLOW**.
6. The **PEEP/CPAP** alarm activates after 25 seconds indicating **PEEP/CPAP** dropped below the alarm threshold for that period of time.
7. When the alarms activate, press the **ALARM SILENCE** to silence the audible alarm for 60 seconds.
8. Reconnect the patient to the ventilator.
9. Press the **ALARM SILENCE** and **VISUAL RESET** to re-arm the audible alarms and cancel the visual indicator.
10. Return humidifier to normal operation.

Inadvertent PEEP

The exhalation block houses a servo-controlled jet/venturi system designed to minimize inadvertent PEEP. The compensation is initially calculated by the microprocessor, based on **FLOW RATE** and **PEEP/CPAP**. The microprocessor is programmed to track the measured PEEP level and automatically adjust the jet/venturi cycle rate to maintain the PEEP level at the set level.

WARNING

The use of some brands of breathing circuits and humidifier reservoirs may result in excessive resistance and an increase in inadvertent PEEP. Flow resistance and inadvertent PEEP are factors of the humidifier reservoir design, the internal diameter of the breathing circuit, length of the expiratory tubing, as well as the small internal orifice of the breathing circuit tubing connection at the patient wye. The supplied breathing circuit is designed to minimize flow resistance and inadvertent PEEP. Care must be taken when using other brands of breathing circuits.

Transport

For transports of less than 30 minutes, assuming a full charge, the internal batteries of the Infant *Star* 500 and 950 will provide all ventilator electrical power requirements. The humidifier will not be powered by the battery.

For periods of longer than 30 minutes, a battery may be connected to the 12 VDC, 5 amp receptacle on the back of the ventilator (voltage must be between 11.8 and 18 VDC). During transport the ventilator should be used with low **BACKGROUND FLOW** to reduce gas consumption. Gas consumption is dependent on the **VENTILATOR RATE**, **PEAK INSP PRESSURE**, **PEEP/CPAP**, **INSPIRATORY TIME**, **FLOW RATE** and **BACKGROUND FLOW**.

CAUTION

If an external battery is being used and the voltage drops below 11.8 VDC, the internal battery will not recharge. Both the internal and external batteries will discharge simultaneously. The EXT POWER LOSS and LOW BATTERY alarms will activate when both batteries are near depletion.

Synchronized Ventilation

Synchronized or Patient-triggered ventilation can be accomplished using the *Star* Sync interface. Assist/control, SIMV, Monitor and CPAP/backup modes are currently available. Mounting is accomplished using ball studs atop the ventilator which allows for easy removal. The *Star* Sync communicates with the ventilator via the interface cable and 9-pin DIN connectors which "thread lock" to provide a secure connection.

For ventilators equipped with this option follow the instructions in the *Star* Sync Operating Instructions, P/N 9910325.

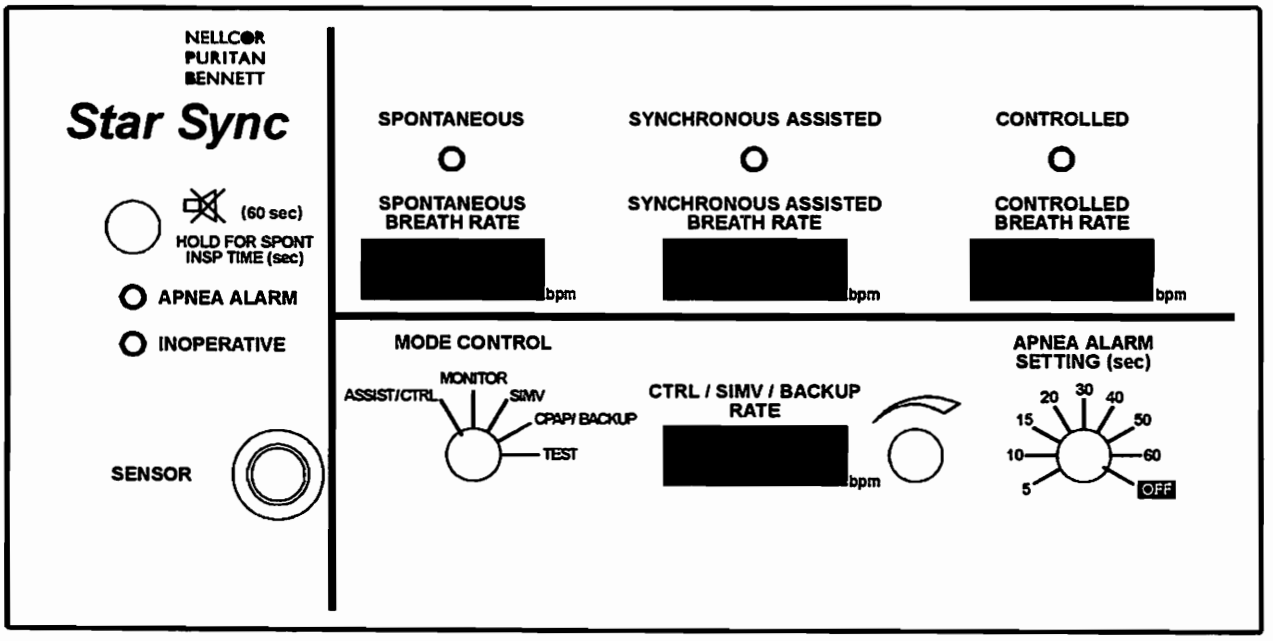


Illustration 10 - *Star* Sync Interface

SECTION 5

INFANT *STAR* 500 QUICK CHECKOUT PROCEDURE

1. Connect both source gases and electrical power, attach the breathing circuit, humidifier and Nellcor Puritan Bennett test lung.
2. Turn **CIRCUIT BREAKER** (MAINS/Battery Charger) to the **ON** (I) position.
3. Turn **VENTILATOR ON / OFF** switch to **ON** and observe the **SELECTED DATA** display.

NOTE: If during start up any number under 103 appears in the **SELECTED DATA** display, the software level should be updated. Call 1-800-NELLCOR.

4. All LED indicators are illuminated except **LOW BATTERY**, **VENTILATOR INOP** and **EXT POWER LOSS**. (The **VENTILATOR INOP** may blink during power up.)
5. The audible alarm is momentarily activated, verifying its function.
6. Establish standard test conditions.

MODE:	IMV
VENTILATOR RATE:	30 BPM
PEAK INSP PRESSURE:	40 cm H_2O
INSPIRATORY TIME:	1.0 secs.
PEEP/CPAP:	0 cm H_2O
FLOW RATE:	20 LPM
BACKGROUND FLOW:	4 LPM
HIGH INSP PRESSURE:	45 cm H_2O
LOW INSP PRESSURE:	30 cm H_2O
SELECTED DATA:	EXPIRATORY TIME (sec)
OXYGEN PERCENT:	60%
PRESSURE RELIEF VALVE:	Fully clockwise

After 30 seconds, observe **MEAN** display is 19 ± 2 cm H_2O

Observe **PIP** display is 40 ± 1 cm H_2O

7. During a mechanical breath, completely kink the "**FROM PATIENT**" tube. Verify that the proximal pressure drops abruptly following an AO3 alarm activation.

8. Disconnect **TO PATIENT** tube at the ventilator and block the connector beneath the **PRESSURE RELIEF VALVE**. Observe **HI PIP**, A05 **OBSTRUCTED TUBE**, **HIGH INSP PRESSURE** and **LOW INSP PRESSURE** alarms and displays. Reconnect the tube, allow the audible to self-cancel, and push **VISUAL RESET**. Observe **PEEP/CPAP** display is 0 ± 2 cm H_2O.

9. Set **MODE:** CPAP
   PEEP/CPAP: 10 cm H_2O
   FLOW RATE: 8 LPM
   BACKGROUND FLOW: 8 LPM

After 30 seconds, observe that 10 ± 1 is indicated in a total of four displays: **PROXIMAL AIRWAY PRESSURE** meter, **PEEP/CPAP**, **MEAN**, and **PEEP/CPAP** setting displays.

After checking at 10 cm H_2O, reset **PEEP/CPAP** to 20 cm H_2O and again observe displays. After 30 seconds, these displays must read 20 ± 2 cm H_2O.

If unit passes the Quick Checkout procedure, set up the ventilator per physician's order, before connecting a patient to the ventilator.

WARNING

To verify that the audible/visual alarms for low oxygen and low air pressure operate, momentarily shut off the sources. The alarms should activate and the audible portion should silence when source pressure is reconnected. Failure to detect a source gas failure will change the FiO2 and may result in patient injury.

WARNING

While running the Quick Checkout Procedure or operating the ventilator, if a mechanical or electrical problem is recognized, the ventilator must be removed from use and referred to qualified personnel for servicing. Using a malfunctioning ventilator may result in patient injury.

SECTION 6

CLEANING AND DISINFECTING

Hospital protocol should be used to clean and disinfect the patient breathing circuit, exhalation block and exhalation diaphragm. They may be washed in a mild detergent, rinsed and then disinfected using ethylene oxide, pasteurmatic or cold chemicals, such as Cidex™.

WARNING

Ventilator components should be well aerated before use following ethylene oxide sterilization. Aeration time will vary depending on temperature used during processing and type of aerator. Follow the sterilizer manufacturer's recommendation regarding aeration time.

WARNING

An electric shock hazard exists when performing cleaning and maintenance procedures. Make sure the VENTILATOR POWER switch and the CIRCUIT BREAKER (MAINS/Battery Charger) are in the OFF position. If maintenance is required, refer the ventilator to qualified personnel for servicing.

CAUTION

Do Not spray any solutions directly on the ventilator. Do Not allow any liquid agent to penetrate to the inside of the ventilator.

CAUTION

Do Not gas or steam sterilize the ventilator. Damage to internal components could result.

To clean exhalation diaphragm:

1. Loosen knob counter-clockwise while holding exhalation block.
2. When loose, swivel the knob and clamp up.
3. Lift block up and out.
4. Remove exhalation diaphragm.
5. Wash exhalation block and diaphragm in mild detergent and disinfect per hospital protocol.

NOTE: For convenience and safety, a minimum of two complete exhalation diaphragms and exhalation blocks per ventilator is recommended, so that one assembly may be in use while the second is being cleaned.

Replace all components when dry:

1. Realign the diaphragm (the nipple facing out) into the circular hole in the front of the lower section. Gently push into recess.

NOTE: The exhalation diaphragm is manufactured with a small nipple in the center on one side of the diaphragm. This nipple must be facing out to ensure proper ventilator operation.

NOTE: When removing and replacing the exhalation diaphragm, the ventilator should be turned off. If the ventilator is left on, gas flow to the diaphragm may hamper realignment.

2. Align the bottom of the exhalation block with the jet venturi.

3. Push the exhalation block down and in, swivel the clamp down and hold while tightening the knob. Do not over tighten

4. Reconnect the patient breathing circuit.

To clean outer surface of ventilator:

1. Wipe with a damp cloth soaked in a germicidal or bactericidal agent.

2. The inner portion of block behind the exhalation valve, should also be disinfected in a similar manner.

Periodically inspect the 02 and air inlet water traps/filters. Drain the water from the bowl when necessary by depressing the stem on the bottom of the bowl. Inspect the filter and replace when it appears dirty. Clean internal components with a warm detergent solution. (See Infant *Star* 500/950 Service Manual, P/N 9910913)

SECTION 7

PREVENTATIVE MAINTENANCE

WARNING

An electric shock hazard exists when performing cleaning and maintenance procedures. Make sure the **VENTILATOR POWER** switch and the **CIRCUIT BREAKER** (MAINS/Battery Charger) are in the **OFF** position. If maintenance is required, refer the ventilator to qualified personnel for servicing.

A program of cleaning, operational checking and preventative maintenance is important to the proper function and life of the ventilator. Using the Quick Checkout Procedure, Section 4, on a routine basis (between patients or at least once each month) will help identify potential problems. Call 1-800-NELLCOR for assistance.

Routine cleaning, inspection and checkout between patients should include:

1. Clean and inspect the exhalation block, exhalation diaphragm and jet venturi O-ring. Wipe the exterior of the ventilator clean with a cloth slightly moistened with disinfectant.
2. Check for proper operation: Air and oxygen water traps, control knobs, switches, circuit breakers and the anti-swivel device (if used on a pedestal).
3. Perform Quick Checkout Procedure, Section 5.

Preventative maintenance should be performed by qualified personnel at six month or 1,500 hour intervals, whichever comes first.

The Preventative Maintenance Procedure is contained in the Infant *Star* 500/950 Service Manual, P/N 9910913, and is combined with the Operational Test. The procedure includes:

1. Visual inspections, internal and external.
2. Cleaning
3. Electrical safety tests for current leakage and ground wire resistance.
4. Performance tests for **PRESSURE**, **FLOW RATE**, **INSPIRATORY TIME**, **EXPIRATORY TIME** and **OXYGEN PERCENT** systems and alarms. If the ventilator fails the operational checks, it should be referred to qualified personnel for servicing.

Overhaul

Nellcor Puritan Bennett recommends that the Infant *Star* 500 and 950 be overhauled every ten thousand (10,000) hours in order to perform at optimum levels. A ventilator seven years old or more should be overhauled even though it may not have reached the ten thousand (10,000) hour mark. Minor overhauls may be performed at every other 10,000 interval, i.e. 10K, 30K etc. Major overhauls would then be performed at 20K and 40K etc.

The factory overhaul involves replacement of many components that are considered to have a useful life of ten thousand (10,000) hours. Current software updates are included at no additional charge. For a complete list of all items replaced and work performed, call 1-800-NELLCOR.

A factory overhauled ventilator has a twelve month parts and labor warranty (major overhaul), except the flow solenoids which have a two year warranty. A minor overhaul has a twelve month warranty on only those parts replaced and six months on the remainder of the unit.

SECTION 8

CLINICAL TROUBLESHOOTING CHART

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to achieve set **PEAK INSP PRESSURE (PIP)**	**LOW INSP PRESSURE** alarm (audible/Visual) Actual **PIP** reading less than **PIP** setting	Leak in system	Check for leak at breathing circuit, humidifier or water trap or excessive leaks around endotracheal tube, chest tubes, etc.
		Alarm threshold set too high	Check for correct setting of alarm threshold
		PRESSURE RELIEF VALVE acting as primary **PIP** control	Verify **PRESSURE RELIEF VALVE** is set properly
		Insufficient **FLOW RATE** or **INSPIRATORY TIME**	Increase **FLOW RATE** or increase **INSPIRATORY TIME**
		Flattened or damaged jet venturi O-ring	Check for flattened or damaged jet venturi O-ring; replace if necessary
Unable to maintain set PEEP. Actual PEEP lower than set	**LOW PEEP/CPAP** alarm "LO CPP" message in display windows	Actual peep drops below the set PEEP for ≥ 25 seconds	Check for leaks in the breathing circuit, water traps or humidifier
	AIRWAY LEAK alarm (audible/visual)	Diaphragm in backwards	Check diagram for proper placement
		Flattened or damaged jet venturi O-ring	Check for flattened or damaged jet venturi O-ring; replace if necessary
		Gross leak in the patient circuit, flow exceeds Backgound Flow by 13 LPM or more for ≥ 4 seconds	Check for leaks in the breathing circuit, water traps or humidifier

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
HIGH INSP PRESSURE alarm display flashing	**HIGH INSP PRESSURE** alarm display flashing	**HIGH INSP PRESSURE** alarm set more than 15 cm H_2O above the **PIP**	Adjust the **HIGH INSP PRESSURE** alarm between **PIP** and **PIP** + 15 cm H_2O
Momentarily high PEAK pressure	**OBSTRUCTED TUBE** and **HIGH INSP PRESSURE** alarms (audible/visual)	Patient fighting the ventilator, hiccuping or crying	If indicated, suction or sedate infant. If problem continues, readjust **HIP** alarm setting or use **PRESSURE RELIEF VALVE** as primary pressure limit
	HI PIP, A01 flashing in the display windows indicating **HIGH INSP PRESSURE** limit exceeded	Aerosol therapy being delivered	
		A blocked breathing circuit, expiratory limb or a non-functioning exhalation valve	Drain water from breathing circuit
			Check for tubing fatigue or crimping; replace if necessary
			Check function of exhalation valve
		A breathing circuit with excessive flow resistance	Test circuit for excessive flow resistance
PIP display flashing	**PIP** display flashing	**PIP** is set less than 5 cm H_2O above **PEEP**	Increase set **PIP** or decrease **PEEP**
Prolonged active exhalation	**OBSTRUCTED TUBE** alarm (audible/visual)	Partial blockage of expiratory limb of circuit	Check tubing for accumulation of water or crimping
	HI PIP, A03 flashing in display windows indicating interference with exhalation		Drain water; replace tubing if necessary

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
High **CPAP** reading	**OBSTRUCTED TUBE** alarm (audible/visual) HI CPP, A04 flashing in display windows indicating CPAP of 6 cm H_2O pressure greater than set PEEP/CPAP ≥ 5 seconds	Water in breathing circuit, tubing fatigue, blocked expiratory limb of breathing circuit	Drain water from tubing and water traps Check for tubing fatigue or crimping; replace tubing if necessary
High **PEAK INSP PRESSURE** detected at ventilator or no pressure registered on analog gauge	**OBSTRUCTED TUBE** alarm (audible/visual) HI PIP, A05 flashing in display windows indicating **HIGH INSP PRESSURE** + 10 cm H_2O pressure (pressure measured at **TO PATIENT** outlet)	Block in inspiratory limb of circuit. Blockage or disconnection of the **PROXIMAL AIRWAY PRESSURE** tube A breathing circuit with excessive flow resistance	Check for blockage of inspiratory limb of circuit, drain water if indicated Check for crimping or obstruction of **PROXIMAL AIRWAY PRESSURE** tube. Remove blockage or replace tube Reconnect **PROXIMAL AIRWAY PRESSURE** tube Test circuit for excessive flow resistance
Unable to achieve set respiratory rate	Activation of **INSUFFICIENT EXP TIME** alarm Flashing **VENTILATOR RATE** display	**VENTILATOR RATE** and **INSPIRATORY TIME** setting incompatible, not allowing for the minimum **EXPIRATORY TIME**	Decrease **VENTILATOR RATE** or **INSPIRATORY TIME**
Ventilator alarm condition <u>does not</u> activate **REMOTE ALARM**	No external alarm activation	Cable <u>not</u> connected Malfunction of **REMOTE ALARM**	Connect cable Troubleshoot **REMOTE ALARM** system

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to achieve desired FiO2	**LOW O2 PRESSURE** alarm (audible/visual) **LOW AIR PRESSURE** alarm (audible/visual)	Drop in oxygen or air source pressure below 35 to 45 psig (241 to 310 kPa). See page 15 (System Specifications).	Restore oxygen or air supply pressure Correct for blockage or damage of high pressure hose
Low internal battery power	**EXT POWER LOSS** and **LOW BATTERY** indicators alternately flashing (intermittent audible alarm)	Operating on internal battery power with approximately 5 to 10 minutes remaining before full discharge	Restore A/C electrical power source Connect ventilator to fully charged 12 VDC external battery
Intermittent clicking noise	Ventilator **ON**, clicking noise present	Produced by snap acting regulator controlling pressures to the accumulator to maintain precise FiO2, ensuring accuracy without waste.	Normal ventilator response
Difficult auscultating infant while using low **BACKGROUND FLOW** rates	Chattering noise heard through stethoscope during both **PIP** plateau and expiratory pause	Solenoids turning off and on, applying intermittent flow to compensate for leaks around the uncuffed endotracheal tube	Increase **BACKGROUND FLOW** during auscultation. Then return to the original **BACKGROUND FLOW** setting
Noise on analog tracing or oscilloscope	Noise during **PIP** plateau and expiratory pause	Solenoids turning off and on, applying intermittent flow to compensate for leaks around the uncuffed endotracheal tube Stripchart recorder artifact 60 cycle noise A/C power	During a stripchart or oscilloscope recording, noise can also be observed on the baseline. This "noise" is <u>not</u> transmitted down the endotracheal tube Filter noise
Light Emitting Diodes (LED's) <u>are not</u> lit	LED's fail to light	A/C or D/C breakers tripped	Reset breakers by depressing breakers momentarily

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Ventilator inoperative	**VENTILATOR INOP** and **LOW BATTERY** alarm (audible/visual) **VENTILATOR INOP** alarm, error code indicated in the **SELECTED DATA** display (audible/visual Can Not be silenced)	Internal battery is fully discharged or ventilator is not connected to a fully charged external 12 VDC battery One or both of the microprocessors stopped functioning Errors found in data between the two microprocessors Other electronic failures which may render the ventilator unsafe to use	Restore electrical power source Provide alternate source of ventilation (Note error code in **SELECTED DATA** display) With ventilator operating, full recharge of internal battery requires 1 1/2 hours With ventilator **OFF**, full recharge of internal battery requires approximately 1 hour Refer ventilator to qualified personnel or servicing
Ventilator stopped functioning	Ventilator power switch in the **ON** position	Internal malfunction Internal battery depleted	If the breaker continues to trip, remove from use and refer to qualified personnel for servicing Check electrical wall outlet for power Both the Circuit/Breaker (MAINS/Battery Charger) and the **VENTILATOR ON/OFF** to **ON** or (I) position
HFV ONLY or **HFV + IMV** modes inoperative	No oscillations occuring **HF OFF** in **HFV AMPLITUDE** window	**AMPLITUDE** setting too low **HFV ON/OFF** switch in the **OFF** position	Increase **AMPLITUDE** knob clockwise Turn **HFV ON/OFF** key switch to **ON**

SECTION 9

ORDERING INFORMATION

ACCESSORIES

4403004	Flowmeter with Block, Rail & Connecting Hose
501011	Infant Breathing Circuit, includes Proximal Wye, Pressure tube, Breathing Tubes & Water Traps.
4403001	Pedestal Stand (caster base & column)
606200-XX	*Star* Sync Patient Triggered Interface (language code in place of XX)
4403054	*Star* Cart, includes 2 accessory power outlets, 115 volt
4403055	*Star* Cart without accessory power outlets
501424	Fisher & Paykel MR 480 humidifier with accessories, 220-240 volt, servo
501426	Fisher & Paykel MR 730 humidifier with accessories, 220-240 volt, dual servo

REPLACEMENT PARTS

501023	High Frequency Breathing Circuit
501204	Heater Wire Assembly (HFV circuit)
4403017	Hydrophobic Proximal Pressure Line Filter (autoclavable)
501201	Fisher & Paykel reusable Humidification Chamber
4402024	Adapter, 15mm x 10mm male (allows use of 4401034 water trap with Infant Breathing Circuit)
4403008	Bacteria Filter
501021	Bacteria Filter with two 10mm x 9 inch Tubes (22.9 cm)
1150024	Exhalation Block Assembly
2101216	Exhalation Valve Diaphragm
4401004	Hose, High Pressure, Oxygen, 12 feet (3.7 m)
4401005	Hose, High Pressure, Air, 12 feet (3.7 m)
4403003	Hose Hanger, Double (attaches to pedestal stand)
501013	Separators, Tubing, package of 6 (included in 501011)
1101262	Test Lung
4300003	Thermometer (connects at Proximal Wye)
4401003	Tube, Infant *Star* to Humidifier, 10 mm I.D. x 18 inches (45.7 cm)
4401001	Tube, Proximal Pressure, 1/8 I.D. x 60 inches (1.52 m)
4401002	Tube, 10 mm I.D. x 24 inches (61 cm)
4401034	Water Trap Assembly (for breathing circuit)
4402002	Water Trap, Air (gas inlet)
4402003	Water Trap, Oxygen (gas inlet)
4402041	Wye, includes temperature "T" adapter

MISCELLANEOUS

9910905	500 / 950 Operating Instructions Manual
9910913	500 / 950 Service Manual

DEFINITION OF SYMBOLS

ALTERNATING CURRENT (A.C.)

DIRECT CURRENT (D.C.)

PROTECTIVE EARTH (GROUND)

ATTENTION, CONSULT ACCOMPANYING DOCUMENTS

TYPE BF EQUIPMENT

VARIABILITY

ALARM LOUDSPEAKER

OFF (POWER: DISCONNECTION FROM MAINS)

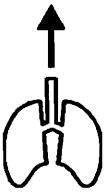
ON (POWER: CONNECTION TO MAINS)

VENTILATOR ON

VENTILATOR OFF

TO PATIENT (BREATHING CIRCUIT)

DEFINITION OF SYMBOLS (cont.)



FROM PATIENT (BREATHING CIRCUIT)

O_2 % OXYGEN PERCENTAGE

The maximum non-destructive voltage that can be applied to the rear panel connectors is:

(a) RS 232	+ 10V DC/-8V DC
(b) ANALOG PRESSURE OUTPUT	± 12V DC
(c) REMOTE ALARM	± 30V DC
(d) 12V DC (External Power)	± 18V DC

INPUT/OUTPUT CONNECTING CABLES

When connecting to the ventilator's input/output electrical connectors, the cable assemblies noted below are required to meet Electromagnetic Compatibility (EMC) requirements:

RS 232 I/O:	P/N 1150072 RS 232 Cable Assembly
ANALOG OUTPUT:	P/N 1150073 Analog Out Cable Assembly
EXTERNAL BATTERY:	P/N 1101289 External Battery Cable Assembly
REMOTE ALARM:	Use Shielded Cable

INFANT *STAR* 950
HIGH FREQUENCY OPERATING INSTRUCTIONS

The following sections describe the operation of the Infant *Star* 950 in the **HFV ONLY** and **HFV + IMV** modes. A complete understanding of the conventional operation of the ventilator, contained in the preceding sections of this manual, is required before using the ventilator in either High Frequency mode.

SECTION I0

INDICATIONS FOR USE

The Infant *Star* 950 is a combined Conventional / High Frequency (HFV) Ventilator. HFV is indicated for critically ill infants in rescue situations where the infant meets all of the following criteria:

1. Are, in the opinion of the attending physician, failing conventional therapy;

2. Have Respiratory Distress Syndrome (RDS) complicated by pulmonary air leaks with an active chest tube or have Pulmonary Interstitial Emphysema (PIE) as evidenced by radiographic data;

3. Have an arterial carbon dioxide concentration ($PaCO_2$) greater than 50 torr and/or an inspired oxygen concentration (FIO2) equal to or greater than 0.5 to maintain an arterial oxygen concentration (PaO_2) of at least 50 torr;

4. Weigh between 500 and 4,100 grams; and

5. Range from 23 to 41 weeks gestational age.

Contraindications, Warnings and Precautions

Use of HFV is contraindicated for any patient who does not meet the criteria in the Indications For Use.

Potential Adverse Effects of the Device

High frequency ventilation, and conventional ventilation, have similar adverse effects in this patient population.

SECTION 11

SUMMARY OF WARNINGS, CAUTIONS, AND NOTES

THE FOLLOWING SHARES THE EXPERIENCE OF CLINICIANS IN THE USE OF HFV; IT IN NO WAY SUBSTITUTES FOR THE SKILLS AND EXPERIENCE OF THE ATTENDING PHYSICIAN.

The following Summary Section in addition to the Summary of Warnings, Cautions and Notes pertaining to the conventional modes of ventilation (pages 1-8), should be read before using the Infant *Star* 950 Ventilator in **HFV ONLY** or **HFV + IMV** mode.

WARNING

When using low background flows with low IMV rates and/or low HFV amplitudes, major changes in the **OXYGEN PERCENT** control may require 30-45 seconds before the new concentration reaches the patients' airway.

WARNING

When using a short **IMV INSPIRATORY TIME** and/or a **HFV** mode, the **PROXIMAL AIRWAY PRESSURE** analog gauge will not respond quickly enough. Under these circumstances, the digital **PIP**, **MEAN** , **PEEP/CPAP** and **HFV AMPLITUDE** displays should be used exclusively. The **PIP** display relates to the IMV breath only.

WARNING

When using the **CPAP** or **HFV ONLY** modes of ventilation, the **PEAK INSPIRATORY PRESSURE** and **INSPIRATORY TIME** controls should be adjusted to appropriate values. When the **MANUAL BREATH** button is engaged, the magnitude and duration of the breath is based on these settings.

WARNING

Pneumatic pulse energy that is lost between the ventilator and the infant can reduce HFV amplitude (tidal volume). Reduction in amplitude can be caused by increased compressible volumes and resistance within the patient breathing circuit and humidifier chamber. Variations in the displayed **HFV AMPLITUDE** can be due to many conditions, including low water level in the humidifier, kinks or leaks in the patient circuit, changing patient compliance or resistance, mucous plugs or a change in position of the endotracheal tube.

* Monitor and maintain the humidifier water level hourly.
* Avoid ninety degree bends within the patient breathing circuit.
* Use only low compliance humidifiers and breathing circuits, such as Part Numbers 0501200 and 0501023, respectively.

WARNING

If in the course of operating the ventilator, a mechanical or electrical problem is suspected, the unit should be removed from use and checked by qualified biomedical personnel.

WARNING

Changes in airway patency, or patient compliance may alter the effect of each HFV pulse. Observing the patient's chest movement is an important aspect of patient monitoring during High Frequency Ventilation. Externally monitor SaO_2, $TcPCO_2$ and arterial blood pressure whenever performing High Frequency Ventilation to provide early detection of changing conditions.

WARNING

The **HIGH INSPIRATORY PRESSURE** alarm control should always be set appropriately when ventilation in the **HFV ONLY** mode. The **HIP** alarm acts as a back-up for the **HIGH PEEP/CPAP** alarm and the **OBSTRUCTED TUBE** alarm (**AO5**) and activates if the internal pressure measured at the **TO PATIENT** outlet constantly exceeds **HIP** + 10 cm H_2O.

NOTE: Patient breathing circuit configuration and position are critical to the successful application of high frequency ventilation. In order to minimize water accumulation within the circuit, the following is recommended:

1) Whenever possible, a heated wire configuration should be used.
2) Prevent water accumulation within the proximal pressure line by draping the circuit in such a manner as to locate the proximal pressure port above the patient or by placing a hydrophobic filter inline P/N 4403017.

NOTE: The full range of amplitude adjustment is achieved in approximately 3 to 4 full turns. The **HFV AMPLITUDE** control knob will continue to turn beyond the minimum and maximum settings, however an increase in rotational resistance will be felt.

NOTE: Employing a "high volume strategy" or some back-up IMV breaths, may reduce the risk of atelectasis. CO2 removal can occur very readily with HFV in a grossly atelectatic lung, however oxygenation is adversely affected. Maintenance of a mean lung volume is essential. Periodic IMV breaths (sighs) may help attain this goal. Serial x-rays may assist in the assessment of mean lung volume.

NOTE: Using gas flow from the **BLENDED GAS OUTLET** when using either HFV mode may decrease the flow output of HFV pulses when at or near the maximum amplitude (HFV flow) setting.

NOTE: HFV should be used with caution during weaning where intermittent apnea is present. The small oscillations do not stimulate spontaneous breaths. IMV tends to trigger spontaneous respirations via the Hering-Breuer and other reflexes. An aggressive transition from HFV to IMV or other patient triggered modes are often required to complete the weaning of an apneic prone infant.

NOTE: *Star* Sync should be turned off during High Frequency Ventilation. Patient triggered ventilation via the *Star* Sync interface is inactive during High Frequency Ventilation. Data displayed on *Star* Sync is inaccurate during HFV.

NOTE: While using either HFV mode, the **PRESSURE RELIEF** valve should be completely closed (turned fully clockwise). For use in any other mode, refer to the Operating Instructions section 4 of this manual.

NOTE: The Quick Checkout Procedure is based upon using a Nellcor Puritan Bennett high frequency breathing circuit (P/N 0501023), a Fisher & Paykel low compressible volume humidifier chamber (P/N 0501209) and standard test lung (P/N 1101262).

NOTE: In-line, continuous, nebulizer therapy is not recommended during HFV due to the effect on HFV Amplitude and Mean Airway Pressure (MAP).

NOTE: When in **HFV ONLY** or **HFV + IMV** modes, the **BACKGROUND FLOW** control is inoperative (indicated by a dimmed display). The **FLOW RATE** control effects only the flow rate during IMV breaths.

NOTE: The **HIGH INSP PRESSURE** and **LOW INSP PRESSURE** alarms apply only to IMV breaths.

NOTE: The **I:E RATIO** and **DUR POS PRESS** displayed values apply only to IMV breaths.

NOTE: Refer to the applicable Humidifier Operating Instructions for the humidifier used before instituting High Frequency Ventilation.

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY AND ON THE ORDER OF A PHYSICIAN.

SECTION 12

HFV THEORY AND INDICATIONS FOR USE

High Frequency Ventilation (HFV) is a type of mechanical ventilation utilizing unusually high ventilatory rates and low tidal volumes. The successful application of HFV raises questions about the fundamental concept of ventilation, especially in relation to mechanical ventilation. Conceptually one should also distinguish between ventilation (CO2 removal), which requires gaseous movement (i.e., convection) in and out of the lungs and oxygenation which can be accomplished by diffusion from the airway to the alveoli.

The classical description of human external respiration involves the low frequency movement of bulk flows of gas. In this scenario, the amount of ventilation in one minute (MV) is the product of respiratory frequency (RR), and tidal volume (V_t).

$$MV = RR \times V_t$$

The tidal volume must be sufficiently large to overcome dead space volume (V_D), the areas of non-gas/blood exchange, (e.g. upper airway, large bronchi, etc.). A respiratory zone exits in which both oxygen and carbon dioxide are exchanged; this is the alveolar volume (V_A). Studies further show that in normal patients approximately two-thirds of the V_t is V_A with the remaining one-third V_D.

$$V_t = V_A + V_D$$

Conventional mechanical ventilators attempt to mimic this pattern of respiration (i.e., normal rates and tidal volumes) by applying either positive pressure at the airway or negative pressure around the thorax.

HFV ventilates using volumes which are at or nearly equivalent to dead space, or $V_{HFV} \leq V_D$. HFV works in spite of the classical theories of ventilation. Several naturally occurring examples exist: a panting dog breathes with tidal volumes far smaller than its average dead space volumes; a hummingbird in flight ventilates through the extremely rapid bi-directional movement of its wings; severe emphysematous patients will often pant at fast rates and small volume; and mixing of pulmonary gases due to the dynamics of a cardiac contraction cycle has been documented. What is the mechanism for such ventilation? One concept is that gas mixing increases due to turbulence at the airway bifurcation's. With each bronchial bifurcation there is a mixing effect that is multiplied with each branching of the airway. Oscillations can independently cause alteration of the front profile of the gas flow and cause deeper gas mixing. Some support a mathematically derived theory which states that turbulence from the instantaneous high flowrates matched with the resonant frequency of the human lung is responsible for the augmented diffusion. Others have argued that CO_2 exchange is helped through the deep airway pulsation's, causing asynchronous filling of lung units, thereby establishing a "Pendeluft" effect. Studies have shown that a well hydrated airway is necessary for gaseous exchange above the classic respiratory zone.[1] A combination of these concepts, along with yet undiscovered mechanisms, is likely the answer.

As new as clinical application of HFV may be, there is already a spectrum of frequencies, tidal volumes and devices used. In present usage, HFV designates anything above 150 cycles/minute. As frequencies increase, it is more convenient to use the Hertz (Hz)

designation; 60 cycles/minute = 1 Hz. With increasing rate, smaller tidal volumes can be used to the point that effective alveolar ventilation occurs at volumes less than that classically referred to as physiologic anatomical dead space. Hence, the most effective HFV rate is dependent on the type of device used. With any device, if the optimal rate range is exceeded, gas entrapment can occur by stacking of fast pulses beyond the narrow ET tube.
The method used for providing HFV varies with the rates used. Basically, there are three methods of HFV. One is the use of a ventilator driven to rates above 60 breaths per minute or High Frequency Positive Pressure Ventilation (HFPPV) first described by Sjostrand.[2] Importantly, conventional ventilators used at fast rates are not doing the same type of ventilation in that most of the gas in the shortened cycle is dissipated in the compliant circuit. Delivered minute volume can be a function of the brand ventilator used.[3]

High Frequency Oscillation was first used clinically by Bryan.[4] The basic instrumentation was first described by Emerson in 1953 as a "new type of ventilator for which a US patent was issued in 1959.[5] The "mechanical oscillator" [1] uses a diaphragm, piston or plate contained in a chamber with a single outlet port. The diaphragm or piston is attached via a mechanical arm to an electric motor, whereas the plate device derives its motion from a magnetic field generated around the chamber. The "pneumatic oscillator" achieves bi-directional gas flow by alternating the phasic positioning of pressure pulses in the ventilator circuit. The Infant *Star* 950 precisely allocates pressure pulses via proportioning valves to create high, instantaneous flow at the inspiratory leg of the ventilator circuit. A negative flow due to an active jet venturi in the exhalation valve provides an opposing outward pulse.[6] The result is that a small volume of gas is moved to and fro at the airway in series with a constant low flow of humidified gas. The optimal rate range for oscillatory devices is 10 to 20 Hz (600 to 1200 breaths per minute).[7] The required delivered V_t is lowest with this technique. The compact size, multiple ventilation modes and backup battery operation lend the Infant *Star* High Frequency Ventilator to bedside and portable use.[8]

The Infant *Star* 950 has been found to improve gas exchange over conventional mechanical ventilation in patients with pulmonary air leaks, e.g., interstitial emphysema and bronchopleural fistula. Others have suggested additional indications for HFV and further studies are underway to broaden its application.

Selected Reading:

1. Mc Evoy RD, Davies NJH, Mannino FL, Schumacker PT, White FC, Wagner PD, West JB: Pulmonary gas exchange during high-frequency ventilation. J Appl Physiol 52:1278-1287,1982.

2. Sjostrand UH: Review of the physiological rationale for and development of high-frequency positive-pressure ventilation- HFPPV. Acta Anesth Scand 64:7-27, 1977.

3. MacDonald K, Wang P, Wirtschafter D: Rapid rate performance of five infant ventilators. In press 1990.

4. Bohn DJ, Miyasaka BE, Marchak WK, Thomson WK, Froese AB, Bryan AC: Ventilation by high-frequency oscillation. J Appl Physiol 48:710-716,1980.

5. Emerson JH: Apparatus for vibrating portions of a patient's airway. US Patent 2,918,917, December 29, 1959.

6. Fredberg JJ, Glass GM, Boynton BR, Frantz ID: Factors influencing mechanical performance of neonatal high-frequency ventilators. J Appl Physiol 62:2485-2490, 1987.

7. Kopotic RJ, Mannino FL: Carbon dioxide removal as affected by high frequency ventilation rate. Crit Care Med 16: 378, 1988.

8. Kopotic, RJ: Concerns with HFV in neonatal transport. Respiratory Care 1994, 39:1061.

9. Kopotic RJ, Mannino FL: Carbon dioxide removal as affected by high frequency ventilation rate. Crit Care Med 16: 378, 1988.

10. Ackerman NB Jr, Coalson JJ, Kuehl TJ, et al: Pulmonary interstitial emphysema in the premature baboon with hyaline membrane disease. Crit Care Med 12:512-516, 1984.

11. Blum-Hoffmann E, Kopotic RJ, Mannino FL: High-frequency oscillatory ventilation combined with intermittent mandatory ventilation in critically ill neonates: 3 years of experience. Eur J Pediatr 147:392-398, 1988.

12. Bell RE, Kuehl TJ, Coalson JJ, Ackerman NB, Null DM, et al: High frequency ventilation compared to conventional positive-pressure ventilation in the treatment of hyaline membrane disease in primates. Crit Care Med 12:764-7, 1984.

13. Mannino FL, McEvoy RD, Hallman M: Surfactant turnover in high frequency oscillatory ventilation (HFOV). Pediatr Res 16:356A, 1982.

14. Carlon GC, Ray C, Klain M, et al: High Frequency Positive Pressure ventilation in management of a patient with bronchialpleural fistula. Anesthesiology 52:160, 1980.

15. Boynton BR, Mannino FL, Davis RF, Kopotic RJ, Friederichsen GH: Combined high-frequency oscillatory ventilation and intermittent mandatory ventilation in critically ill neonates. J Pediatr 105:297-302, 1984.

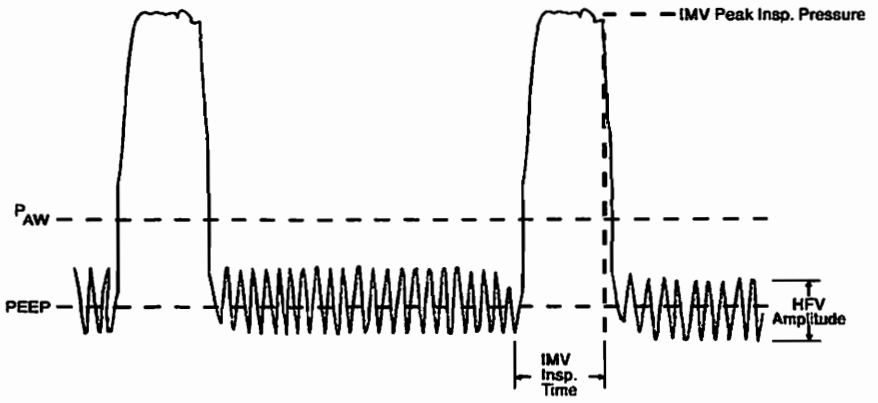
16. Clark RH, Gerstmann DR, Null DM, Yoder BA, Cornish JD Glasier C, Ackerman NB, Bell RE, deLemos RA: Pulmonary Interstitial Emphysema treated by high frequency oscillatory ventilator. Crit Care Med 14:926-30, 1986.

SECTION 13

SYSTEM DESCRIPTION - INFANT *STAR* 950 HFV MODES

General Statement:

As in the conventional modes (IMV, CPAP etc), operation of the High Frequency Option is via the electronically controlled, flow proportioning valves. Therefore, variation of any one operating parameter will not affect function of another, i.e., the controls are independent of each other. There is one exception to this rule, the use of IMV with HFV (this is addressed below). Refer to the System Description section in the front of this manual for a more complete description of routine ventilator operation. Tracing 1 delineates the various parameter set points seen with HFV in combination with IMV.



TRACING 1

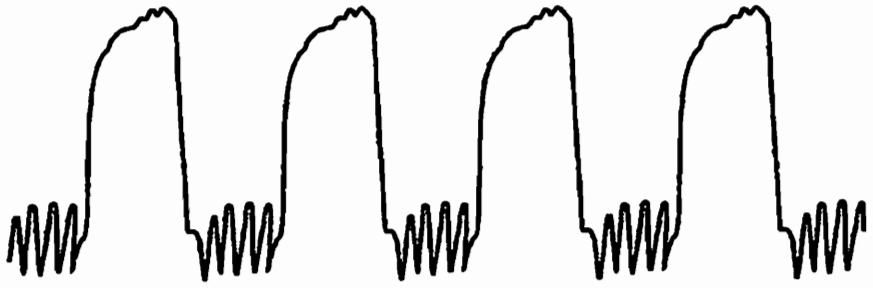
IMV Breaths During HFV:

During an IMV breath, the HFV mode is momentarily shut off before and after the IMV breath. The IMV breath is applied by closing the exhalation valve for the preselected Inspiratory Time (IT). Flow is proportioned to achieve the desired Peak inspiratory Pressure. The exhalation diaphragm then releases and the circuit returns to the preselected PEEP value. The HFV pulses cease approximately 50 msec. before, during and 60 to 250 msec. (depending on the time to return to baseline) after each IMV breath (Tracing 2).

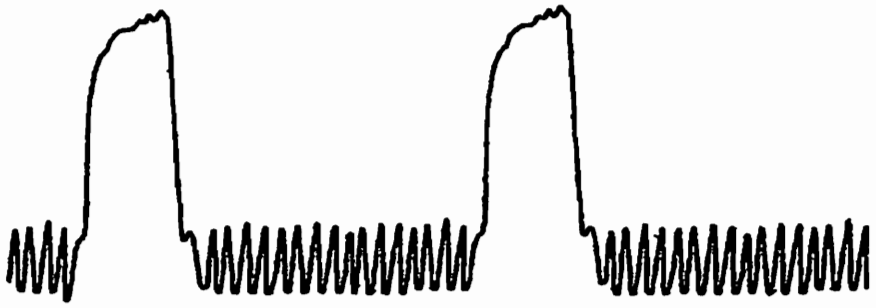
TRACING 2

NOTE: The HFV flow is reduced for the first HFV pulse following an IMV breath.

The IMV rate is unaffected by the simultaneous use of HFV. However if the IMV rate or IT is too great, there will not be adequate time for HFV pulses to occur at an effective rate. This is shown in Tracing 3a where the settings are: IMV rate = 50 bpm, IT = 0.5 seconds and HFV = 10 Hz, with Tracing 3b where the IMV rate was reduced to 25 bpm; notice that the number of HFV pulses increased four-fold (from 4 to 16 HFV pulses between IMV breaths).



TRACING 3a



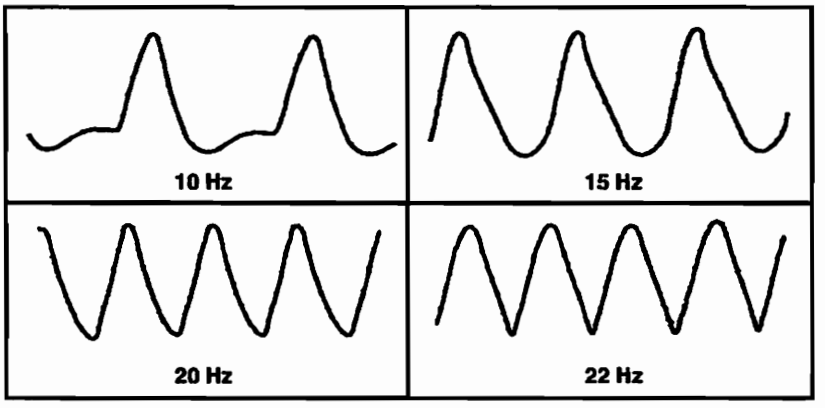
TRACING 3b

Generation of the HFV rate:

The HFV rate is defined as HFV pulse frequency and has an adjustment from 2 to 22 Hz (120 to 1320 pulses/minute). The frequency control is responsible for the rate of simultaneous opening of flow proportioning valves. The sequencing is controlled via microprocessor. Recall that if the **IMV** mode is used in combination with HFV, there is a pause in HFV pulsing before, during and following each IMV breath. Hence, when the IMV mode is active, the actual HFV rate will be somewhat less than the frequency control set point. However, the set **HFV RATE** is accurate for the periods between IMV breaths and in the **HFV ONLY** mode.

Generation of the Positive Pressure HFV Phase:

The Infant *Star* 950 has a bank of 10 computer-controlled proportioning valves which precisely time a titrated flow out of the ventilator. Individual 2, 4, and 8 LPM valves in combination with seven 16 LPM valves provide the cummulative positive pressure pulse. Other than the greater number of valves, the HFV mode generates its functions in a fashion similar to that of the conventional ventilator features, i.e., PEEP, Peak Inspiratory Pressure, Inspiratory Time and IMV rate. The proportioning valves open and the exhalation valve closes for a period of 18 msec. to generate each HFV positive pressure pulse, regardless of the HFV frequency. A composite of various HFV frequencies is shown in Tracing 4. The pulse intensity or amplitude is a function of the amount of flow allowed to exit the proportioning valves; the maximum flow is 120 liters/minute and the minimum flow rate is 12 LPM during HFV. As the **HFV AMPLITUDE** control knob is rotated clockwise, flow is increased in increments of 2 liters/minute.

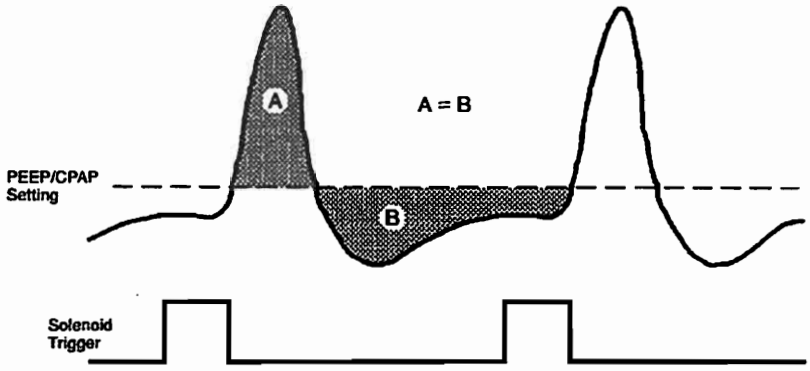


TRACING 4

At maximum flow, a volume of 36 ml is generated at the ventilator during each HFV pulse. However, the tidal volume delivered to the infant's lungs is considerably less and is dependent upon the compliance and resistance of the circuit tubing and humidifier; the ET tube diameter and length; and the characteristics of the patient's airways, pulmonary parenchyma and thorax. The drop in the generated-to-delivered volume is predictable and has been optimized in the Infant *Star* 950 by use of a low compliance tubing circuit and humidifier.

The general shape of the pulse at the proximal wye is shown in Tracing 5. Also shown is the electrical signal that energizes the flow proportioning valves or solenoids. The HFV pulse is

created when the solenoids are opened, allowing flow and the rise of the positive pressure pulse. The solenoids are then de-energized, causing the fall in positive pressure pulse. There is a delay between the time the solenoids are energized and a pulse produced; the solenoids take 3 to 5 msec. to turn on and off and the pulse takes time to traverse the circuit.

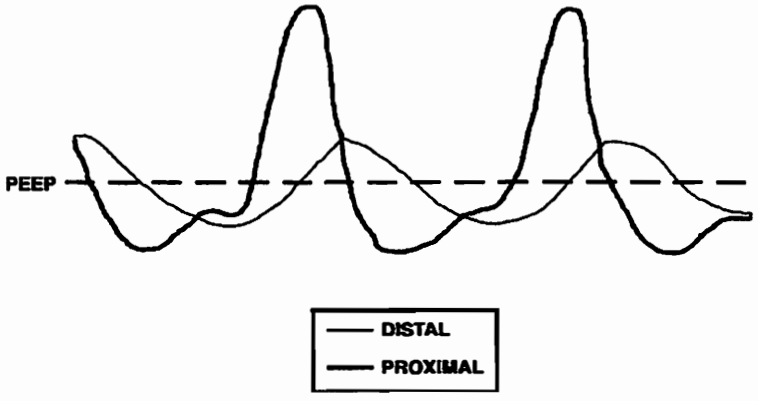


TRACING 5

During HFV, the exhalation venturi flow and diaphragm back pressure are adjusted to maintain the desired PEEP (i.e., mean of the HFV pulses). The exhalation valve is simultaneously pulsed to create an increased expiratory resistance during the HFV pulse, thereby directing more energy (volume) toward the patient.

Generation of the Negative Pressure HFV Phase:

An active jet venturi is built into the exhalation valve which, in combination with the recoil phenomenon following each positive HFV pulse, assists exhalation. This is termed "active exhalation." A typical tracing of the proximal HFV pressure reveals that the negative and positive pulse phases are equal in area above and below the PEEP/CPAP setting. Moreover, the distal or tracheal tracing reveals that the two phasic pulse patterns are quite similar (Tracing 6).



TRACING 6

Display of HFV Amplitude:

The proximal amplitude bears little resemblance to that measured distally (tracheal end of the ET tube). Depending on the disease state, the two may approximate in situations of poor compliance. However, distal pressure is generally greatly attenuated. The proximal amplitude display is derived by sampling the greatest positive and negative HFV points. Pressure is measured every 5 msec and displayed as the difference seen in the greatest peak to trough value over a period of 2 seconds. The accumulation of points which comprise the display value is done to reduce the effects of artifact, e.g. tubing vibration, patient movement or humidifier condensate. For any setting of amplitude, changes in the amplitude display can occur for many reasons, such as a change in water level in the humidifier, kinks or leaks in the patient circuit, changing patient compliance, mucous plugs or a change in position of the endotracheal tube.

Control of PEEP and Mean Airway Pressure:

The PEEP/CPAP system is a servo system based upon a transducer feedback loop. PEEP/CPAP is a function of gas loading on the backside of the exhalation valve and an expiratory jet venturi system. The operation of this feature is identical in all modes.

High frequency oscillations are positive as well as negative around PEEP. Be aware that there are negative pressures below PEEP when using HFV. In the HFV ONLY mode PEEP/CPAP is maintained as the average pressure around which the pulses are occurring. Therefore, the mean airway pressure and PEEP/CPAP pressure is the same. The definition of PEEP/CPAP is that the area of the pulse above the PEEP/CPAP setting equals the area of the pulse below the PEEP/CPAP setting, (Review again Tracing 5). The ventilator exhalation valve/jet venturi adjusts the flow resistance until the area of the pulse above and below the PEEP/CPAP setting are equal, i.e., A=B. The ventilator adjusts the flow resistance by varying the pressure on the back of the exhalation diaphragm as well as adjusting flow to the jet venturi to meet the desired PEEP/CPAP setting.

Airway pressure samplings occur every 5 msec. The computer averages the points over a 30 second time interval and displays the amount as mean airway pressure. The displayed result can therefore be somewhat delayed. It is best to first make a change in a setting which is likely to alter the mean airway pressure (i.e., PEEP, IT, IMV rate and IMV peak inspiratory pressure), and then view the MEAN display to be certain it has stabilized before making additional setting changes.

Selected Reading:

1. Boynton BR, Mannino FL, Meathe EA, Kopotic RJ, Friederichsen GH: Airway pressure measurement during high frequency oscillatory ventilation. Crit Care Med 12:39-43. 1984.

2. Bancalari A, Gerhardt T, Bancalari E, et al: Gas trapping with high-frequency ventilation: jet versus oscillatory ventilation . J Pediatr 110:617-622, 1987.

SECTION 14

LIMITATIONS / WARNINGS - USES OF THE DEVICE

The ventilator circuit, endotrachael tube and airways are critical to delivery of HFV pulses. The more narrow or longer (more resistant), the greater the compliance (more distensible), or the longer and wider the circuit (greater volume for gas expansion), results in lower HFV pulse transmission to the patient. HFV is hampered in the presence of resistive elements (Table 1). Being composed of a rapid succession of phasic pressure bursts, each pulse is so short (18 msec) that there is little time for equilibration of pressure beyond a point of resistance (Figure 1). Contrast this with IMV, where the inspiratory time is typically 0.3 to 0.8 sec. (or 300 to 800 msec). The IMV breath has time to deliver its pressure (volume) beyond a point of partial obstruction; however, air can be trapped beyond the area of resistance, (e.g. the barreled chest radiograph of a meconium aspiration pneumonitis).

TABLE 1

Resistive Elements	Corrective Action
1. long, narrow or tortuous circuit	use Nellcor Puritan Bennett approved HFV circuit or equivalent
2. long, or narrow ET tube	use shortest & largest ET tube which will fit the airway
3. ET tube secretions	lavage and suction when needed
4. airway secretions	lavage and suction when needed
5. lung and thorax	position patient for maximal HFV vibration

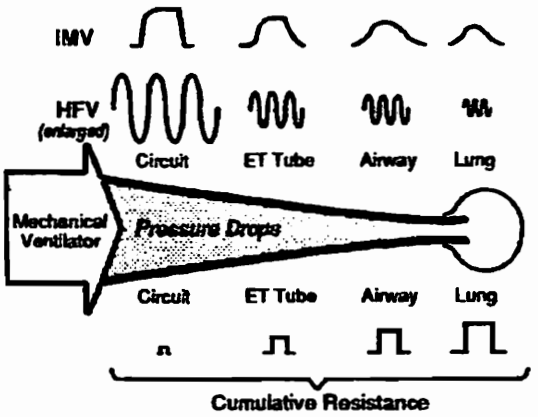


Figure 1: Affects of Resistance on IMV and HFV Pressure Waveforms

SECTION 15

950 HFV MODES OPERATING INSTRUCTIONS

A. Initial Preparation and Considerations

Refer to Illustrations 11 and 12, front and rear ventilator views, to become familiar with the position of controls and features.

The Infant *Star* 950 can provide **HFV ONLY**, or a combination of **HFV + IMV**. The transition from conventional ventilation (IMV) to HFV, with or without IMV back-up, is easily accomplished. Below we will describe both **HFV + IMV** and **HFV ONLY** techniques. The following instructions are based on the assumption that the patient is already receiving conventional ventilation. Refer to sections 1-9 of this manual for Operating Instructions related to conventional modes **IMV** and **CPAP**.

The following techniques are discussed in a generic format. They are not intended to replace or be a substitute for trained physician experience.

WARNING

Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons:
1) Some malfunctions require immediate corrective action.
2) An alarm, or combination of alarms, is not assurance of warning in the event of any and every form of malfunction of the ventilator or system components.

WARNING

Pneumatic pulse energy that is lost between the ventilator and the infant can reduce HFV amplitude (tidal volume). Reduction in amplitude can be caused by increased compressible volumes and resistance within the patient breathing circuit and humidifier chamber. Variations in the displayed **HFV AMPLITUDE** can be due to many conditions, including low water level in the humidifier, kinks or leaks in the patient circuit, changing patient compliance or resistance, mucous plugs or a change in position of the endotracheal tube.
* Monitor and maintain the humidifier water level hourly.
* Avoid ninety degree bends within the patient breathing circuit.
* Use only low compliance humidifiers and breathing circuits, such as Part Numbers 0501200 and 0501023, respectively.

NOTE: *Star* Sync should be turned off during High Frequency Ventilation. Patient triggered ventilation via the *Star* Sync interface is inactive during High Frequency Ventilation. Data displayed on *Star* Sync is inaccurate during HFV.

NOTE: Patient breathing circuit configuration and position are critical to the successful application of high frequency ventilation. In order to minimize water accumulation within the circuit, the following is recommended:

1) Whenever possible, a heated wire configuration should be used.
2) Prevent water accumulation within the proximal pressure line by draping the circuit in such a manner as to locate the proximal pressure port above the patient or by placing a hydrophobic filter inline P/N 4403017.

B. Pre-HFV Initiation

1. Adjust the **HFV AMPLITUDE** control counter-clockwise to select the minimum setting.

NOTE: The full range of amplitude adjustment is achieved in approximately 3 to 4 full turns. The **HFV AMPLITUDE** control knob will continue to turn beyond the minimum and maximum settings, however an increase in rotational resistance will be felt.

2. Rotate the mechanical **PRESSURE RELIEF** valve fully clockwise (5 o'clock position).

NOTE: While using either HFV mode, the **PRESSURE RELIEF** valve should be completely closed (turned fully clockwise). For use in any other mode, refer to the Operating Instructions section 4 of this manual.

3. Turn the **HFV ON/OFF** key lock mechanism to the **ON** position (located on the rear of the pneumatics compartment).
4. Set the desired **HFV RATE**.
5. Record the **MAP** (displayed in the **MEAN** window).

NOTE: Employing a "high volume strategy" or some back-up IMV breaths, may reduce the risk of atelectasis. CO_2 removal can occur very readily with HFV in a grossly atelectatic lung, however oxygenation is adversely affected. Maintenance of a mean lung volume is essential. Periodic IMV breaths (sighs) may help attain this goal. Serial x-rays may assist in the assessment of mean lung volume.

C. Technique of Initiating High Frequency Ventilation

1. Turn the **MODE** control knob to **HFV ONLY** or **HFV + IMV**. Oscillation pulses will Start. If **HFV + IMV** mode selected, oscillations will cease immediately before, during and immediately after each IMV breath (tracing 3a & 3b).
2. Increase the amplitude to the desired level (the patient's chest visibly vibrates).

WARNING

Changes in airway patency, or patient compliance may alter the effect of each HFV pulse. Observing the patient's chest movement is an important aspect of patient monitoring during High Frequency Ventilation. Externally monitor SaO_2, $TcPCO_2$ and arterial blood pressure whenever performing High Frequency Ventilation to provide early detection of changing conditions.

3. If **HFV + IMV** mode is selected the IMV rate is typically reduced to between 1 and 10 breaths/minute.
4. The **PEEP/CPAP** setting is used to adjust MAP. Typically the MAP is restored to pre-HFV level, recorded in Pre-HFV Initiation step 5, to maintain oxygenation.

WARNING

When using low background flows with low IMV rates and/or low HFV amplitudes, major changes in the **OXYGEN PERCENT** control may require 30-45 seconds before the new concentration reaches the patients' airway.

WARNING

When using a short IMV **INSPIRATORY TIME** and/or a **HFV** mode, the **PROXIMAL AIRWAY PRESSURE** analog gauge will not respond quickly enough. Under these circumstances, the digital **PIP**, **MEAN**, **PEEP/CPAP** and **HFV AMPLITUDE** displays should be used exclusively. The **PIP** display relates to the IMV breath only.

D. Auscultation, ultrasound and chest radiography

Chest auscultation for breath or heart sounds is virtually impossible in the HFV mode. Cardiac ultrasonography shows some movement associated with HFV, but this does not hinder performance of a complete study. Chest x-rays can be performed without concern of HFV.

E. Airway Suctioning

Airway care is critical to HFV performance. It is a common finding to have an abundance of secretions in the first several hours of HFV therapy. It may become necessary to lavage and suction about every 30 minutes for the first few hours. Pre-treatment may be needed to help reduce a fall in PaO_2 and rise in $PaCO_2$ during suctioning.
You may wish to:

a) Increase IMV rate by 10 bpm one minute before suctioning or use manual breaths if **HFV ONLY** mode selected. Remember to return the **VENTILATOR RATE** to the pre-suction value.
b) Increase **OXYGEN PERCENT** setting to pre-oxygenate one minute before suctioning. Remember to return to the previous setting following the procedure.

Closed suction systems specially designed for HFV are available, e.g. Ballard, to avoid disconnecting the patient for suctioning. However, if the patient can tolerate a short disconnection period (3-5 seconds), disconnect the wye and instill saline allowing time for

the solution to traverse the ET tube. Otherwise, the saline may be propelled out of the ET tube by HFV pulse activity. A double lumen ET tube, if available, would provide an excellent port for instilling saline at the distal end of the ET tube without the need for disconnection.

Selected Reading:

1. Kopotic RJ, Mannino FL: Carbon dioxide removal as affected by high frequency ventilation rate. Crit Care Med 16: 378, 1988.

2. McCulloch PR, Forkert PG, Froese AB: The role of lung volume maintenance during high frequency oscillatory ventilation in surfactant deficient rabbits. Am Rev Resp Dis 133: A154, 1986.

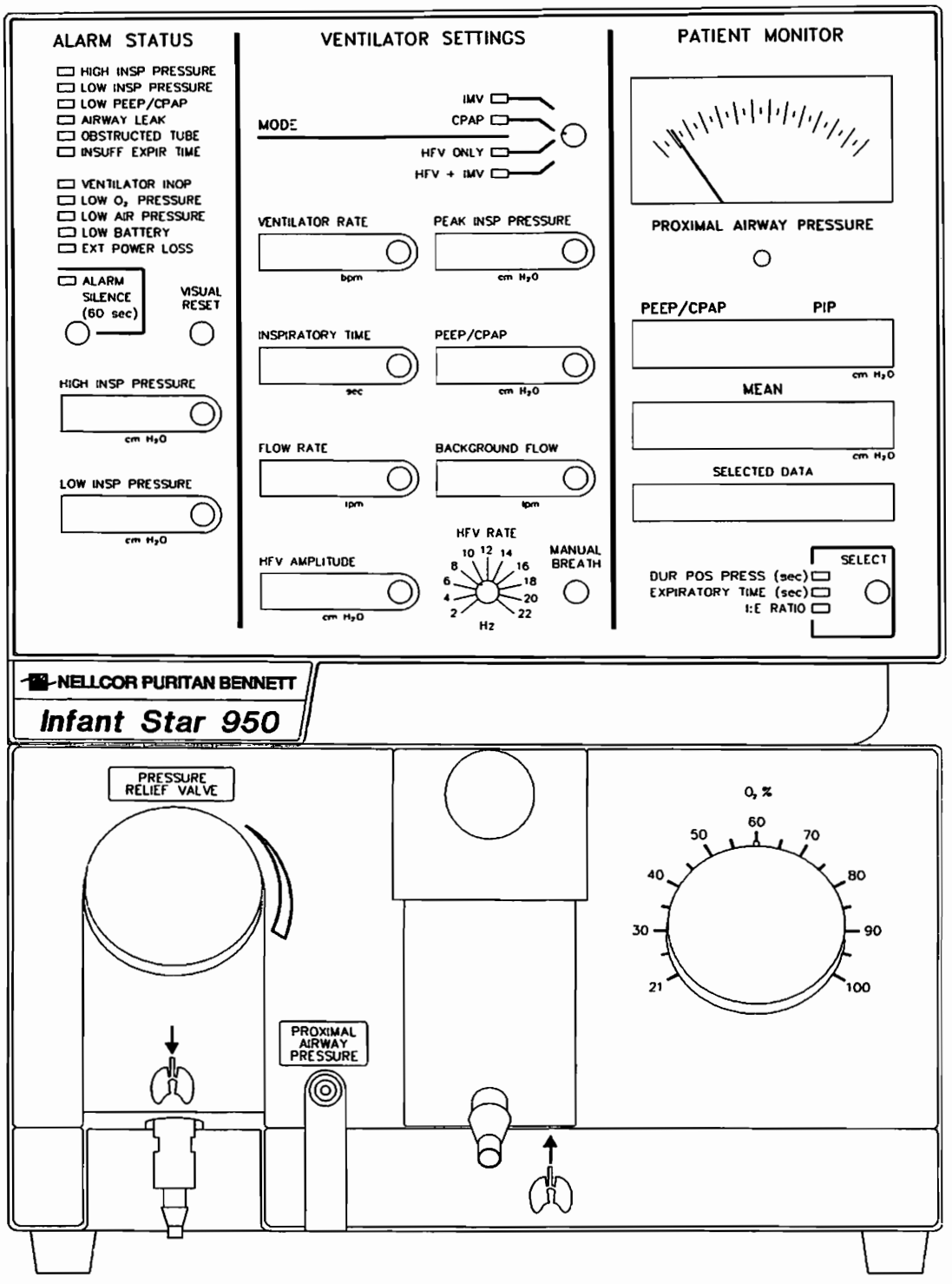


Illustration 11 - Front of Infant *Star* 950

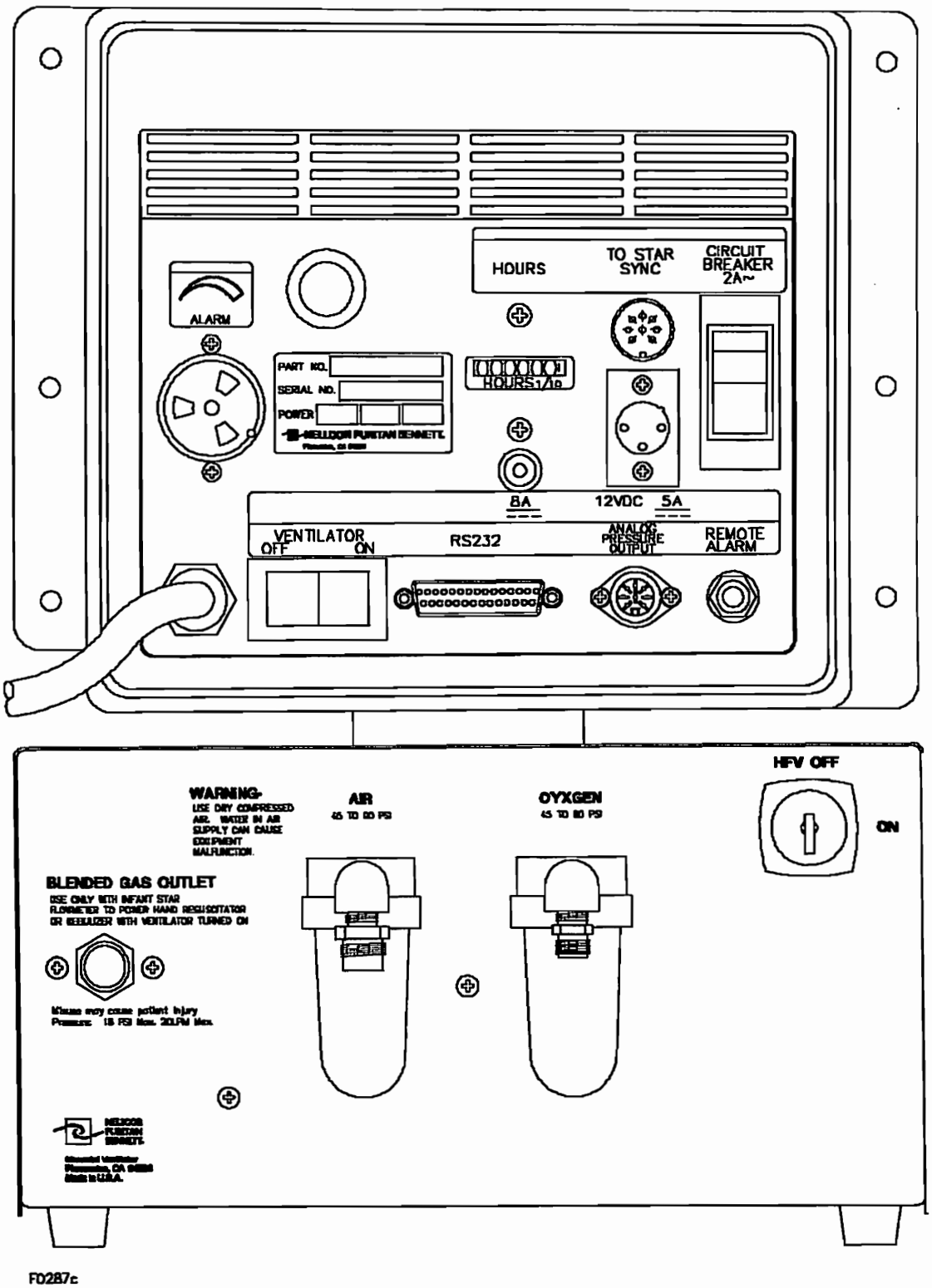


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Illustration 12- Back of Infant *Star* 950

SECTION 16

ASSOCIATED COMPONENTS

The High Frequency Ventilator is only part of the overall gas exchange system. This system consists of the ventilator, humidifier, breathing circuit and patient. Since the compliance and resistances encountered in this system affect the overall peak high frequency amplitude (and therefore delivered tidal volume) it is necessary to optimize the efficiency of these components. This has been done with the Nellcor Puritan Bennett breathing circuit and humidifier designs discussed below. Refer to the Fisher & Paykel Operating Manual for guidelines on the care, cleaning and sterilization of the humidifier components.

A. Circuit:

The Nellcor Puritan Bennett reusable HFV breathing circuit, P/N 0501023, is highly recommended in conjunction with the F&P humidifier for HFV use. Together they will provide approximately 25% greater amplitude proximally, which translates to a 12% increase distally (in 3.0 E.T. tube, 1 ml/cm test lung) over the conventional Nellcor Puritan Bennett circuit (P/N 0501011). The HFV circuit (P/N 0501023) will function in both conventional and high frequency modes.

The low compliance breathing circuit consists of a 30-inch Tygon inspiratory tube with a Tygon expiratory tube of 36 inches. A water trap is located 24 inches from the proximal wye. To reduce condensation accumulation, maximize water vapor delivery and minimize gas turbulence, the inspiratory tube contains a special Teflon jacketed, small diameter heater wire. Finally, a 32-inch proximal pressure tube, infant wye, and a 6-inch Tygon tube from ventilator to humidifier complete the circuit.

B. Humidifier:

The Fisher & Paykel Humidifier (P/N 0501200) should be used in the HFV mode. Several models are available. This unit can also be used in conventional modes. The reusable (P/N 0501209), or single-use (P/N 0501210) low compressible chambers are used with the F&P humidifier. The special Teflon jacketed, inspiratory tube heater wire should also be included.

Beware that the humidifier represents the greatest area of compliance in the circuit. It is imperative that the fluid level be maintained at or near "maximum water level" marking. Failure to do so will cause a reduction in HFV amplitude. The higher the desired amplitude, the greater the flow output and water consumed for humidification. There is currently no automatic water feed, hence, the water level should be checked often and water added at least every hour while in the HFV mode.

Selected Reading:

1. Kopotic RJ: The role of humidifiers in regulation of neutral thermal environment. J Perinatl 1:66-70, 1981.

Mandatory Reading:

1. MR 600, 700 or 730 Dual Servo Heated Respiratory Humidifier Operating Manuals, Fisher and Paykel Medical Products~ LTD., New Zealand.

NOTE: Refer to the applicable Humidifier Operating Instructions for the model humidifier used before instituting High Frequency Ventilation.

SECTION 17

INFANT *STAR* 950 QUICK CHECKOUT PROCEDURE

WARNING

If in the course of operating the ventilator, a mechanical or electrical problem is suspected, the unit should be removed from use and checked by qualified biomedical personnel.

NOTE: NOTE:The Quick Checkout Procedure is based using a Nellcor Puritan Bennett high frequency breathing circuit (P/N 0501023), a Fisher & Paykel low compressible volume humidifier chamber (P/N 0501209) and standard test lung (P/N 1101262).

1. Connect both source gases and electrical power, attach the patient circuit, humidifier, and test lung. Turn the **VENTILATOR ON/OFF** power switch to **ON** position. Observe:

   a. All segments on all digital displays are illuminated and bright.
   b. All LED indicators are illuminated except **EXT POWER LOSS**, **VENTILATOR INOP**, and **LOW BATTERY**. **VENTILATOR INOP** may blink during power up.
   c. An audible alarm momentarily sounds.
   d. A software revision number appears in the **SELECTED DATA** window

2. Establish the following Standard Test Conditions:

MODE	IMV
VENTILATOR RATE	30 bpm
PEAK INSP PRESSURE	40 cm H_2O
PEEP/CPAP	0 cm H_2O
INSPIRATORY TIME	0.5 sec
FLOW RATE	20 lpm
BACKGROUND FLOW	4 lpm
HIGH INSP PRESSURE	45 cm H_2O
LOW INSP PRESSURE	3 cm H_2O
HFV RATE	12 Hz.
HFV AMPLITUDE	Fully Counterclockwise
SELECTED DATA display	ExpiratoryTime
OXYGEN PERCENT	60
PRESSURE RELIEF VALVE	Fully Clockwise
HFV Key	ON

3. Observe the following:
   a. No HFV Oscillations can be heard
   b. **PEEP/CPAP** OF 0 cm H_2O
   c. **PEAK INSP PRESSURE** of 40 +/- 1 cm H_2O
   d. **MEAN** Airway Pressure of 9 +/- 1 cm H_2O
   e. **EXPIRATORY TIME** of 1.5 sec.

4. During a mechanical breath, completely kink the **FROM PATIENT** tube. Verify that the proximal pressure drops abruptly following an **A03** alarm activation.

5. Disconnect **TO PATIENT** tube at the ventilator and occlude outlet. Verify an **A05 OBSTRUCTED TUBE** alarm and **LOW INSP PRESSURE** alarms and displays. Reconnect the tube and the alarm should self cancel. Push the visual reset button to clear the visual alarms.

6. Turn **MODE** switch to **HFV + IMV**. Rotate the **HFV AMPLITUDE** control fully clockwise. High Frequency pulses should become visible on the analog gauge and audible in between the mechanical IMV breaths. High Frequency pulses should not occur during an IMV breath. **HFV AMPLITUDE** display should register at least 34 cm H_2O. **HFV AMPLITUDE** level will vary based upon compressible volumes in the humidifier, breathing circuit, and test lung. For example, if the water level within the humidifier is low, the compressible volume increases and amplitude decreases.

7. Rotate the **HFV RATE** control to 20 Hz. HFV pulses should become extremely rapid (too numerous to count). Turn the **HFV RATE** control back to 2 Hz and HFV should be relatively slow (approximately 3 pulses in between IMV breaths). Set the **HFV RATE** back to 12 Hz.

8. Turn the **HFV AMPLITUDE** control knob fully counter-clockwise. Amplitude should incrementally decrease to a minimum of 6 to 13 cm H_2O.

9. Set the following:

MODE	CPAP
PEEP/CPAP	10 cm H_2O
BACKGROUND FLOW	8 lpm

Notice that the **PEEP** of 10 cm H_2O is shown in a total of five displays: **PROXIMAL AIRWAY PRESSURE** gauge; **PEEP/CPAP** and **MEAN** Airway Pressure monitor displays; **PEEP/CPAP** and **LOW INSP PRESSURE** setting displays.

There should be no high frequency oscillations.

After checking at 10 cm H_2O set the **PEEP/CPAP** control to 20 cm H_2O and again observe the five displays now read 20 cm H_2O.

If the unit does not pass the Quick Checkout Procedure, the ventilator should be removed from use and referred to qualified biomedical personnel.

CE 0123

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1.800.NELLCOR
Customer Service, Press 1
Technical Service Press 2

INFANT STAR

Reference Sheet

- ON-OFF button located on the back of ventilator, takes 30 seconds for ventilator to go through a self-check.
- ALARM button last 60 seconds.
- VENTILATOR KNOBS push in first, then turn.
- FiO2 takes 30 seconds for set O2 to initiate.

NEW CIRUIT SET-UP

- Short blue tubing connects at the inspiratory port down to the choncha column.
- Long blue tubing connects at the choncha column.
- White tubing connects at the expiratory block.

- **PRE-SET SETTINGS**

- Flow rate 10 liters
- I-time .35 sec.
- Pip 20 cmH20
- Rate 30 bpm
- Peep 5 cmH20
- Low pressure alarm ~~set the same as peep~~
- Pop-off 5 cmH20 above set pip
- FiO2 100%

• TROUBLESHOOTING

Pop off

Clockwise turn will increase

Counterclockwise will decrease

To achieve 5 cm H_2O above set PIP turn knob counterclockwise until PIP display reads one below set PIP then turn pop-off clockwise 1/3 turn. That should be at least 4–6 cm H_2O above set PIP.

To check set pop-off pressure turn PIP knob until it reads 5 above your set PIP (Do not do this part when baby is on the ventilator). You can also do this part for pop-off check without doing the 1/3 turn.

Heater

Set dial at 4 to initiate temperature control

Rainout dial is at the bottom of the heater that shows an arrow and the arrow should be one quarter turn clockwise from the start

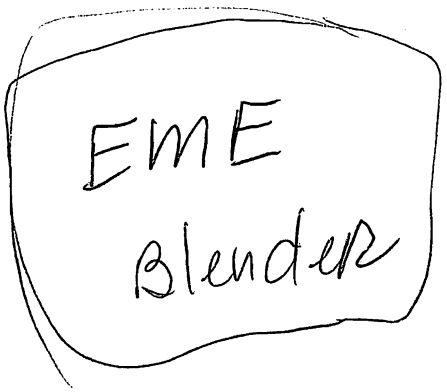
STAR SYNC

Turn the infant star to CPAP cont. flow then on the star sync turn the knob to SIMV then set the rate you want.

Even though the infant star says CPAP the STAR SYNC rate overrides the rate on the ventilator.

- **MOST COMMON ALARMS AND PROBLEMS WITH THE INFANT STAR**

1. **Heater alarm - H_2O may not be plugged in or H_2O is empty**
2. **High pressure alarm - H_2O in tubing or tubing is kinked**
3. **Low pressure alarm – Check all connections]**
4. **H_2O in tubing – Decrease rainout by turning the arrow counterclockwise on bottom of heater**


EME
Blender

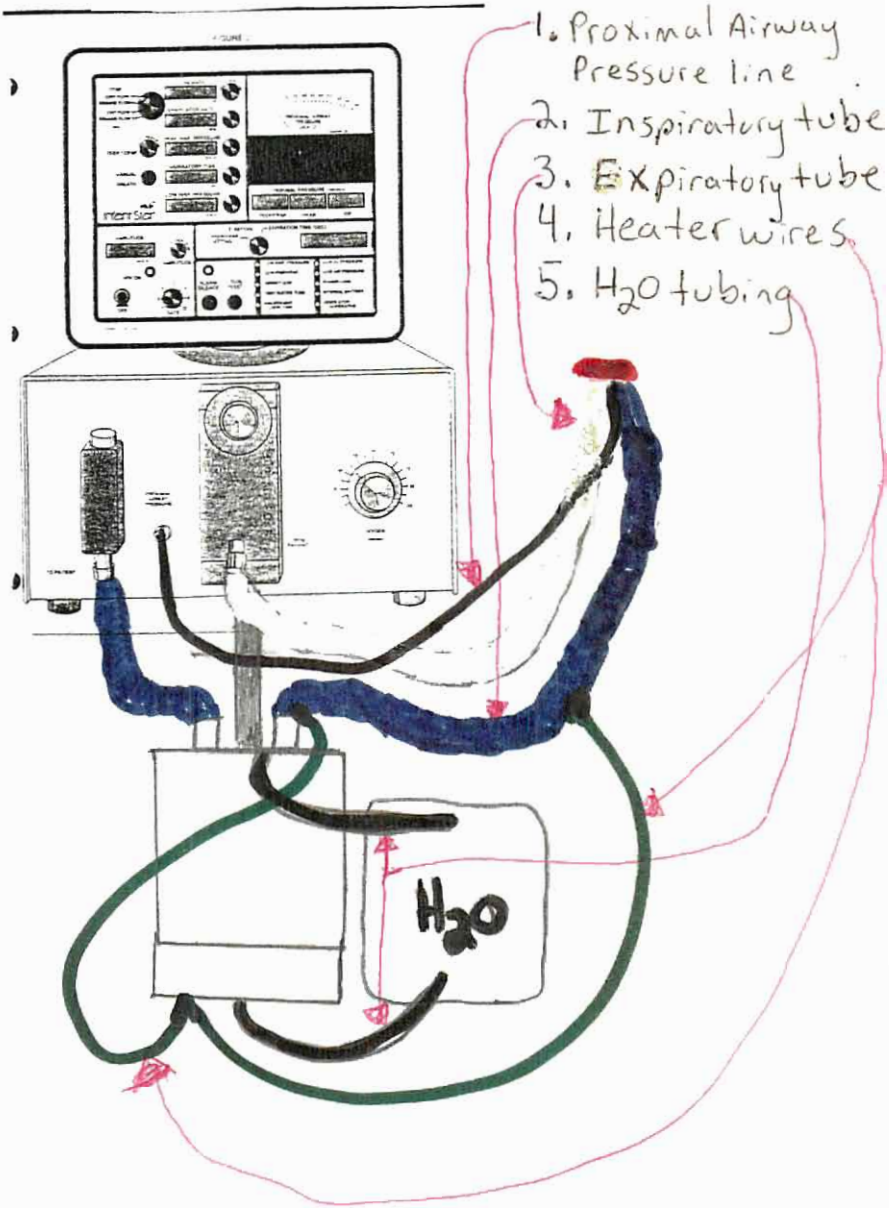
- **TREATMENTS**

MDIs

Disconnect tube port from baby ETT tube, but push alarm button first
Then with the baby ambu-bag attach to MDI spacer and connect it to ETT tube and bag MDI treatment.
FYI **Check to see if pre-oxygenate to 100% before treatment!**

NEBs

Connect tubing to blue inspiratory tubing close to the patient port
Turn pop-off counterclockwise to either set PIP or one below PIP to ensure baby does not receive a higher set PIP
Set flow for neb at 6 to 8 liters and watch both the patient and ventilator
After treatment put pop-off back to original setting


1. Proximal Airway Pressure line
2. Inspiratory tube
3. Expiratory tube
4. Heater wires
5. H_2O tubing
H_2O

INFANT STAR

Reference Sheet

- **ON-OFF button located on the back of ventilator, takes 30 seconds for**
- **ALARM button last 60 seconds.**
- **VENTILATOR KNOBS push in first, then turn.**
- **FiO2 takes 30 seconds for set O2 to intiate.**

NEW CIRUIT SET-UP

- short blue tubing connects at the inspiratory port down to the choncha column.
- Long blue tubing connects at the choncha column.
- White tubing connects at the expiratory block.

STAR SYNC

Turn the infant star to CPAP cont. flow then on the star sync turn the knob to SIMV then set the rate you want.

Even though the infant star says CPAP the STAR SYNC rate overrides the rate on the ventilator.

- PRE-SET SETTINGS

- Flow rate 10 liters
- I-time .35 sec.
- Pip 20 cmH20
- Rate 30 bpm
- Peep 5 cmH20
- Low pressure alarm set the same as peep
- Pop-off 5 cmH20 above set pip
- FiO2 100%

• TREATMENTS

MDIs

First push the alarm button then disconnect the circuit port from the ETT.
Then with the baby ambu-bag attach the MDI spacer and connect it to ETT tube and bag MDI treatment.
Check to see if pre-oxygenate to 100% before treatment is ok.

NEBs

First push the alarm button then connect neb to inspiratory tubing.
Turn pop-off counterclockwise to either set PIP or one below PIP to ensure baby does not receive a higher set PIP
Set flow for neb at 6 to 8 liters and watch ventilator pressure manometer.
After treatment put pop-off back to original setting

• MOST COMMON ALARMS AND PROBLEMS WITH THE INFANT STAR

1. **Heater alarm - H_2O may not be plugged in or H_2O is empty**
2. **High pressure alarm - H_2O in tubing or tubing is kinked**
3. **Low pressure alarm – Check all connections]**
4. **H_2O in tubing – Decrease rainout by turning the arrow counterclockwise on bottom of heater**

CONCHATHERM® IV *Plus* Quick Reference Guide

Initiate Gas Flow:

Minimum Flow Rates
Adult Mode: 3 LPM heated-wire circuit, 5 LPM non-heated wire circuit
Infant Mode: 2 LPM heated-wire or non-heated wire circuit

On/Off:

Toggle switch located beneath *Hudson RCI* logo on underneath side

Adult/Infant Mode:

Hold SET key and press ADULT/INFANT key to select (once for infant, twice for adult)

Patient Airway Temperature:

Hold SET key and press the Up/Down TEMPERATURE keys (Range: 30 - 39°C)
Note: The humidifier must have 10 seconds of keypad inactivity to record the *new* setting into memory

Temperature Gradient:

Hold SET key and press TEMP GRADIENT arrows to **left** for **less** moisture or right for more moisture (each bar represents 0.5° C)
Recommendation: Begin 2 bars to the left of zero, observe condensate in inspiratory tubing and modify temperature gradient as needed.
Note: The humidifier must have 10 seconds of keypad inactivity to record the *new* setting into memory

Pause:

Adjustable from 5-60 minutes, in 5-minute increments
To adjust pause time, hold PAUSE key and press Up/Down TEMPERATURE keys
Note: The humidifier must have 10 seconds of keypad inactivity to record the *new* setting into memory
To view the pause time, press PAUSE key
To Activate or deactivate the pause mode, press SET and PAUSE simultaneously

Note: When multiple settings have been changed, the humidifier must have 10 seconds of keypad inactivity, after the last change, to record all settings into memory

HUDSON RCI
Breathing, made easier

CONCHATHERM® IV *Plus* Alarms

Press ALARM MUTE to silence the audible alarm for 60 seconds

Priority Alarms (Red Status Indicator Light and Audible Alarm):

To reset alarm, turn power off, wait 60 seconds, and then apply power

HIGH TEMP: High temperature at column outlet

3) Low/no flow through column or reservoir, correct low/no flow condition
4) Low water level in column or reservoir, replace water reservoir and/or column

CHECK PROBE: Temp probe dislodged or disconnected, insert probe securely into breathing circuit

BAD PROBE: Open circuit or short circuit in temperature probe

1) Temp probe not properly connected, properly connect probe
2) Temp probe/cable failure, replace temp probe

SERVICE: Unit failed self-diagnostic check, remove unit from service

INSP WIRE DISCONNECT: Inspiratory heated-wire disconnected. Reconnect inspiratory wire. To reset alarm, press SET and RESET

Cautionary Alarms (Yellow Status Indicator Light and Audible Alarm):

To reset alarm, press SET and RESET

HIGH TEMP: Airway temperature > 41°C or more than 2°C above Set Temp, power is discontinued to heater and wires, power returns when temp falls back w/in limits (self-correcting), check temperature setting

LOW TEMP:

3) Airway temp more than 2°C below set temp, initiate an additional warm-up period
4) Column temperature < 31°C, airway temp improperly set for ambient and/or ventilatory conditions, set proper airway temp

EXP WIRE DISCONNECT: Expiratory heated-wire disconnected, reconnect expiratory wire

Any protocol which has been established for initiating conventional mechanical ventilation is equally appropriate for the addition of Star Sync with the following recommendations:

1. Establish the standard ventilator parameters for the infant to be ventilated.

2. Make sure all Star Sync and Infant Star connectors and/or cables are intact.

3. Connect the abdominal sensor to the front of Star Sync.

4. Turn the Mode Switch to MONITOR.

5. Turn **ON** the Star Sync ON/OFF switch.

6. Proper sensor placement is achieved by:

   a. Visually locating a point of optimum outward movement of the abdomen during inspiration.

   b. Supine - In supine position, assessment of the patient's breath pattern must be noted:

      - paradoxical breathing (abdomen moving outward and the chest moving inward) is the most common neonatal respiration pattern. Midline, anterior placement, midway between the umbilicus and xiphisternum is usually optimal (See Illustration 16)

      - Severe sub-costal retractions or pectus excavatum may occur. If these patterns are present, extreme care must be taken to avoid the portion of the upper abdomen that collapses with the chest during inspiration, thus moves outward during expiration (Noted as "A" in Illustration 15). This area may trigger breaths asynchronously and is easily avoided by repositioning the capsule. In large infants, a site on the upper chest, detecting intercostal muscle movement, may be utilized for reliable synchronization.

   c. Prone - In the prone position, non-respiratory movements may be detected if the capsule remains under the infant. Placement of the sensor laterally on the abdomen, with the tubing over the back, may be necessary to avoid asynchrony.

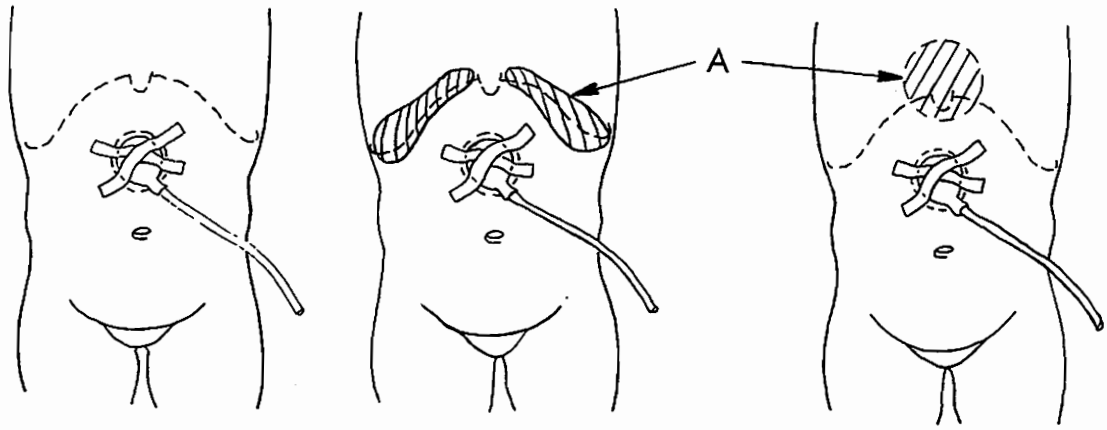


Illustration 16 - Patient Interface Placement (Supine Position)

d. Tape the sensor firmly into position with two 2 inch lengths of non-allergenic micropore tape, making an "X" over the capsule. Position the tubing toward the ventilator.

7. Select the mode of ventilation:

a. If the infant is being monitored only (without Apnea Backup ventilation), leave the Mode Control in the MONITOR position. Set the APNEA ALARM Setting to the desired delay from 5-60 seconds.

b. If the infant is to be on CPAP with BACKUP ventilation, establish the following parameters:

- Set the APNEA ALARM Setting to the desired apnea interval (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired rate of mechanical breaths to be delivered, should an apnea episode be detected.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the CPAP/BACKUP selection.
- Insure that the SPONTANEOUS LED flashes with each spontaneous breath.

c. If the infant is to be ventilated in SIMV, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired number of mechanical breaths.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the SIMV selection.
- Insure that the SYNCHRONOUS ASSISTED LED flashes with each mechanical breath.
- After one minute, compare the SYNCHRONOUS ASSISTED BREATH RATE to the set CONTROL/SIMV/BACKUP RATE. The two numbers should be similar.

  If they are not similar, there are three possible reasons: (1) the abdominal sensor is not picking up the signal properly. Reposition it according to step 6 above; (2) the infant is having periods of apnea in which controlled breaths are being delivered that are not synchronized; (3) the SIMV Rate is set higher than the spontaneous respiratory rate..

- After one minute, note the number of controlled breaths delivered. A large number of controlled breaths may indicate that the sensor is improperly positioned or ventilator settings are improperly set.

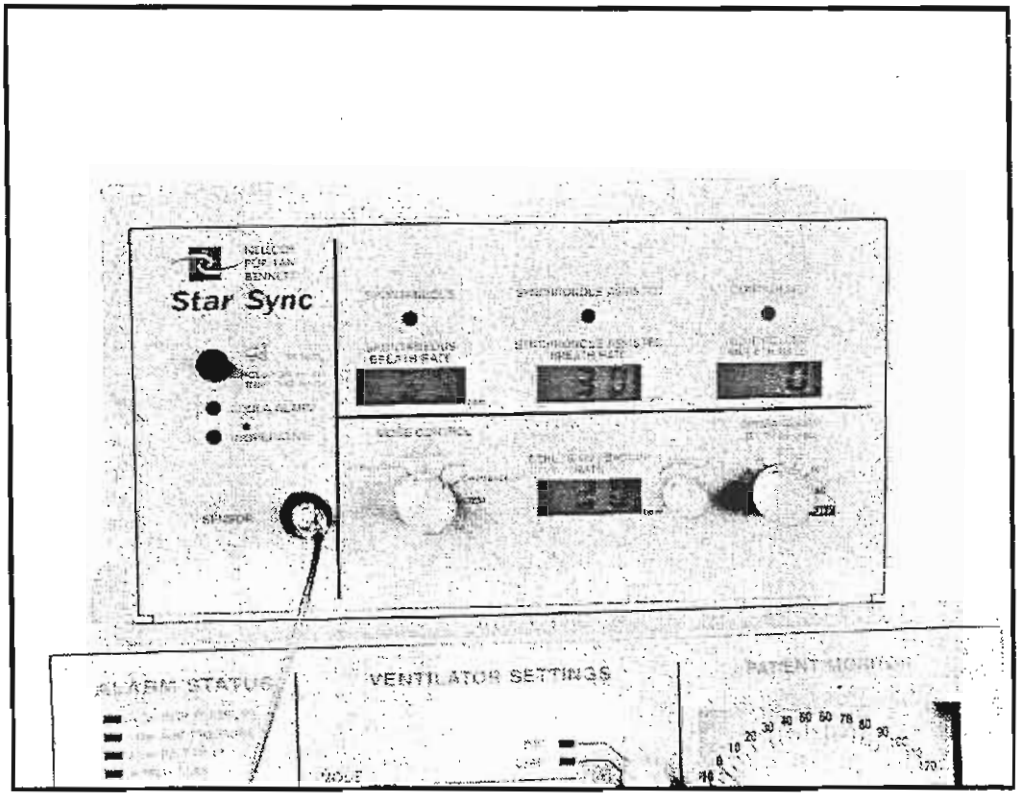
d. If the infant is to be ventilated in ASSIST CONTROL, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).

Star Sync®

Patient-Triggered Interface

OPERATING INSTRUCTIONS



NELLCOR
PURITAN
BENNETT™

Star® Series

Table of Contents

List of Illustrations

DEFINITION OF WARNING, CAUTION, AND NOTE

Statements in the Operating Instructions preceded by the words "WARNING", "CAUTION", and "NOTE" carry special significance. The definitions of these words are as follows:

WARNING
Means there is a possibility of injury to oneself or others.

CAUTION
Means there is a possibility of damage to the instrument or other property.

NOTE Indicates points of particular interest for more efficient and convenient operation.

SUMMARY OF WARNINGS, CAUTIONS, AND NOTES

The WARNINGS, CAUTIONS, and NOTES summarized in this section apply only to the Star Sync Patient Triggered Interface. This unit must be used in conjunction with the Infant Star Ventilator and therefore all WARNINGS, CAUTIONS, and NOTES for the Infant Star apply equally. Prior to use, in addition to this manual, the Infant Star Ventilator Operating Instructions (PN 9910005) should be read.

WARNING
Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons: **1) Some malfunctions require immediate corrective action.** **2) An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.**

WARNING
Failure of the Star Sync will result in the ventilator providing only Continuous Positive Airway Pressure (CPAP) to the patient.

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

WARNING

The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

WARNING

APNEA ALARM SETTING should be set whenever Star Sync is connected to a patient.

WARNING

When establishing ventilator settings, compatibility between mechanical IMV rate and set inspiratory time must be considered. If incompatibility occurs, an alarm will sound, an E2 error code will be displayed in the controlled breath window and the CONTROL/SIMV/BACKUP RATE Display will flash for 5 seconds.

CAUTION

Care must be taken when affixing Star Sync to the Infant Star to prevent damage to the electronics module.

NOTE If TEST Mode is selected after the first 2 seconds following power up, the TEST Mode is not activated and will function identically to the MONITOR Mode.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

NOTE During ASSIST CONTROL and SIMV, the Infant Star Ventilator Rate Display will be blank and the PIP Display will change from Baseline Pressure to Peak Inspiratory Pressure upon delivery of a mechanical breath.

NOTE In the monitor mode, the CONTROL/SIMV/BACKUP Rate display will show the set mechanical rate, however, it is disabled.

NOTE The Star Sync will NOT function during high frequency ventilation with the Infant Star.

NOTE The ALARM SILENCE switch can be activated only during an alarm condition. If not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists.

INTRODUCTION AND SYSTEM DESCRIPTION

The purpose of Star Sync is to promote Patient Triggered Ventilation (PTV) by providing an intelligent link between an abdominal respiration sensor and the Infant Star Ventilator. "Fighting the ventilator" is a common occurrence during asynchrony. Studies have shown that spontaneously breathing infants can easily be synchronized to the mechanical ventilator by the use of PTV. Patient Triggered Ventilation has been shown to reliably match an infant's respiratory needs by a factor of 98.9%.[1]

A picture of the unit is shown below.

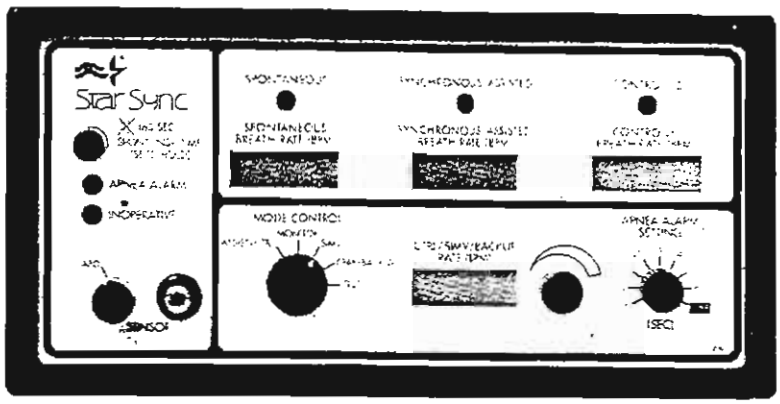


Illustration 1 - Star Sync Patient Triggered Interface

Synchronized Ventilation has long been a standard mode of ventilation in the adult intensive care unit. Today all major adult ventilators have some type of synchronized ventilation.

While IMV is considered a controlled mechanical rate combined with spontaneous breathing, SIMV is viewed as an assisted mechanical rate combined with spontaneous breathing.[2]

SIMV is believed to prevent excessive pressures during mechanical ventilation when the patient is beginning exhalation at the same time as the IMV breath occurs. With standard methods of SIMV, there is some delay in response time due to the delay between the onset of inspiration and time to measure a pressure drop at the proximal airway. Although the concept of SIMV ventilation is the same utilizing Star Sync, the means by which the synchronization occurs is completely different.

Since infants are primarily abdominal breathers, diaphragmatic movement is the first indication of a spontaneous breath. Triggering an SIMV breath on this early indicator of a spontaneous effort, is far more efficient than waiting until an airway pressure gradient occurs.

[1]Bernstein G., et al. "Reliability, Response Time and Consistency of Ventilation during Neonatal Synchronous Intermittent Mandatory Ventilation". Society for Pediatric Research Abstract, Vol. 29, No. 4, Part 2, 1991.

[2]Spearman CB, Sheldon RL, Egan DF. "Chapter 13, Mechanical Ventilation", Egan's Fundamentals of Respiratory Therapy, Fourth Edition, p. 504, 1982.

In the case of Star Sync, the respiratory sensor functions by monitoring intra-abdominal pressure changes due to diaphragm movement. The sensor delivers that signal to Star Sync which connects directly to the Infant Star Ventilator. Sampling of the abdominal sensor occurs 8 times every 5 milliseconds. The response time is 47 $\pm$ 18 milliseconds from the start of inspiration to the onset of the triggered mechanical breath.[3]

The ASSIST CONTROL mode combines patient triggered ventilation with a mechanically set rate as a "backup". In this mode, the patient is allowed to establish a mechanical breath rate by triggering the ventilator with every spontaneous effort. A minimum backup rate is set below that of the patient, in case the patient's breathing pattern slows or stops completely.

The CPAP/BACKUP mode is designed for the patient who has adequate spontaneous ventilation except during brief periods of apnea. Should the patient become apneic, Star Sync will automatically convert to backup ventilation and trigger mechanical breaths attempting to maintain an adequate minute ventilation.

The placement of the abdominal sensor is important in establishing the reliability of the response. During SIMV, the CONTROL/SIMV/BACKUP RATE Display and the SYNCHRONOUS ASSISTED BREATH RATE Display should be close to the same value. A wide difference between these two values may indicate improper sensor placement or periodic patient apneic episodes. The difference between the two displays is the number of controlled, non-synchronized, mechanical breaths per minute and is displayed in the CONTROLLED BREATH RATE window.

All of the patient's spontaneous respiratory movements are monitored and Star Sync synchronizes a mechanical breath in response to the signal received from the sensor, when appropriate.

The Star Sync Patient Triggered Interface is a microprocessor controlled device that connects to the Infant Star Ventilator via a standard DIN connector and cable. Both the power and communication links are conducted through this cable. Since the power for Star Sync is received from the Infant Star, all battery backed features of the ventilator are available.

Standard features of the Infant Star continue to function, including:

1. Full microprocessor control of the gas delivery system.
2. Demand Flow Ventilation to reduce the work of breathing.
3. Automatic correction of inadvertent PEEP.
4. Automatic Obstructed Tube alarms.
5. Built-in patient monitoring.
6. Data output to computer or printer via RS-232.
7. Internal battery for short-term transport. External battery (12VDC) connection for longer transport requirements.
8. Software updatable in the hospital.
9. High Frequency Ventilation Option, when included.

[3]Bernstein, G., et al. "Reliability, Response Time and Consistency of Ventilation, during Neonatal Synchronous Intermittent Mandatory Ventilation", Society for Pediatric Research Abstract, vol. 29, No. 4, Part II, 1991.

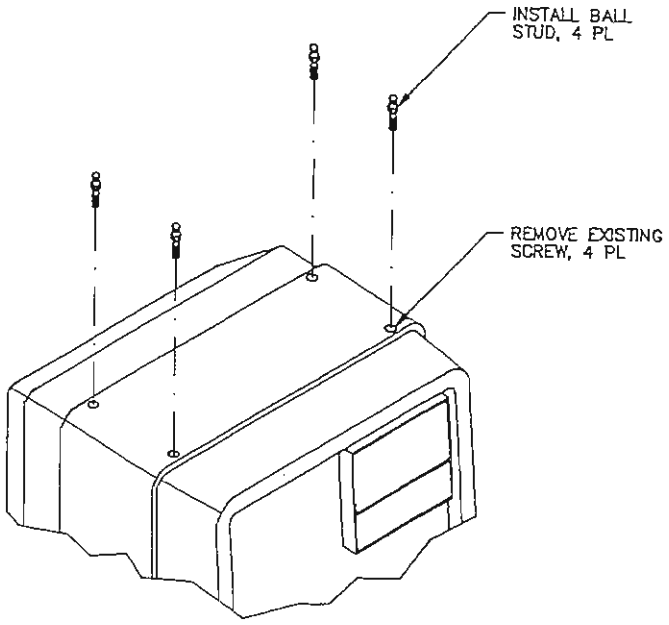


Illustration 2 - Mounting

Star Sync mounts conveniently on top of the Infant Star by replacing the four existing screws with four mounting ball studs. After the mounting studs have been installed, Star Sync will "SNAP" onto the ventilator and swivel in tandem with the electronics module. See Illustration 2.

WARNING

Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons:

1) Some malfunctions require immediate corrective action.

2) An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.

CAUTION

Care must be taken when affixing Star Sync to the Infant Star to prevent damage to the electronics module.

NOTE The Star Sync will NOT function during high frequency ventilation with the Infant Star.

MODES OF OPERATION

Monitor:

When in the monitor mode, the Star Sync will monitor and display the spontaneous respiratory rate. The spontaneous inspiratory time is available by depressing and holding the ALARM SILENCE button for 1 second. The spontaneous inspiratory time will be displayed in the SPONTANEOUS BREATH RATE display window. All other display windows will be blank during this time. A rate will be displayed in the CONTROL/SIMV/BACKUP RATE window, however, this will not be active. Mechanical settings must be obtained directly from the ventilator. The APNEA ALARM setting will be active and may be used as a safety alarm.

When this mode is selected by the operator, Star Sync only monitors the patient. Information is received, but signals are not transmitted back to the Infant Star. This mode has no impact upon patient ventilation and may be used with the Infant Star turned off.

Using the monitoring mode assists in the placement of the abdominal sensor, which is discussed later in this manual.

Synchronized Intermittent Mandatory Ventilation (SIMV):

In this mode, the Star Sync will interface with the Infant Star to synchronize the patient's spontaneous effort with a mechanical ventilator breath.

The SIMV rate will be set on the Star Sync while the Infant Star Ventilator is placed in Continuous or Demand CPAP mode; all mechanical ventilatory parameters and alarms must be established in order to provide the desired minute ventilation. The adjustment range is from 2 - 150 breaths per minute and is displayed in the CONTROL/SIMV/BACKUP RATE display. This rate will determine the mechanical cycle time. For example, if the SIMV rate is set to 30, the cycle time will be 2 seconds (60 seconds/minute divided by 30 breaths/minute).

In between mechanical breaths, the patient may breathe spontaneously from the background flow of gas provided by the Infant Star. If the patient's inspiratory flow exceeds that selected by the operator, the ventilator's inspiratory demand system provides extra gas based upon the pressure gradient created. Unless the breath was synchronized originally, this effort does not trigger the ventilator.

WARNING
Failure of the Star Sync will result in the ventilator providing only Continuous Positive Airway Pressure (CPAP) to the patient.

WARNING
When establishing ventilator settings, compatibility between mechanical IMV rate and set inspiratory time must be considered. If incompatibility occurs, an alarm will sound, an E2 error code will be displayed in the controlled breath window and the CONTROL/SIMV/BACKUP RATE Display will flash for 5 seconds.

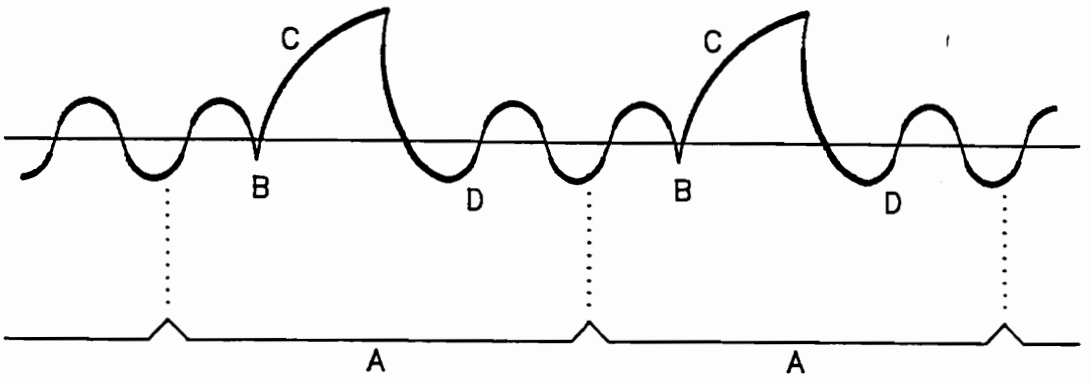


Illustration 3 - SIMV Cycle

Using the 30 breath/minute example, every 2 seconds the SIMV cycle "window" opens. The SIMV "windows" are noted as points "A" in Illustration 3. When Star Sync detects a patient inspiratory effort, (point B) a synchronized mechanical breath is delivered (point C). Upon completion of the mechanical breath, the patient returns to breathing spontaneously on the background flow (point D).

If the patient does not initiate a breath during the SIMV cycle, the ventilator will deliver a controlled breath at the end of that cycle. Star Sync will rearm for the subsequent SIMV cycle. It is important to note that if the patient initiates a breath at the beginning of an SIMV window and then becomes apneic, the patient will not receive another mechanical breath until the end of the next SIMV window, however, the set SIMV rate will be maintained. When these apneic episodes occur, the Apnea Alarm, if active, will trigger audible visual indicators.

WARNING
The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

During the SIMV Mode, Star Sync monitors and displays the spontaneous breath rate, synchronous mandatory breath rate, and controlled breath rate. The spontaneous inspiratory time is available by depressing and holding the ALARM SILENCE button for 1 second.

Assist Control (Assist/Ctrl):

In this mode, the Star Sync will interface with the Infant Star to synchronize every spontaneous effort with a mechanical ventilator breath.

In ASSIST CONTROL, the minimum mechanical ventilator rate is set on the Star Sync (in the CONTROL/SIMV/BACKUP RATE display window) while the Infant Star is placed in Continuous or Demand CPAP mode; all other mechanical ventilatory parameters and alarms must be established in order to provide desired mechanical breaths. The minimum controlled breath range is from 2-120 breaths per minute.

In ASSIST CONTROL, Star Sync synchronizes every spontaneous effort with a mechanical breath. The total mechanical breath rate will be dependent on the baby's spontaneous breath rate.

The selected CONTROL/SIMV/BACKUP RATE will determine the duration of the minimum mechanical window. Every spontaneous breath that is synchronized with a mechanical breath resets the window. Should the spontaneous breath rate decrease to a rate such that the time between breaths is equal to the duration of the mechanical window, a CONTROLLED breath will be delivered and Star Sync will rearm for another cycle.

If Star Sync delivers a mechanical rate of 120 breaths per minute or greater an audible alarm will sound and an "E4" will be displayed in the CONTROLLED BREATH RATE window. The alarm can be silenced for 60 seconds by depressing the ALARM SILENCE button. Engaging the ALARM SILENCE will silence the audible alarm, however, the E4 will continue to flash in the controlled breath display until the ASSIST CONTROL RATE falls below 120 breaths per minute.

CPAP/Backup

In this mode, Star Sync will monitor the patient's spontaneous effort and display the spontaneous respiratory rate. Should the patient become apneic for a period longer than the APNEA ALARM SETTING, Star Sync will automatically convert to Backup Ventilation at the selected mechanical rate (displayed in the CONTROL/SIMV/BACKUP RATE window). The selected mechanical rate is used to identify the starting point for backup ventilation. Following its initiation, Star Sync utilizes a 60 second linear regression to decrease the backup ventilation rate to CPAP. For example, if a backup rate of 30 breaths per minute is selected, the regression shown in Illustration 4 will be employed. After the 60 second period, Star Sync will rearm in the CPAP Mode. The selected backup breath range is from 2-150 breaths per minute.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

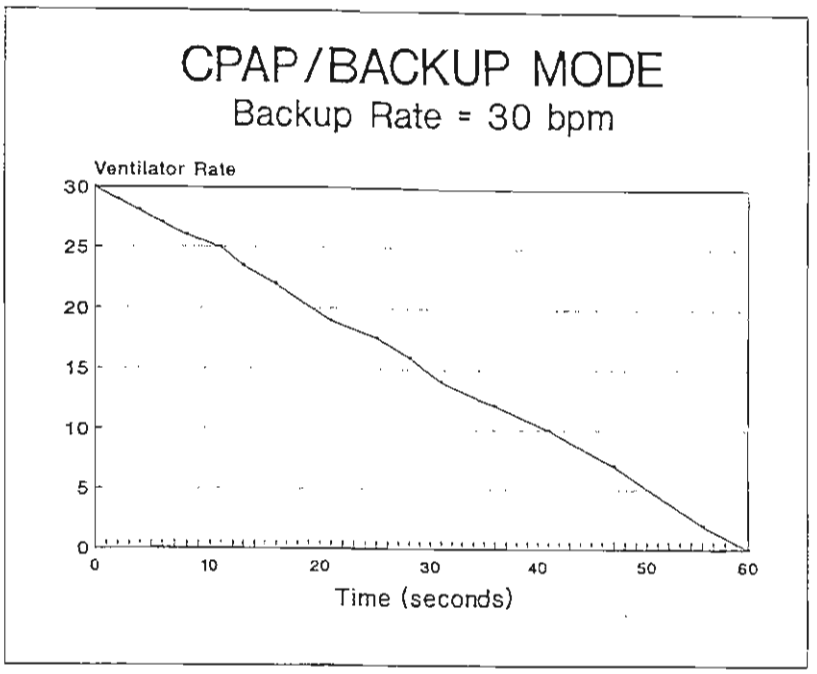


Illustration 4 - CPAP/BACKUP Mode

Test:

This mode is accessible only within the first 2 seconds of powering up the unit. When selected, this mode will verify that the Star Sync Patient Triggered Interface is functioning correctly.

Upon entry, the microprocessor first enables, then disables and counts all the decimal displays. It then displays raw data in the respective display windows as follows:

1. The CONTROL/SIMV/BACKUP RATE display will show the analog signal from the rate adjustment potentiometer.

2. The SPONTANEOUS BREATH RATE display will show the analog signal from the respiration sensor.

3. The SYNCHRONOUS ASSISTED BREATH RATE display will show the switch data from the Sensor Control.

4. The CONTROLLED BREATH RATE display will show the switch data from the APNEA ALARM Setting and the ALARM SILENCE Button.

5. All lamps from the front panel will blink simultaneously.

For more detailed discussion of the TEST Mode, see Star Sync Service & Repair Instructions (PN 9910265).

NOTE If TEST Mode is selected after the first 2 seconds following power up, the TEST Mode is not activated and will function identically to the monitor mode.

CONTROLS AND DISPLAYS

Mode Control:

This control is a multi-position switch located on the front panel (See Illustration 5). The mode of Star Sync operation is established by the operator from the five available selections: ASSIST CONTROL, MONITOR, SIMV, CPAP/BACKUP and TEST. These positions are clearly labeled and described in the previous section of this manual.

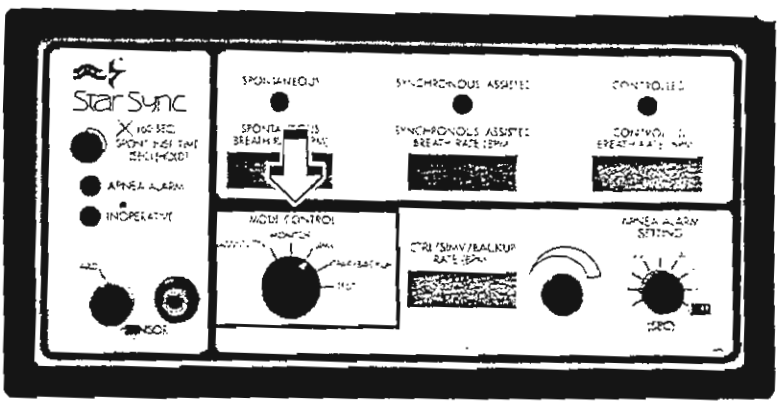


Illustration 5 - Mode Control

Control/SIMV/Backup Rate:

This section is composed of an adjustable control knob and a display window (See Illustration 6).

To set, depress the knob and turn to display desired setting. Clockwise rotation increases the rate and counterclockwise rotation decreases the rate. The function of this display window is dependent on the mode selected.

In the SIMV mode of operation, this knob controls the mechanical breath rate of the ventilator. It is adjustable from 2 - 150 breaths per minute in 1 breath increments.

In the ASSIST CONTROL mode of operation, this knob controls the minimum mechanical breath rate of the ventilator. It is adjustable from 2-120 breaths per minute in 1 breath increments.

In the CPAP/BACKUP mode of operation, this knob controls the starting point for mechanical breaths during backup ventilation.

NOTE In the MONITOR mode, the CONTROL/SIMV/BACKUP Rate display will show the set mechanical rate, however, it is disabled.

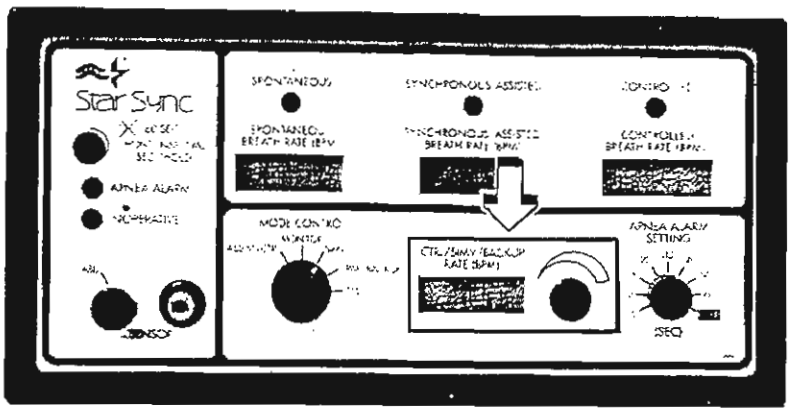


Illustration 6 - CONTROL/SIMV/BACKUP RATE Knob and Display Window

Apnea Alarm Setting:

This control is a multi-position rotary switch located on the front panel (See Illustration 7). It allows the operator to adjust the apnea alarm delay time. Turning the knob fully clockwise to the OFF position will deactivate the alarm, while rotation counterclockwise will establish the apnea delay from 5 - 60 seconds.

In ASSIST CONTROL, SIMV and MONITOR modes the operator may choose to activate the APNEA ALARM. However, during CPAP/BACKUP, an APNEA ALARM must be selected or an audible alarm and an error code will be displayed.

Should spontaneous respirations cease for longer than the selected time, an audible alarm will sound simultaneously accompanied by a flashing red LED. Should the patient resume breathing, the audible alarm ceases and the APNEA ALARM LED continues to illuminate without flashing for 60 seconds. This LED may be reset by pressing the ALARM SILENCE button, or will automatically reset in 60 seconds. This alarm is adjustable in intensity using the APNEA ALARM VOLUME control found on the back panel.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

WARNING
APNEA ALARM SETTING should be set whenever Star Sync is connected to a patient.

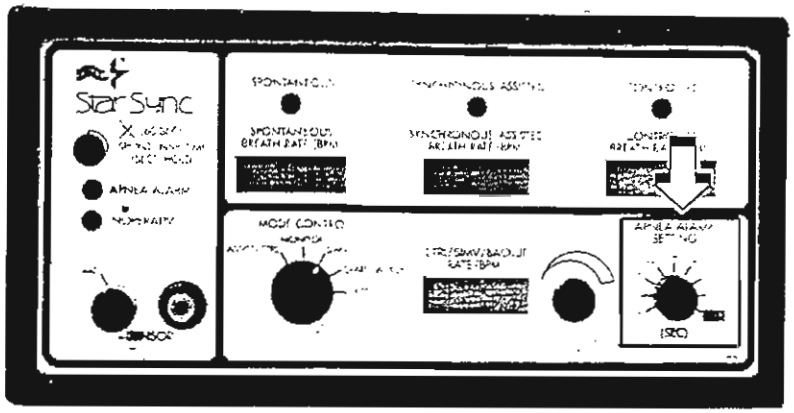


Illustration 7 - Apnea Alarm Setting

Alarm Silence/Spontaneous Inspiratory Time:

The ALARM SILENCE/SPONTANEOUS INSPIRATORY TIME button is located on the front panel (See Illustration 8).

ALARM SILENCE Button - This button will silence an alarm for 60 seconds, however, if the alarm condition still persists, the error code or APNEA ALARM LED will continue to flash. Pushing this button a second time reactivates the alarm immediately.

SPONTANEOUS INSPIRATORY TIME - To access the spontaneous inspiratory time, depress and hold the ALARM SILENCE button for 1 second. The spontaneous inspiratory time will be displayed in the SPONTANEOUS BREATH RATE window. All other windows will be blank during this function. Upon release of the ALARM SILENCE button, all display windows will revert back to previous condition.

NOTE The ALARM SILENCE switch can be activated only during an alarm condition. If not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists.

WARNING
The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

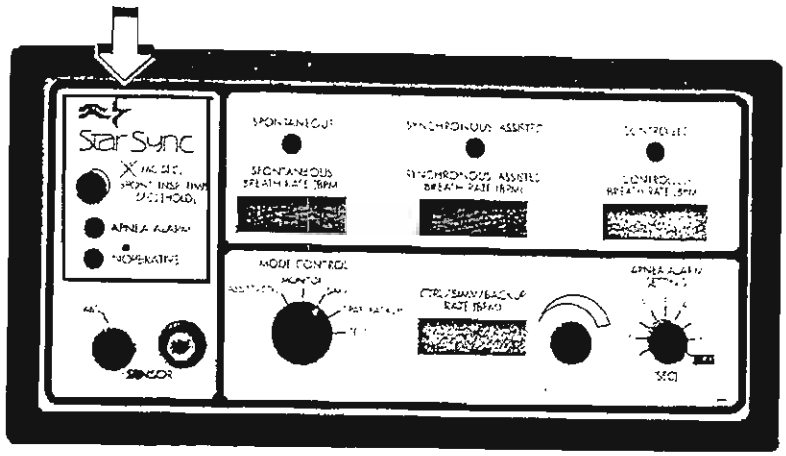


Illustration 8 - Alarm Silence/Spontaneous Inspiratory Time

Abdominal Sensor Port:

The Star Sync sensor port is a Luer-type locking mechanism which connects the patient's abdominal sensor to Star Sync. Adjacent to the sensor port is a rotary switch which is locked in the ABD (abdominal) position. (See Illustration 9) The abdominal sensor must be carefully taped into position so as to respond to abdominal movement (see Patient Interface, Placement Protocol). Improper positioning is the most common cause of poor synchronization.

For specific details concerning proper sensor placement, consult the Patient Interface section.

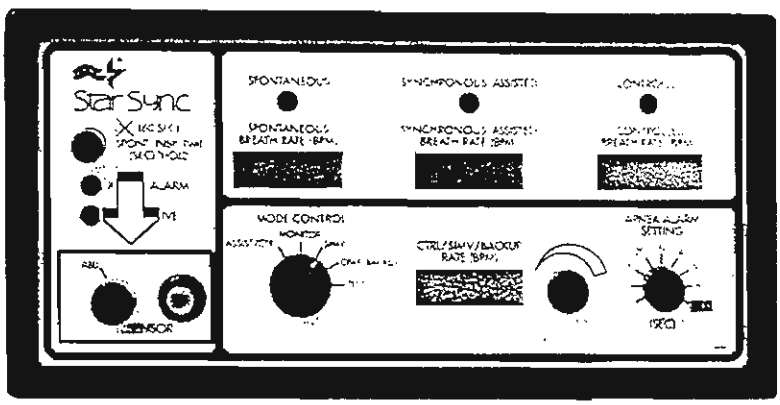


Illustration 9 - Sensor Port and Sensor Site Control

Spontaneous Breath Rate:

The SPONTANEOUS BREATH RATE display window is active in all modes. This window will display all spontaneous breaths detected, including unassisted spontaneous breaths and spontaneous breaths that trigger assisted mechanical breaths. (See Illustration 10)

The Breath Rate is updated every second by counting the number of breaths during the previous 60 seconds.

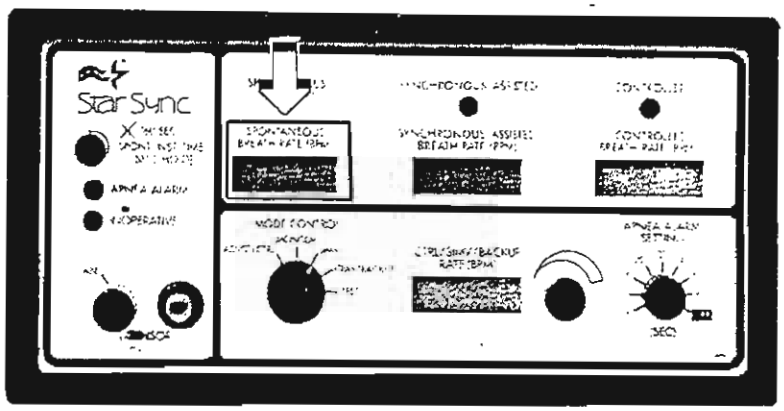


Illustration 10 - Spontaneous Breath Rate Display Window

Synchronous Assisted Breath Rate:

This window displays all synchronized mechanical breaths. (See Illustration 11) It is updated every second by counting the number of synchronized ventilations for the previous 60 seconds. This window is active during ASSIST CONTROL and SIMV and blank during MONITOR and CPAP/BACKUP.

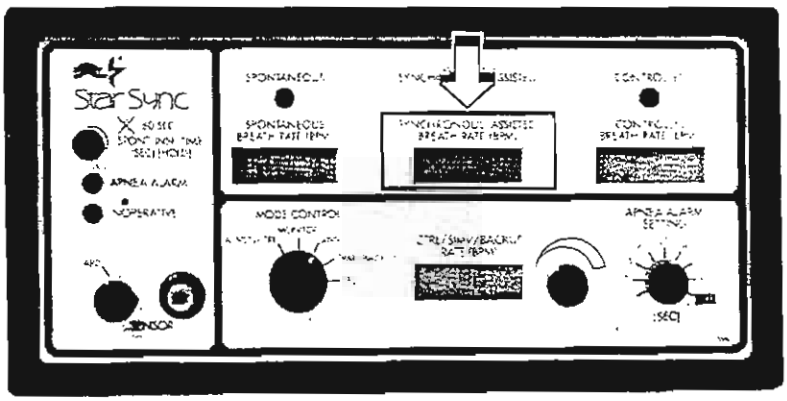


Illustration 11- Synchronous Assisted Breath Rate Display Window

Controlled Breath Rate:

The CONTROLLED BREATH RATE display window is active in all modes. (See Illustration 12) This window will display all controlled, non-synchronized, mechanical breaths. This display is updated every second by counting the number of controlled breaths delivered during the past 60 seconds.

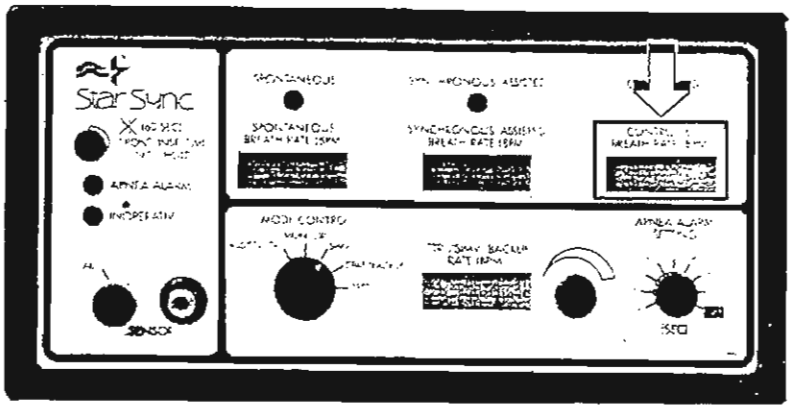


Illustration 12 - Controlled Breath Rate Display Window

Spontaneous, Synchronous, and Controlled Breath LED's:

Small LED's located on top of the Star Sync front panel illuminate, identifying the appropriate breath type. (See Illustration 13)

A spontaneous breath is defined as a patient initiated spontaneous inspiratory effort. A synchronous assisted breath is a mechanical breath which was delivered in response to a patient's inspiratory effort. A controlled breath is a mechanical breath which was delivered without synchronizing to a patient's inspiratory effort.

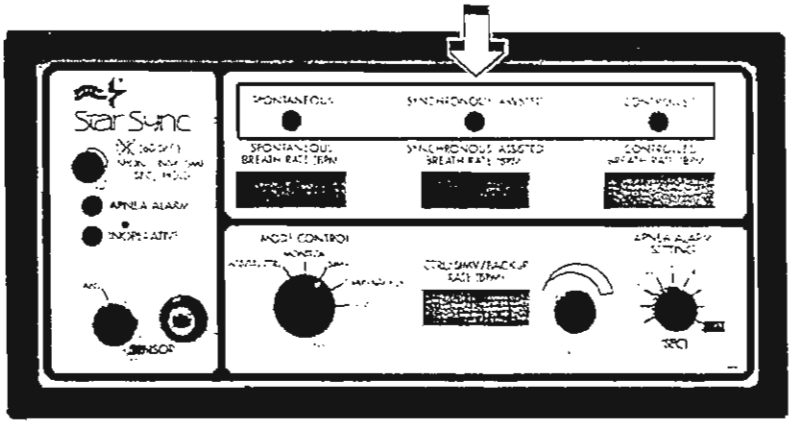


Illustration 13 - Spontaneous, Synchronous, and Controlled LED's

System Inoperative LED:

The System Inoperative LED illuminates simultaneously with the audible alarm when Star Sync cannot operate according to specifications. The Audible alarm cannot be silenced. An error code (listed below) will be displayed in the CONTROLLED BREATH RATE window indicating the cause of the malfunction. This error code should be noted, written down and retained, to assist appropriate service personnel in troubleshooting the System INOP problem.

Error Codes

Error codes occur at two levels. The first level (E1-E5) are usually correctable errors related to incorrect set-up. The second level (E10-E21) indicate mechanical problems with the Star Sync which require Star Sync to be removed from service and evaluated by qualified personnel.

ERROR CODE	REASON FOR FAILURE
E1-	Ventilator did not trigger a breath after it was commanded
E2-	Insufficient expiratory time - indicates incompatible settings
E3-	Ventilator triggered without being told - indicates Infant Star is in IMV
E4-	High Assist Control Rate - mechanical breath rate exceeded 120 breaths per minute
E5-	CPAP/Backup Error - indicates that the Apnea Alarm setting is in the OFF position
E10-	Incorrect signal from the ventilator
E11-	Mode Control switch failure
E12-	Apnea alarm setting switch failure
E13-	Control/SIMV/Backup potentiometer failure
E14-	Speaker failure
E15-	7.5 volt failure
E16-	4.8 volt internal battery failure
E17-	J8 is not connected to the power switch
E18-	Power up ROM checksum failure
E19-	Background ROM checksum failure
E20-	Power up RAM checksum failure
E21-	Background RAM checksum failure

See "Troubleshooting Chart" for possible cause and necessary corrective action when an Error Code is detected.

CONNECTORS AND SWITCHES

ON/OFF Switch:

The rocker-type switch turns the Star Sync unit ON and OFF independent of the Infant Star.

Analog Output:

A BNC connector functions as the respiration sensor's analog signal output. When connected to other instruments, it can be used to view the sensor signal on a strip-chart recorder or oscilloscope. (Not available on TUV/IEC 601 Approved units).

Inspiratory Time:

A BNC connector functions as the signal output for spontaneous inspiratory time. Viewing this signal with a strip-chart or oscilloscope will show how Star Sync is interpreting the analog signal from the respiratory sensor. (Not available on TUV/IEC 601 Approved units).

Output Port:

This port is provided to download information to a printer, terminal, or other intelligent device. (Not available on TUV/IEC 601 Approved units).

"To Infant Star" Connection:

A 9 pin DIN connector serves as the interconnect between Star Sync and the Infant Star Ventilator. Power for the Star Sync, as well as all two-way communication between the two devices is conducted through this connection.

Alarm Volume Control:

This control adjusts the loudness of the audible apnea and inoperative alarms. Turning the knob clockwise increases the volume.

Click Volume Control:

An audible "click" accompanies each spontaneous breath detected by Star Sync. This tone can only be heard when the user is within the immediate vicinity of the unit. Turning the knob clockwise increases the volume and turning couterclockwise decreases the volume.

PATIENT INTERFACE

A single patient use sensor capsule (balloon-type) is taped firmly onto a portion of the patient's abdomen that moves outward during inspiration. This capsule senses any diaphragm downward movement which precedes inspiration. This technique eliminates the "lag time" associated with other types of triggering mechanisms which employ a pressure or flow drop at the patient wye or ventilator.

The most commonly encountered errors in synchronization occur with the improper placement of the sensor. The 72 inch tube provides connection flexibility in between the infant and the Star Sync Patient Interface. The Star Sync electronics have been optimized for the 72 inch length. Varying this length may cause sensitivity problems.

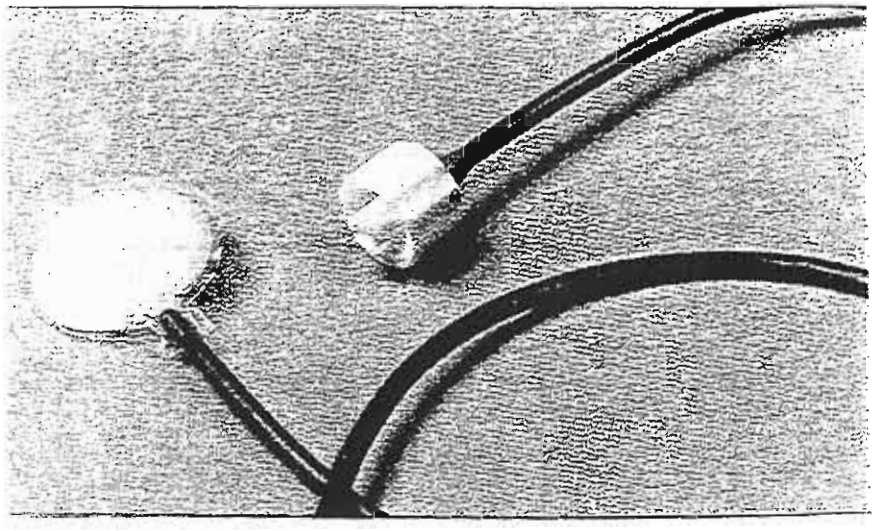


Illustration 15 - Patient Interface

Placement Protocol

Any spontaneously breathing infant who is receiving conventional mechanical ventilation with the Infant Star Ventilator is a candidate for synchronization. "Active expiration against ventilator inflation" occurs most commonly at IMV Rate less than 60 bpm.[4] This describes asynchrony with a negative effect on gas exchange and places the infant at increased risk of barotrauma.[5] SIMV is reliable in preventing this situation[6]; oxygenation particularly improves during the acute phase of disease and weaning is also facilitated.[7]

[4]Greenough A., Morley C.J., Davis J: Interaction of Spontaneous Respiration with Artificial Ventilation in Preterm Babies. J of **Pediatrics** 1983; 103:769-773.

[5]Greenough A., Morley CJ, Davis JA, et al: Pancuronium Prevents Pneumothoraces in Ventilated Premature Babies Who Actively Expire Against Positive Pressure Ventilation. **Lancet** 1984; i:1-3.

[6]Bernstein G., et al. "Reliability and Response Time of a Real-Time Adjustable Ratio Patient Triggered Ventilation System in Neonates". Society for Pediatric Research Abstract, 1989.

[7]Mehta A., Wright BM, Callan KA, et al: Patient Triggered Ventilation in the Newborn. **Lancet** 1986; ii:17-19.

Any protocol which has been established for initiating conventional mechanical ventilation is equally appropriate for the addition of Star Sync with the following recommendations:

1. Establish the standard ventilator parameters for the infant to be ventilated.
2. Make sure all Star Sync and Infant Star connectors and/or cables are intact.
3. Connect the abdominal sensor to the front of Star Sync.
4. Turn the Mode Switch to MONITOR.
5. Turn **ON** the Star Sync ON/OFF switch.
6. Proper sensor placement is achieved by:
   a. Visually locating a point of optimum outward movement of the abdomen during inspiration.
   b. Supine - In supine position, assessment of the patient's breath pattern must be noted:
      - paradoxical breathing (abdomen moving outward and the chest moving inward) is the most common neonatal respiration pattern. Midline, anterior placement, midway between the umbilicus and xiphisternum is usually optimal (See Illustration 16)
      - Severe sub-costal retractions or pectus excavatum may occur. If these patterns are present, extreme care must be taken to avoid the portion of the upper abdomen that collapses with the chest during inspiration, thus moves outward during expiration (Noted as "A" in Illustration 15). This area may trigger breaths asynchronously and is easily avoided by repositioning the capsule. In large infants, a site on the upper chest, detecting intercostal muscle movement, may be utilized for reliable synchronization.
   c. Prone - In the prone position, non-respiratory movements may be detected if the capsule remains under the infant. Placement of the sensor laterally on the abdomen, with the tubing over the back, may be necessary to avoid asynchrony.

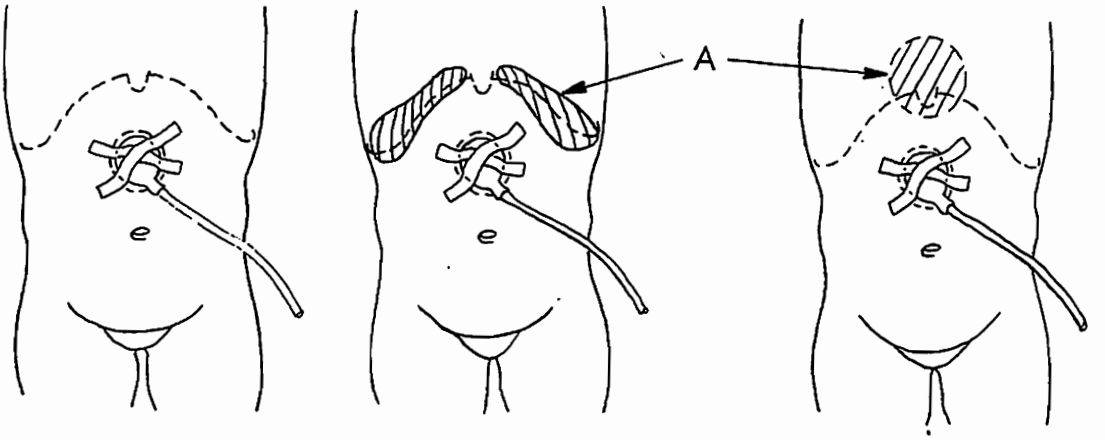


Illustration 16 - Patient Interface Placement (Supine Position)

d. Tape the sensor firmly into position with two 2 inch lengths of non-allergenic micropore tape, making an "X" over the capsule. Position the tubing toward the ventilator.

7. Select the mode of ventilation:

a. If the infant is being monitored only (without Apnea Backup ventilation), leave the Mode Control in the MONITOR position. Set the APNEA ALARM Setting to the desired delay from 5-60 seconds.

b. If the infant is to be on CPAP with BACKUP ventilation, establish the following parameters:

- Set the APNEA ALARM Setting to the desired apnea interval (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired rate of mechanical breaths to be delivered, should an apnea episode be detected.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the CPAP/BACKUP selection.
- Insure that the SPONTANEOUS LED flashes with each spontaneous breath.

c. If the infant is to be ventilated in SIMV, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired number of mechanical breaths.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the SIMV selection.
- Insure that the SYNCHRONOUS ASSISTED LED flashes with each mechanical breath.
- After one minute, compare the SYNCHRONOUS ASSISTED BREATH RATE to the set CONTROL/SIMV/BACKUP RATE. The two numbers should be similar.

  If they are not similar, there are three possible reasons: (1) the abdominal sensor is not picking up the signal properly. Reposition it according to step 6 above; (2) the infant is having periods of apnea in which controlled breaths are being delivered that are not synchronized; (3) the SIMV Rate is set higher than the spontaneous respiratory rate..

- After one minute, note the number of controlled breaths delivered. A large number of controlled breaths may indicate that the sensor is improperly positioned or ventilator settings are improperly set.

d. If the infant is to be ventilated in ASSIST CONTROL, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).

- Turn the CONTROL/SIMV/BACKUP RATE to the desired minimum number of mechanical breaths.

- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.

- Rotate the Mode Control to the SIMV and ASSIST CONTROL selection.

- Insure that the SYNCHRONOUS ASSISTED LED flashes with each mechanical breath.

- After one minute, note the number of controlled breaths delivered. A large number of controlled breaths may indicate that the sensor is improperly positioned, ventilator settings are improperly set, or the patient is having periods of apnea.

8. Adjust the PIP, PEEP, and Inspiratory Time on the Infant Star to obtain the desired patient ventilation.

9. Regular checks of synchrony will ensure optimal function. This can be achieved by:

   a. Increasing the click volume and watching the infant's inspiratory effort, or

   b. Simultaneously observing the abdominal movement and the Infant Star's analog pressure manometer.

   c. Noting number of controlled breaths delivered. A spontaneously breathing patient should recieve minimal controlled breaths.

QUICK CHECK PROCEDURE

Upon powering up the unit, Star Sync does a self-check of the system. Any detected problems will be converted to an Audible/Visual Alarm. Should an inoperative condition be detected, refer to "Troubleshooting Chart" for additional information.

The following Quick Check should be performed prior to placing Star Sync on a patient.

1. Place MODE CONTROL switch to Monitor.
2. Turn Star Sync On.
3. Attach Abdominal Sensor to Star Sync.
4. **Lightly** squeeze sensor a few times and note that the spontaneous LED illuminates with each squeeze.
5. Turn APNEA ALARM to 5 second delay.
6. Without squeezing the abdominal sensor, note that the APNEA ALARM sounds within 5 seconds.
7. **Lightly** squeeze Abdominal Sensor and note that the APNEA ALARM is immediately silenced, leaving the APNEA ALARM LED illuminated. This LED will reset after 60 seconds or when the ALARM SILENCE button is pushed.

CLEANING AND DECONTAMINATION

Clean the exterior of the Star Sync case as you would the ventilator by wiping it down with an appropriate bactericidal or bacteriostatic solution. Care should be taken to prevent the liquid agent from penetrating the inside of the unit. Do not spray any solutions directly on the control panel surface.

The abdominal sensor is considered "Single Patient Use Only" and should be discarded after each use. Any attempt to clean and reuse the sensor may result in moisture and/or liquid entering the balloon, causing it to be less sensitive.

ORDERING INFORMATION

606100	Star Sync Patient Triggered Interface Includes: 2 Abdominal Sensors and Connecting Cable.
606001	Disposable Abdominal Sensor (12/Pkg)
606003	Connecting Cable (Star Sync to Infant Star)
606004	Mounting Kit (4 Ball Studs)
1101342-3	Cable (Internal)
1101342-4	Cable (Internal) (For use with IEC 601-TUV Units)
1102153	Rear Cover Assembly,
7700137	Connector, Piggyback (Use with 1101342)
9910265	Service & Repair Instructions
9910325	Operating Instructions

TROUBLESHOOTING CHART

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Star Sync Inoperative	No displays illuminated Audible Alarm	- No power - Damaged external cable - Cable/connector assy. disconnected inside Infant Star	- Check top to ensure proper connection with external cable - Replace cable (PN 606003) - Check for proper connection
Audible Alarm	E1	- Damaged external cable Infant Star off	- Replace cable (PN 606003) - Turn Infant Star on
	E2	- Insufficient expiratory time	- Check settings to ensure compatible inspiratory time and CTRL/SIMV/BACKUP RATE
	E3	- Star Sync in the SIMV mode and the Infant Star in the IMV mode	- The Infant Star must be in CPAP mode in order to deliver SIMV
	E4	- Mechanical Rate during ASSIST CONTROL greater than 120 bpm	- Patient tachypneic - Improperly placed abdominal sensor
	E5	- APNEA ALARM setting in OFF position	- In CPAP/BACKUP a valid APNEA ALARM setting must be established - Set APNEA ALARM for desired duration
Star Sync Inoperative	E10-E21	- See "Error Code" section for individual explanations	- Contact Infrasonics
APNEA ALARM	Audible APNEA ALARM	- Patient Apneic - Abdominal sensor untaped - Abdominal sensor damaged - Abdominal sensor tubing kinked at capsule - Abdominal sensor disconnected from ABD port on Star Sync	- Refer to hospital protocol - Reapply sensor using 2 pieces of 1/2" micropore tape - Replace sensor - Unkink and inspect . If damaged, replace - Reconnect abdominal sensor

TROUBLESHOOTING CHART

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Small % of SIMV breaths synchronized	Wide margin between the selected SIMV and the SYNCHRONIZED/ASSISTED BREATH RATE	- Improper placement of abdominal sensor - Damaged sensor - Patient Apneic	- See "Star Sync Operators Manual" p. 19 - Replace sensor - Refer to hospital Protocol

Star Sync®

Patient-Triggered Interface

OPERATING INSTRUCTIONS

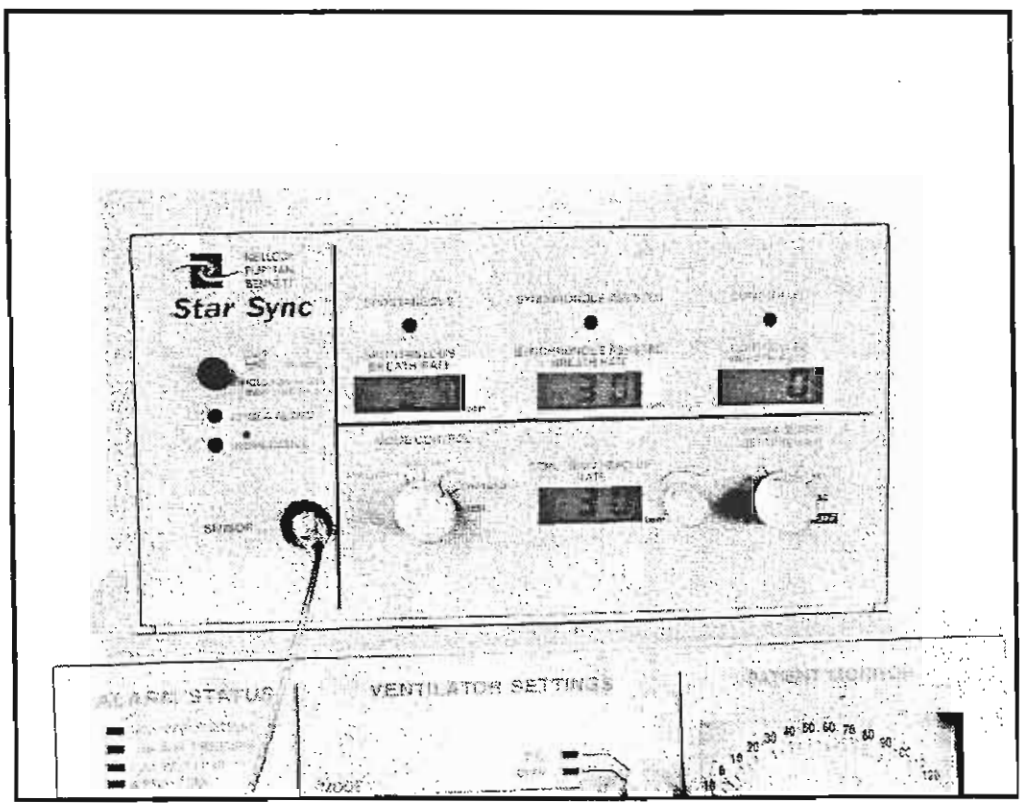


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Table of Contents

List of Illustrations

DEFINITION OF WARNING, CAUTION, AND NOTE

Statements in the Operating Instructions preceded by the words **"WARNING"**, **"CAUTION"**, and **"NOTE"** carry special significance. The definitions of these words are as follows:

WARNING
Means there is a possibility of injury to oneself or others.

CAUTION
Means there is a possibility of damage to the instrument or other property.

NOTE Indicates points of particular interest for more efficient and convenient operation.

SUMMARY OF WARNINGS, CAUTIONS, AND NOTES

The WARNINGS, CAUTIONS, and NOTES summarized in this section apply only to the Star Sync Patient Triggered Interface. This unit must be used in conjunction with the Infant Star Ventilator and therefore all WARNINGS, CAUTIONS, and NOTES for the Infant Star apply equally. Prior to use, in addition to this manual, the Infant Star Ventilator Operating Instructions (PN 9910005) should be read.

WARNING
Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons: **1) Some malfunctions require immediate corrective action.** **2) An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.**

WARNING
Failure of the Star Sync will result in the ventilator providing only Continuous Positive Airway Pressure (CPAP) to the patient.

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

WARNING

The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

WARNING

APNEA ALARM SETTING should be set whenever Star Sync is connected to a patient.

WARNING

When establishing ventilator settings, compatibility between mechanical IMV rate and set inspiratory time must be considered. If incompatibility occurs, an alarm will sound, an E2 error code will be displayed in the controlled breath window and the CONTROL/SIMV/BACKUP RATE Display will flash for 5 seconds.

CAUTION

Care must be taken when affixing Star Sync to the Infant Star to prevent damage to the electronics module.

NOTE If TEST Mode is selected after the first 2 seconds following power up, the TEST Mode is not activated and will function identically to the MONITOR Mode.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

NOTE During ASSIST CONTROL and SIMV, the Infant Star Ventilator Rate Display will be blank and the PIP Display will change from Baseline Pressure to Peak Inspiratory Pressure upon delivery of a mechanical breath.

NOTE In the monitor mode, the CONTROL/SIMV/BACKUP Rate display will show the set mechanical rate, however, it is disabled.

NOTE The Star Sync will NOT function during high frequency ventilation with the Infant Star.

NOTE The ALARM SILENCE switch can be activated only during an alarm condition. If not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists.

INTRODUCTION AND SYSTEM DESCRIPTION

The purpose of Star Sync is to promote Patient Triggered Ventilation (PTV) by providing an intelligent link between an abdominal respiration sensor and the Infant Star Ventilator. "Fighting the ventilator" is a common occurrence during asynchrony. Studies have shown that spontaneously breathing infants can easily be synchronized to the mechanical ventilator by the use of PTV. Patient Triggered Ventilation has been shown to reliably match an infant's respiratory needs by a factor of 98.9%.[1]

A picture of the unit is shown below.

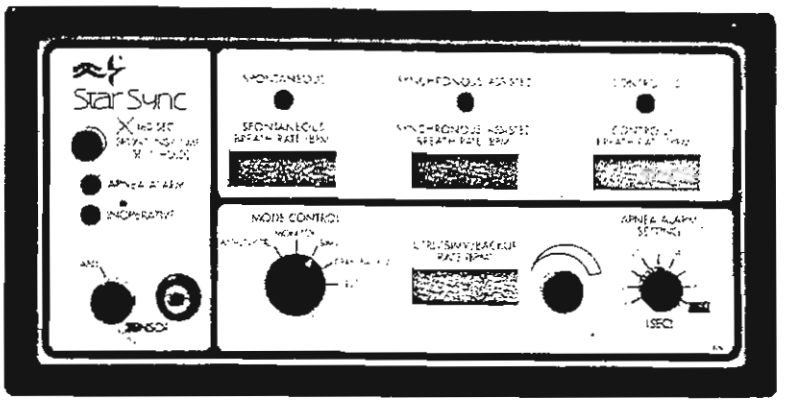


Illustration 1 - Star Sync Patient Triggered Interface

Synchronized Ventilation has long been a standard mode of ventilation in the adult intensive care unit. Today all major adult ventilators have some type of synchronized ventilation.

While IMV is considered a controlled mechanical rate combined with spontaneous breathing, SIMV is viewed as an assisted mechanical rate combined with spontaneous breathing.[2]

SIMV is believed to prevent excessive pressures during mechanical ventilation when the patient is beginning exhalation at the same time as the IMV breath occurs. With standard methods of SIMV, there is some delay in response time due to the delay between the onset of inspiration and time to measure a pressure drop at the proximal airway. Although the concept of SIMV ventilation is the same utilizing Star Sync, the means by which the synchronization occurs is completely different.

Since infants are primarily abdominal breathers, diaphragmatic movement is the first indication of a spontaneous breath. Triggering an SIMV breath on this early indicator of a spontaneous effort, is far more efficient than waiting until an airway pressure gradient occurs.

[1]Bernstein G., et al. "Reliability, Response Time and Consistency of Ventilation during Neonatal Synchronous Intermittent Mandatory Ventilation". Society for Pediatric Research Abstract, Vol. 29, No. 4, Part 2, 1991.

[2]Spearman CB, Sheldon RL, Egan DF. "Chapter 13, Mechanical Ventilation", Egan's Fundamentals of Respiratory Therapy, Fourth Edition, p. 504, 1982.

In the case of Star Sync, the respiratory sensor functions by monitoring intra-abdominal pressure changes due to diaphragm movement. The sensor delivers that signal to Star Sync which connects directly to the Infant Star Ventilator. Sampling of the abdominal sensor occurs 8 times every 5 milliseconds. The response time is 47 $\pm$ 18 milliseconds from the start of inspiration to the onset of the triggered mechanical breath.[3]

The ASSIST CONTROL mode combines patient triggered ventilation with a mechanically set rate as a "backup". In this mode, the patient is allowed to establish a mechanical breath rate by triggering the ventilator with every spontaneous effort. A minimum backup rate is set below that of the patient, in case the patient's breathing pattern slows or stops completely.

The CPAP/BACKUP mode is designed for the patient who has adequate spontaneous ventilation except during brief periods of apnea. Should the patient become apneic, Star Sync will automatically convert to backup ventilation and trigger mechanical breaths attempting to maintain an adequate minute ventilation.

The placement of the abdominal sensor is important in establishing the reliability of the response. During SIMV, the CONTROL/SIMV/BACKUP RATE Display and the SYNCHRONOUS ASSISTED BREATH RATE Display should be close to the same value. A wide difference between these two values may indicate improper sensor placement or periodic patient apneic episodes. The difference between the two displays is the number of controlled, non-synchronized, mechanical breaths per minute and is displayed in the CONTROLLED BREATH RATE window.

All of the patient's spontaneous respiratory movements are monitored and Star Sync synchronizes a mechanical breath in response to the signal received from the sensor, when appropriate.

The Star Sync Patient Triggered Interface is a microprocessor controlled device that connects to the Infant Star Ventilator via a standard DIN connector and cable. Both the power and communication links are conducted through this cable. Since the power for Star Sync is received from the Infant Star, all battery backed features of the ventilator are available.

Standard features of the Infant Star continue to function, including:

1. Full microprocessor control of the gas delivery system.
2. Demand Flow Ventilation to reduce the work of breathing.
3. Automatic correction of inadvertent PEEP.
4. Automatic Obstructed Tube alarms.
5. Built-in patient monitoring.
6. Data output to computer or printer via RS-232.
7. Internal battery for short-term transport. External battery (12VDC) connection for longer transport requirements.
8. Software updatable in the hospital.
9. High Frequency Ventilation Option, when included.

[3]Bernstein, G., et al. "Reliability, Response Time and Consistency of Ventilation, during Neonatal Synchronous Intermittent Mandatory Ventilation", Society for Pediatric Research Abstract, vol. 29, No. 4, Part II, 1991.

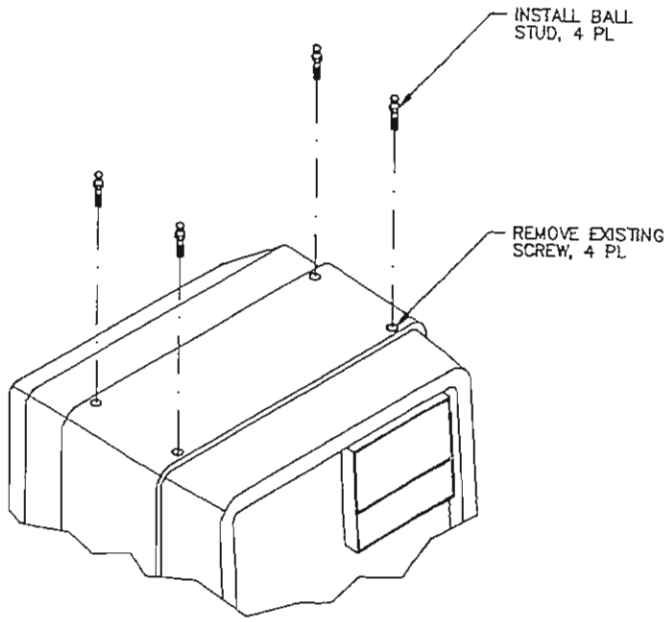


Illustration 2 - Mounting

Star Sync mounts conveniently on top of the Infant Star by replacing the four existing screws with four mounting ball studs. After the mounting studs have been installed, Star Sync will "SNAP" onto the ventilator and swivel in tandem with the electronics module. See Illustration 2.

WARNING

Constant attention by a qualified medical attendant is required whenever a patient is attached to a ventilator for two reasons:

1) Some malfunctions require immediate corrective action.

2) An alarm, or any combination of alarms, does not give total assurance of warning in the event of any and every form of malfunction of the ventilator system.

CAUTION

Care must be taken when affixing Star Sync to the Infant Star to prevent damage to the electronics module.

NOTE The Star Sync will NOT function during high frequency ventilation with the Infant Star.

MODES OF OPERATION

Monitor:

When in the monitor mode, the Star Sync will monitor and display the spontaneous respiratory rate. The spontaneous inspiratory time is available by depressing and holding the ALARM SILENCE button for 1 second. The spontaneous inspiratory time will be displayed in the SPONTANEOUS BREATH RATE display window. All other display windows will be blank during this time. A rate will be displayed in the CONTROL/SIMV/BACKUP RATE window, however, this will not be active. Mechanical settings must be obtained directly from the ventilator. The APNEA ALARM setting will be active and may be used as a safety alarm.

When this mode is selected by the operator, Star Sync only monitors the patient. Information is received, but signals are not transmitted back to the Infant Star. This mode has no impact upon patient ventilation and may be used with the Infant Star turned off.

Using the monitoring mode assists in the placement of the abdominal sensor, which is discussed later in this manual.

Synchronized Intermittent Mandatory Ventilation (SIMV):

In this mode, the Star Sync will interface with the Infant Star to synchronize the patient's spontaneous effort with a mechanical ventilator breath.

The SIMV rate will be set on the Star Sync while the Infant Star Ventilator is placed in Continuous or Demand CPAP mode; all mechanical ventilatory parameters and alarms must be established in order to provide the desired minute ventilation. The adjustment range is from 2 - 150 breaths per minute and is displayed in the CONTROL/SIMV/BACKUP RATE display. This rate will determine the mechanical cycle time. For example, if the SIMV rate is set to 30, the cycle time will be 2 seconds (60 seconds/minute divided by 30 breaths/minute).

In between mechanical breaths, the patient may breathe spontaneously from the background flow of gas provided by the Infant Star. If the patient's inspiratory flow exceeds that selected by the operator, the ventilator's inspiratory demand system provides extra gas based upon the pressure gradient created. Unless the breath was synchronized originally, this effort does not trigger the ventilator.

WARNING
Failure of the Star Sync will result in the ventilator providing only Continuous Positive Airway Pressure (CPAP) to the patient.

WARNING
When establishing ventilator settings, compatibility between mechanical IMV rate and set inspiratory time must be considered. If incompatibility occurs, an alarm will sound, an E2 error code will be displayed in the controlled breath window and the CONTROL/SIMV/BACKUP RATE Display will flash for 5 seconds.

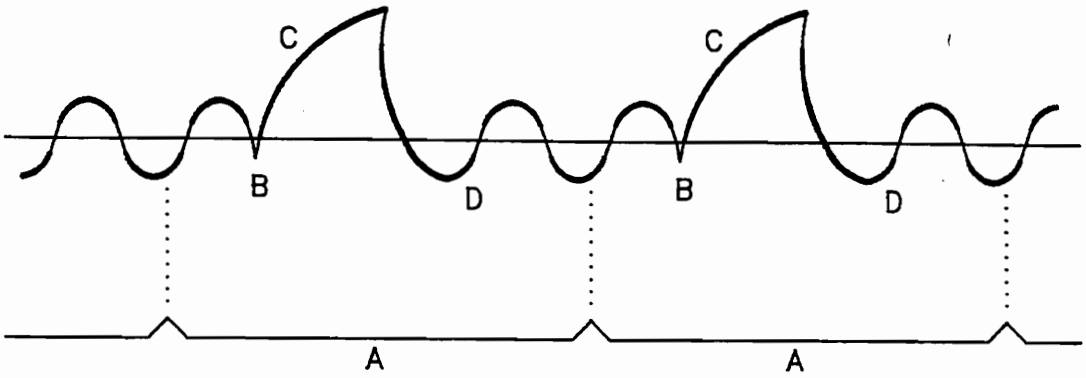


Illustration 3 - SIMV Cycle

Using the 30 breath/minute example, every 2 seconds the SIMV cycle "window" opens. The SIMV "windows" are noted as points "A" in Illustration 3. When Star Sync detects a patient inspiratory effort, (point B) a synchronized mechanical breath is delivered (point C). Upon completion of the mechanical breath, the patient returns to breathing spontaneously on the background flow (point D).

If the patient does not initiate a breath during the SIMV cycle, the ventilator will deliver a controlled breath at the end of that cycle. Star Sync will rearm for the subsequent SIMV cycle. It is important to note that if the patient initiates a breath at the beginning of an SIMV window and then becomes apneic, the patient will not receive another mechanical breath until the end of the next SIMV window, however, the set SIMV rate will be maintained. When these apneic episodes occur, the Apnea Alarm, if active, will trigger audible visual indicators.

WARNING
The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

During the SIMV Mode, Star Sync monitors and displays the spontaneous breath rate, synchronous mandatory breath rate, and controlled breath rate. The spontaneous inspiratory time is available by depressing and holding the ALARM SILENCE button for 1 second.

Assist Control (Assist/Ctrl):

In this mode, the Star Sync will interface with the Infant Star to synchronize every spontaneous effort with a mechanical ventilator breath.

In ASSIST CONTROL, the minimum mechanical ventilator rate is set on the Star Sync (in the CONTROL/SIMV/BACKUP RATE display window) while the Infant Star is placed in Continuous or Demand CPAP mode; all other mechanical ventilatory parameters and alarms must be established in order to provide desired mechanical breaths. The minimum controlled breath range is from 2-120 breaths per minute.

In ASSIST CONTROL, Star Sync synchronizes every spontaneous effort with a mechanical breath. The total mechanical breath rate will be dependent on the baby's spontaneous breath rate.

The selected CONTROL/SIMV/BACKUP RATE will determine the duration of the minimum mechanical window. Every spontaneous breath that is synchronized with a mechanical breath resets the window. Should the spontaneous breath rate decrease to a rate such that the time between breaths is equal to the duration of the mechanical window, a CONTROLLED breath will be delivered and Star Sync will rearm for another cycle.

If Star Sync delivers a mechanical rate of 120 breaths per minute or greater an audible alarm will sound and an "E4" will be displayed in the CONTROLLED BREATH RATE window. The alarm can be silenced for 60 seconds by depressing the ALARM SILENCE button. Engaging the ALARM SILENCE will silence the audible alarm, however, the E4 will continue to flash in the controlled breath display until the ASSIST CONTROL RATE falls below 120 breaths per minute.

CPAP/Backup

In this mode, Star Sync will monitor the patient's spontaneous effort and display the spontaneous respiratory rate. Should the patient become apneic for a period longer than the APNEA ALARM SETTING, Star Sync will automatically convert to Backup Ventilation at the selected mechanical rate (displayed in the CONTROL/SIMV/BACKUP RATE window). The selected mechanical rate is used to identify the starting point for backup ventilation. Following its initiation, Star Sync utilizes a 60 second linear regression to decrease the backup ventilation rate to CPAP. For example, if a backup rate of 30 breaths per minute is selected, the regression shown in Illustration 4 will be employed. After the 60 second period, Star Sync will rearm in the CPAP Mode. The selected backup breath range is from 2-150 breaths per minute.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

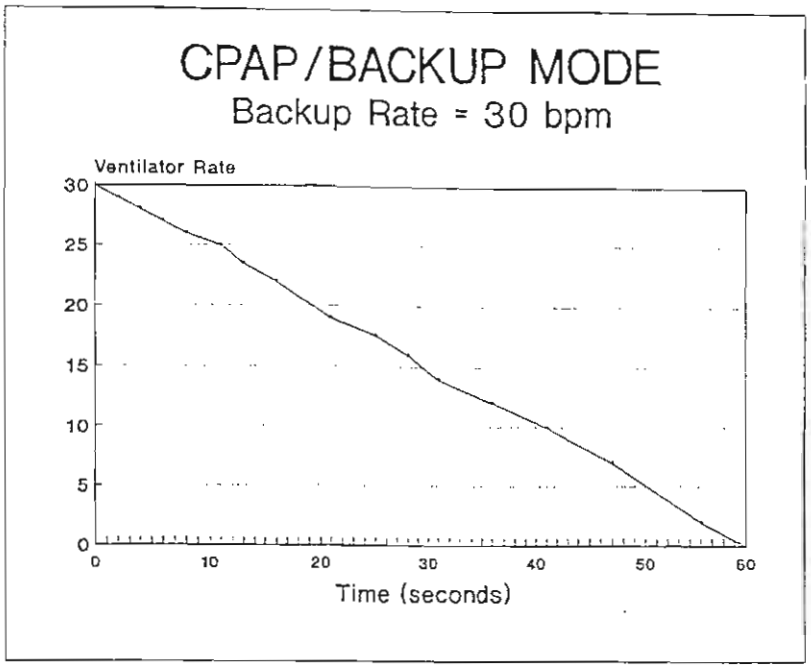


Illustration 4 - CPAP/BACKUP Mode

Test:

This mode is accessible only within the first 2 seconds of powering up the unit. When selected, this mode will verify that the Star Sync Patient Triggered Interface is functioning correctly.

Upon entry, the microprocessor first enables, then disables and counts all the decimal displays. It then displays raw data in the respective display windows as follows:

1. The CONTROL/SIMV/BACKUP RATE display will show the analog signal from the rate adjustment potentiometer.

2. The SPONTANEOUS BREATH RATE display will show the analog signal from the respiration sensor.

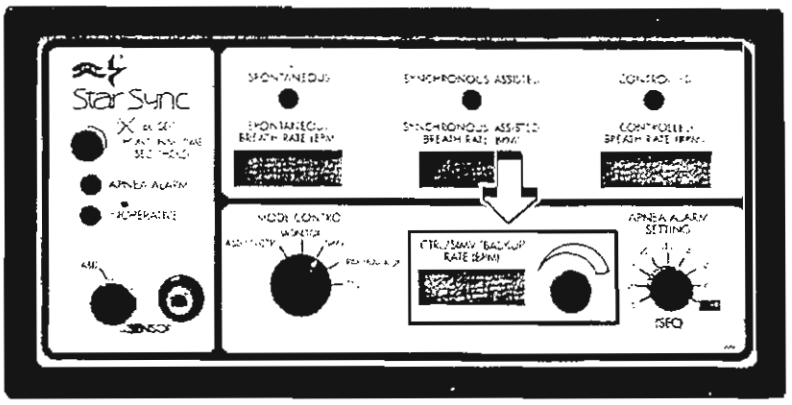
3. The SYNCHRONOUS ASSISTED BREATH RATE display will show the switch data from the Sensor Control.

4. The CONTROLLED BREATH RATE display will show the switch data from the APNEA ALARM Setting and the ALARM SILENCE Button.

5. All lamps from the front panel will blink simultaneously.

For more detailed discussion of the TEST Mode, see Star Sync Service & Repair Instructions (PN 9910265).

NOTE If TEST Mode is selected after the first 2 seconds following power up, the TEST Mode is not activated and will function identically to the monitor mode.



Ilustration 6 - CONTROL/SIMV/BACKUP RATE Knob and Display Window

Apnea Alarm Setting:

This control is a multi-position rotary switch located on the front panel (See Illustration 7). It allows the operator to adjust the apnea alarm delay time. Turning the knob fully clockwise to the OFF position will deactivate the alarm, while rotation counterclockwise will establish the apnea delay from 5 - 60 seconds.

In ASSIST CONTROL, SIMV and MONITOR modes the operator may choose to activate the APNEA ALARM. However, during CPAP/BACKUP, an APNEA ALARM must be selected or an audible alarm and an error code will be displayed.

Should spontaneous respirations cease for longer than the selected time, an audible alarm will sound simultaneously accompanied by a flashing red LED. Should the patient resume breathing, the audible alarm ceases and the APNEA ALARM LED continues to illuminate without flashing for 60 seconds. This LED may be reset by pressing the ALARM SILENCE button, or will automatically reset in 60 seconds. This alarm is adjustable in intensity using the APNEA ALARM VOLUME control found on the back panel.

NOTE The CPAP/BACKUP mode requires a valid APNEA ALARM setting. Failure to set an APNEA ALARM will result in an audible alarm and an E5 error code displayed in the controlled breath window.

WARNING
APNEA ALARM SETTING should be set whenever Star Sync is connected to a patient.

CONTROLS AND DISPLAYS

Mode Control:

This control is a multi-position switch located on the front panel (See Illustration 5). The mode of Star Sync operation is established by the operator from the five available selections: ASSIST CONTROL, MONITOR, SIMV, CPAP/BACKUP and TEST. These positions are clearly labeled and described in the previous section of this manual.

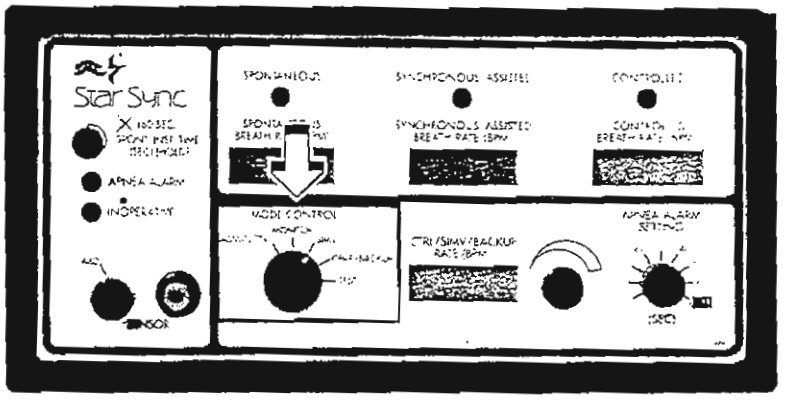


Illustration 5 - Mode Control

Control/SIMV/Backup Rate:

This section is composed of an adjustable control knob and a display window (See Illustration 6).

To set, depress the knob and turn to display desired setting. Clockwise rotation increases the rate and counterclockwise rotation decreases the rate. The function of this display window is dependent on the mode selected.

In the SIMV mode of operation, this knob controls the mechanical breath rate of the ventilator. It is adjustable from 2 - 150 breaths per minute in 1 breath increments.

In the ASSIST CONTROL mode of operation, this knob controls the minimum mechanical breath rate of the ventilator. It is adjustable from 2-120 breaths per minute in 1 breath increments.

In the CPAP/BACKUP mode of operation, this knob controls the starting point for mechanical breaths during backup ventilation.

NOTE In the MONITOR mode, the CONTROL/SIMV/BACKUP Rate display will show the set mechanical rate, however, it is disabled.

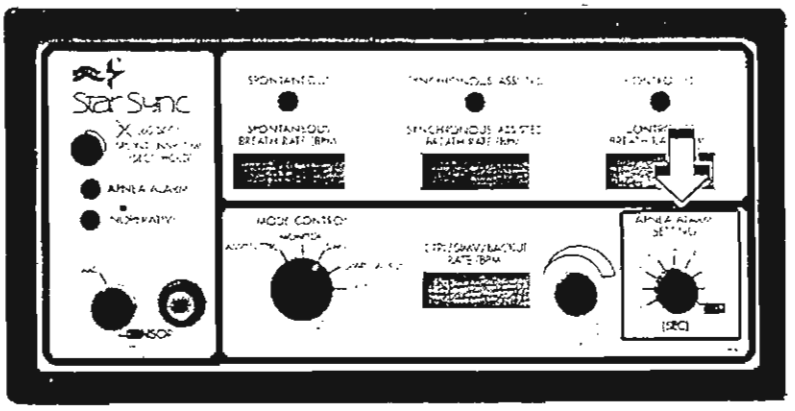


Illustration 7 - Apnea Alarm Setting

Alarm Silence/Spontaneous Inspiratory Time:

The ALARM SILENCE/SPONTANEOUS INSPIRATORY TIME button is located on the front panel (See Illustration 8).

ALARM SILENCE Button - This button will silence an alarm for 60 seconds, however, if the alarm condition still persists, the error code or APNEA ALARM LED will continue to flash. Pushing this button a second time reactivates the alarm immediately.

SPONTANEOUS INSPIRATORY TIME - To access the spontaneous inspiratory time, depress and hold the ALARM SILENCE button for 1 second. The spontaneous inspiratory time will be displayed in the SPONTANEOUS BREATH RATE window. All other windows will be blank during this function. Upon release of the ALARM SILENCE button, all display windows will revert back to previous condition.

NOTE The ALARM SILENCE switch can be activated only during an alarm condition. If not reactivated (pushed) within 60 seconds, it will automatically reset and the audible alarm will be heard if the alarm situation persists.

WARNING
The ALARM SILENCE is used to silence an audible alarm while corrective action is taken. The operator must still assume responsibility for proper ventilator function and/or patient safety if an alarm occurs. Failure to identify and correct alarm situations may result in patient injury.

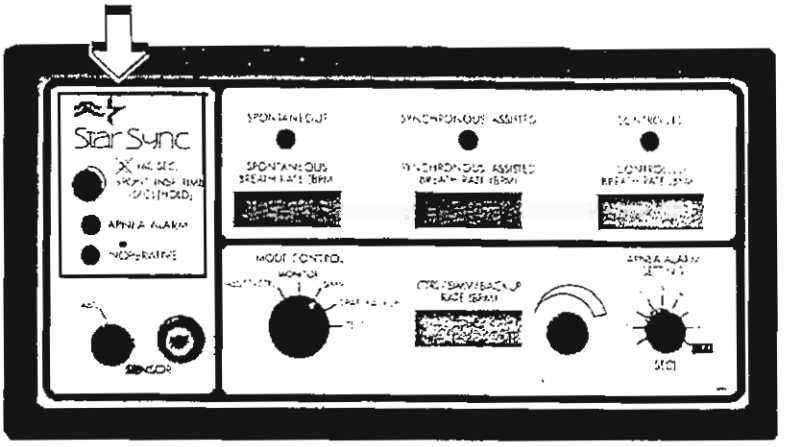


Illustration 8 - Alarm Silence/Spontaneous Inspiratory Time

Abdominal Sensor Port:

The Star Sync sensor port is a Luer-type locking mechanism which connects the patient's abdominal sensor to Star Sync. Adjacent to the sensor port is a rotary switch which is locked in the ABD (abdominal) position. (See Illustration 9) The abdominal sensor must be carefully taped into position so as to respond to abdominal movement (see Patient Interface, Placement Protocol). Improper positioning is the most common cause of poor synchronization.

For specific details concerning proper sensor placement, consult the Patient Interface section.

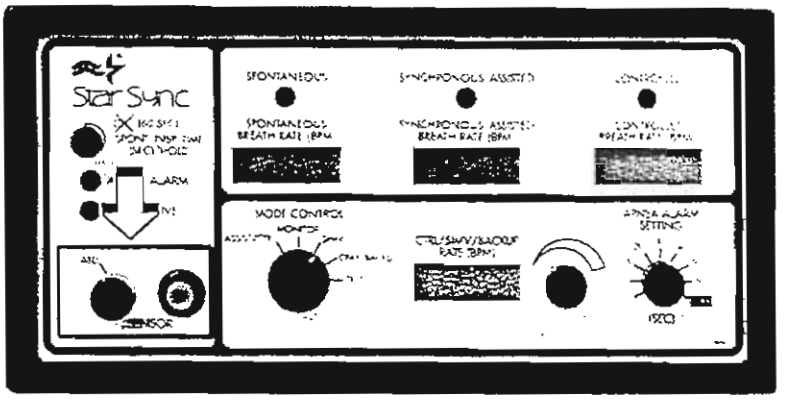


Illustration 9 - Sensor Port and Sensor Site Control

Spontaneous Breath Rate:

The SPONTANEOUS BREATH RATE display window is active in all modes. This window will display all spontaneous breaths detected, including unassisted spontaneous breaths and spontaneous breaths that trigger assisted mechanical breaths. (See Illustration 10)

The Breath Rate is updated every second by counting the number of breaths during the previous 60 seconds.

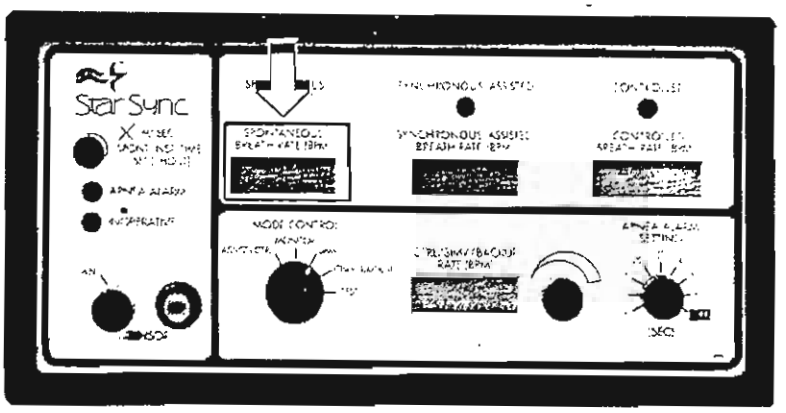


Illustration 10 - Spontaneous Breath Rate Display Window

Synchronous Assisted Breath Rate:

This window displays all synchronized mechanical breaths. (See Illustration 11) It is updated every second by counting the number of synchronized ventilations for the previous 60 seconds. This window is active during ASSIST CONTROL and SIMV and blank during MONITOR and CPAP/BACKUP.

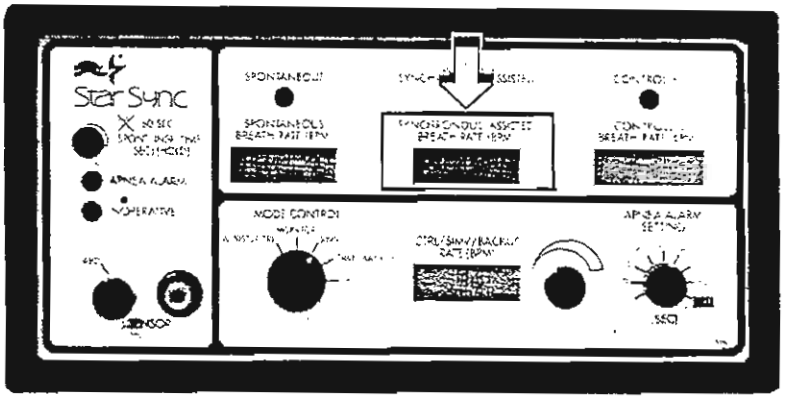


Illustration 11- Synchronous Assisted Breath Rate Display Window

Controlled Breath Rate:

The CONTROLLED BREATH RATE display window is active in all modes. (See Illustration 12) This window will display all controlled, non-synchronized, mechanical breaths. This display is updated every second by counting the number of controlled breaths delivered during the past 60 seconds.

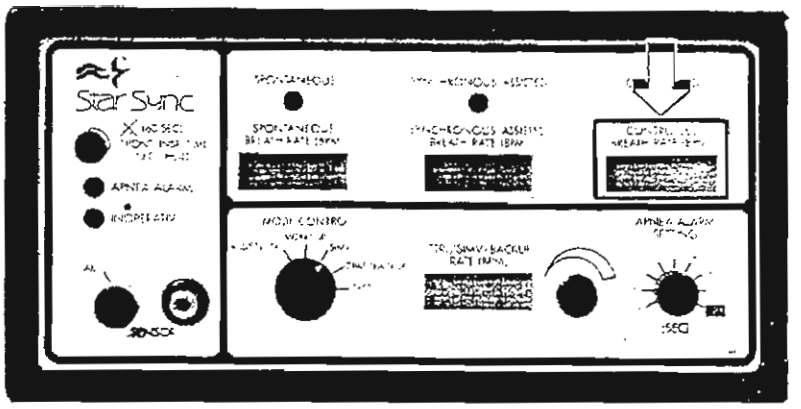


Illustration 12 - Controlled Breath Rate Display Window

Spontaneous, Synchronous, and Controlled Breath LED's:

Small LED's located on top of the Star Sync front panel illuminate, identifying the appropriate breath type. (See Illustration 13)

A spontaneous breath is defined as a patient initiated spontaneous inspiratory effort. A synchronous assisted breath is a mechanical breath which was delivered in response to a patient's inspiratory effort. A controlled breath is a mechanical breath which was delivered without synchronizing to a patient's inspiratory effort.

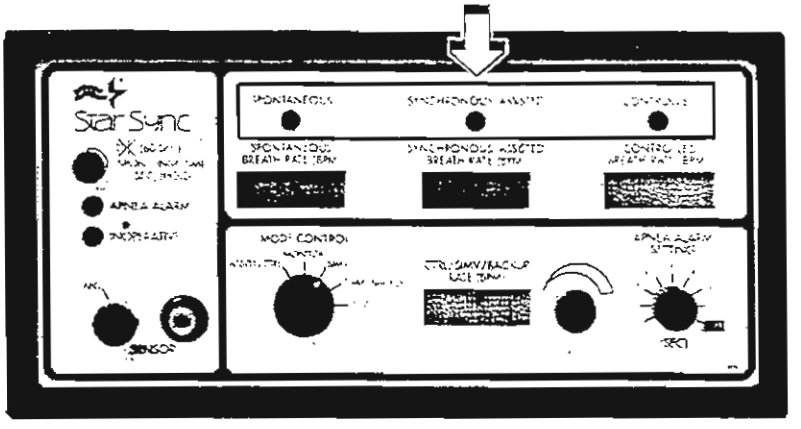


Illustration 13 - Spontaneous, Synchronous, and Controlled LED's

System Inoperative LED:

The System Inoperative LED illuminates simultaneously with the audible alarm when Star Sync cannot operate according to specifications. The Audible alarm cannot be silenced. An error code (listed below) will be displayed in the CONTROLLED BREATH RATE window indicating the cause of the malfunction. This error code should be noted, written down and retained, to assist appropriate service personnel in troubleshooting the System INOP problem.

Error Codes

Error codes occur at two levels. The first level (E1-E5) are usually correctable errors related to incorrect set-up. The second level (E10-E21) indicate mechanical problems with the Star Sync which require Star Sync to be removed from service and evaluated by qualified personnel.

ERROR CODE	REASON FOR FAILURE
E1-	Ventilator did not trigger a breath after it was commanded
E2-	Insufficient expiratory time - indicates incompatible settings
E3-	Ventilator triggered without being told - indicates Infant Star is in IMV
E4-	High Assist Control Rate - mechanical breath rate exceeded 120 breaths per minute
E5-	CPAP/Backup Error - indicates that the Apnea Alarm setting is in the OFF position
E10-	Incorrect signal from the ventilator
E11-	Mode Control switch failure
E12-	Apnea alarm setting switch failure
E13-	Control/SIMV/Backup potentiometer failure
E14-	Speaker failure
E15-	7.5 volt failure
E16-	4.8 volt internal battery failure
E17-	J8 is not connected to the power switch
E18-	Power up ROM checksum failure
E19-	Background ROM checksum failure
E20-	Power up RAM checksum failure
E21-	Background RAM checksum failure

See "Troubleshooting Chart" for possible cause and necessary corrective action when an Error Code is detected.

CONNECTORS AND SWITCHES

ON/OFF Switch:

The rocker-type switch turns the Star Sync unit ON and OFF independent of the Infant Star.

Analog Output:

A BNC connector functions as the respiration sensor's analog signal output. When connected to other instruments, it can be used to view the sensor signal on a strip-chart recorder or oscilloscope. (Not available on TUV/IEC 601 Approved units).

Inspiratory Time:

A BNC connector functions as the signal output for spontaneous inspiratory time. Viewing this signal with a strip-chart or oscilloscope will show how Star Sync is interpreting the analog signal from the respiratory sensor. (Not available on TUV/IEC 601 Approved units).

Output Port:

This port is provided to download information to a printer, terminal, or other intelligent device. (Not available on TUV/IEC 601 Approved units).

"To Infant Star" Connection:

A 9 pin DIN connector serves as the interconnect between Star Sync and the Infant Star Ventilator. Power for the Star Sync, as well as all two-way communication between the two devices is conducted through this connection.

Alarm Volume Control:

This control adjusts the loudness of the audible apnea and inoperative alarms. Turning the knob clockwise increases the volume.

Click Volume Control:

An audible "click" accompanies each spontaneous breath detected by Star Sync. This tone can only be heard when the user is within the immediate vicinity of the unit. Turning the knob clockwise increases the volume and turning couterclockwise decreases the volume.

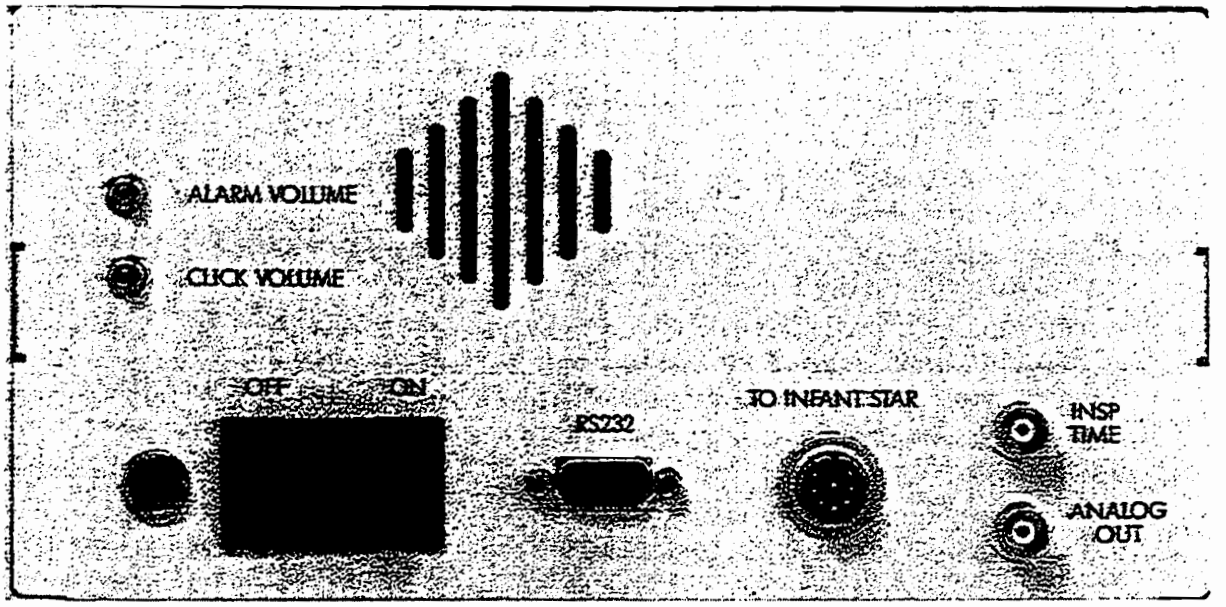


Illustration 14 - Back Panel

PATIENT INTERFACE

A single patient use sensor capsule (balloon-type) is taped firmly onto a portion of the patient's abdomen that moves outward during inspiration. This capsule senses any diaphragm downward movement which precedes inspiration. This technique eliminates the "lag time" associated with other types of triggering mechanisms which employ a pressure or flow drop at the patient wye or ventilator.

The most commonly encountered errors in synchronization occur with the improper placement of the sensor. The 72 inch tube provides connection flexibility in between the infant and the Star Sync Patient Interface. The Star Sync electronics have been optimized for the 72 inch length. Varying this length may cause sensitivity problems.

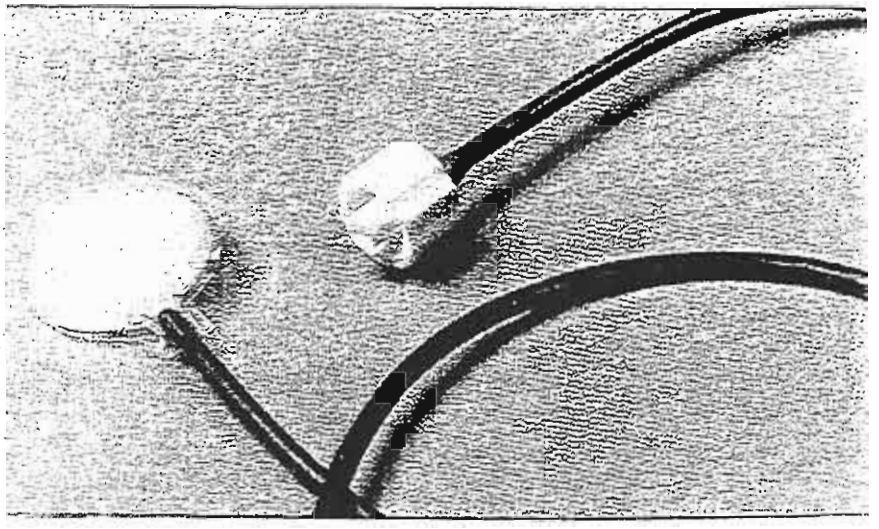


Illustration 15 - Patient Interface

Placement Protocol

Any spontaneously breathing infant who is receiving conventional mechanical ventilation with the Infant Star Ventilator is a candidate for synchronization. "Active expiration against ventilator inflation" occurs most commonly at IMV Rate less than 60 bpm.[4] This describes asynchrony with a negative effect on gas exchange and places the infant at increased risk of barotrauma.[5] SIMV is reliable in preventing this situation[6]; oxygenation particularly improves during the acute phase of disease and weaning is also facilitated.[7]

[4]Greenough A., Morley C.J., Davis J: Interaction of Spontaneous Respiration with Artificial Ventilation in Preterm Babies. **J of Pediatrics** 1983; 103:769-773.

[5]Greenough A., Morley CJ, Davis JA, et al: Pancuronium Prevents Pneumothoraces in Ventilated Premature Babies Who Actively Expire Against Positive Pressure Ventilation. **Lancet** 1984; i:1-3.

[6]Bernstein G., et al. "Reliability and Response Time of a Real-Time Adjustable Ratio Patient Triggered Ventilation System in Neonates". Society for Pediatric Research Abstract, 1989.

[7]Mehta A., Wright BM, Callan KA, et al: Patient Triggered Ventilation in the Newborn. **Lancet** 1986; ii:17-19.

Any protocol which has been established for initiating conventional mechanical ventilation is equally appropriate for the addition of Star Sync with the following recommendations:

1. Establish the standard ventilator parameters for the infant to be ventilated.
2. Make sure all Star Sync and Infant Star connectors and/or cables are intact.
3. Connect the abdominal sensor to the front of Star Sync.
4. Turn the Mode Switch to MONITOR.
5. Turn **ON** the Star Sync ON/OFF switch.
6. Proper sensor placement is achieved by:
   a. Visually locating a point of optimum outward movement of the abdomen during inspiration.
   b. Supine - In supine position, assessment of the patient's breath pattern must be noted:
      - paradoxical breathing (abdomen moving outward and the chest moving inward) is the most common neonatal respiration pattern. Midline, anterior placement, midway between the umbilicus and xiphisternum is usually optimal (See Illustration 16)
      - Severe sub-costal retractions or pectus excavatum may occur. If these patterns are present, extreme care must be taken to avoid the portion of the upper abdomen that collapses with the chest during inspiration, thus moves outward during expiration (Noted as "A" in Illustration 15). This area may trigger breaths asynchronously and is easily avoided by repositioning the capsule. In large infants, a site on the upper chest, detecting intercostal muscle movement, may be utilized for reliable synchronization.
   c. Prone - In the prone position, non-respiratory movements may be detected if the capsule remains under the infant. Placement of the sensor laterally on the abdomen, with the tubing over the back, may be necessary to avoid asynchrony.

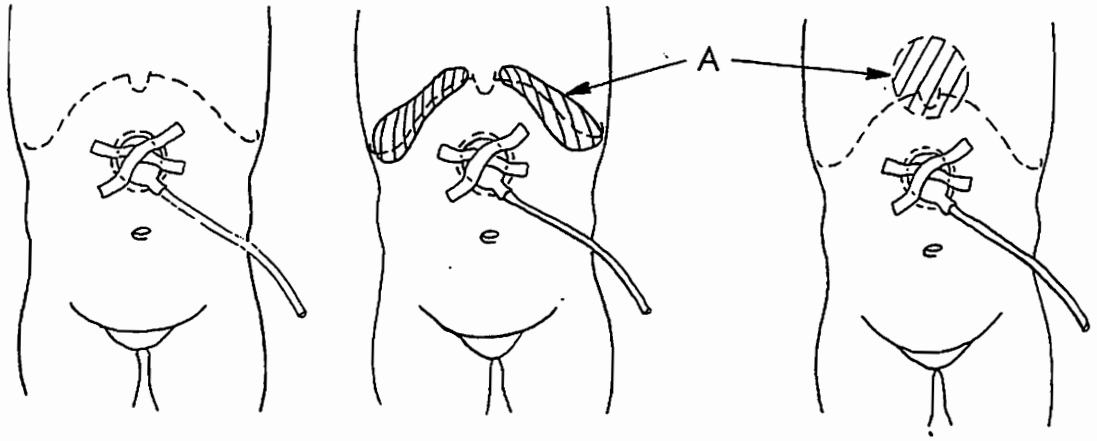


Illustration 16 - Patient Interface Placement (Supine Position)

d. Tape the sensor firmly into position with two 2 inch lengths of non-allergenic micropore tape, making an "X" over the capsule. Position the tubing toward the ventilator.

7. Select the mode of ventilation:

a. If the infant is being monitored only (without Apnea Backup ventilation), leave the Mode Control in the MONITOR position. Set the APNEA ALARM Setting to the desired delay from 5-60 seconds.

b. If the infant is to be on CPAP with BACKUP ventilation, establish the following parameters:

- Set the APNEA ALARM Setting to the desired apnea interval (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired rate of mechanical breaths to be delivered, should an apnea episode be detected.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the CPAP/BACKUP selection.
- Insure that the SPONTANEOUS LED flashes with each spontaneous breath.

c. If the infant is to be ventilated in SIMV, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).
- Turn the CONTROL/SIMV/BACKUP RATE to the desired number of mechanical breaths.
- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.
- Rotate the Mode Control to the SIMV selection.
- Insure that the SYNCHRONOUS ASSISTED LED flashes with each mechanical breath.
- After one minute, compare the SYNCHRONOUS ASSISTED BREATH RATE to the set CONTROL/SIMV/BACKUP RATE. The two numbers should be similar.

  If they are not similar, there are three possible reasons: (1) the abdominal sensor is not picking up the signal properly. Reposition it according to step 6 above; (2) the infant is having periods of apnea in which controlled breaths are being delivered that are not synchronized; (3) the SIMV Rate is set higher than the spontaneous respiratory rate..

- After one minute, note the number of controlled breaths delivered. A large number of controlled breaths may indicate that the sensor is improperly positioned or ventilator settings are improperly set.

d. If the infant is to be ventilated in ASSIST CONTROL, establish the following parameters:

- Set the APNEA ALARM Setting to the desired alarm time (5-60 seconds).

- Turn the CONTROL/SIMV/BACKUP RATE to the desired minimum number of mechanical breaths.

- Turn the Infant Star to CONTINUOUS or DEMAND CPAP mode.

- Rotate the Mode Control to the SIMV and ASSIST CONTROL selection.

- Insure that the SYNCHRONOUS ASSISTED LED flashes with each mechanical breath.

- After one minute, note the number of controlled breaths delivered. A large number of controlled breaths may indicate that the sensor is improperly positioned, ventilator settings are improperly set, or the patient is having periods of apnea.

8. Adjust the PIP, PEEP, and Inspiratory Time on the Infant Star to obtain the desired patient ventilation.

9. Regular checks of synchrony will ensure optimal function. This can be achieved by:

   a. Increasing the click volume and watching the infant's inspiratory effort, or

   b. Simultaneously observing the abdominal movement and the Infant Star's analog pressure manometer.

   c. Noting number of controlled breaths delivered. A spontaneously breathing patient should recieve minimal controlled breaths.

QUICK CHECK PROCEDURE

Upon powering up the unit, Star Sync does a self-check of the system. Any detected problems will be converted to an Audible/Visual Alarm. Should an inoperative condition be detected, refer to "Troubleshooting Chart" for additional information.

The following Quick Check should be performed prior to placing Star Sync on a patient.

1. Place MODE CONTROL switch to Monitor.

2. Turn Star Sync On.

3. Attach Abdominal Sensor to Star Sync.

4. **Lightly** squeeze sensor a few times and note that the spontaneous LED illuminates with each squeeze.

5. Turn APNEA ALARM to 5 second delay.

6. Without squeezing the abdominal sensor, note that the APNEA ALARM sounds within 5 seconds.

7. **Lightly** squeeze Abdominal Sensor and note that the APNEA ALARM is immediately silenced, leaving the APNEA ALARM LED illuminated. This LED will reset after 60 seconds or when the ALARM SILENCE button is pushed.

CLEANING AND DECONTAMINATION

Clean the exterior of the Star Sync case as you would the ventilator by wiping it down with an appropriate bactericidal or bacteriostatic solution. Care should be taken to prevent the liquid agent from penetrating the inside of the unit. Do not spray any solutions directly on the control panel surface.

The abdominal sensor is considered "Single Patient Use Only" and should be discarded after each use. Any attempt to clean and reuse the sensor may result in moisture and/or liquid entering the balloon, causing it to be less sensitive.

ORDERING INFORMATION

606100	Star Sync Patient Triggered Interface Includes: 2 Abdominal Sensors and Connecting Cable.
606001	Disposable Abdominal Sensor (12/Pkg)
606003	Connecting Cable (Star Sync to Infant Star)
606004	Mounting Kit (4 Ball Studs)
1101342-3	Cable (Internal)
1101342-4	Cable (Internal) (For use with IEC 601-TUV Units)
1102153	Rear Cover Assembly,
7700137	Connector, Piggyback (Use with 1101342)
9910265	Service & Repair Instructions
9910325	Operating Instructions

TROUBLESHOOTING CHART

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Star Sync Inoperative	No displays illuminated Audible Alarm	- No power	- Check top to ensure proper connection with external cable
		- Damaged external cable	- Replace cable (PN 606003)
		- Cable/connector assy. disconnected inside Infant Star	- Check for proper connection
Audible Alarm	E1	- Damaged external cable Infant Star off	- Replace cable (PN 606003) - Turn Infant Star on
	E2	- Insufficient expiratory time	- Check settings to ensure compatible inspiratory time and CTRL/SIMV/BACKUP RATE
	E3	- Star Sync in the SIMV mode and the Infant Star in the IMV mode	- The Infant Star must be in CPAP mode in order to deliver SIMV
	E4	- Mechanical Rate during ASSIST CONTROL greater than 120 bpm	- Patient tachypneic - Improperly placed abdominal sensor
	E5	- APNEA ALARM setting in OFF position	- In CPAP/BACKUP a valid APNEA ALARM setting must be established - Set APNEA ALARM for desired duration
Star Sync Inoperative	E10-E21	- See "Error Code" section for individual explanations	- Contact Infrasonics
APNEA ALARM	Audible APNEA ALARM	- Patient Apneic	- Refer to hospital protocol
		- Abdominal sensor untaped	- Reapply sensor using 2 pieces of 1/2" micropore tape
		- Abdominal sensor damaged	- Replace sensor
		- Abdominal sensor tubing kinked at capsule	- Unkink and inspect . If damaged, replace
		- Abdominal sensor disconnected from ABD port on Star Sync	- Reconnect abdominal sensor

TROUBLESHOOTING CHART

SYMPTOM	INDICATED BY	POSSIBLE CAUSE	CORRECTIVE ACTION
Small % of SIMV breaths synchronized	Wide margin between the selected SIMV and the SYNCHRONIZED/ASSISTED BREATH RATE	- Improper placement of abdominal sensor - Damaged sensor - Patient Apneic	- See "Star Sync Operators Manual" p. 19 - Replace sensor - Refer to hospital Protocol

Boulder Community Hospital

Boulder, Colorado

INFANT STAR FLOW SHEET

Date: _____ **Therapist:** _____

Physician: _____

Gestation: _____ **Weight:** _____

Tube Size: _____ **cm at lip:** _____

Time								
Mode								
FiO_2								
PIP								
PEEP								
Respiratory Rate								
I-Time								
E-Time								
I:E Ratio								
Mean Airway Pressure MAP								
Flow								
O_2 Sat								
HR								
Concha Temp								
Low PEEP								
Low Pres								
Pop Off								

Time	Breath sounds, suction, comments

ABG's

Time	Site	PH	$PaCO_2$	PaO_2	SaO_2	HCO_3	B.E.

Patient Label

Boulder Community Hospital

Boulder, Colorado

INFANT STAR

[redacted] **Ventilator Check Off / Set-Up Sheet**

_____ Ventilator clean

_____ Ventilator holds pressure

_____ Holds PEEP

_____ Alarms function

_____ Circuit and filters intact

_____ New concha in place

_____ Pre-Set:

Pressure 20 cm H_20 _____
I-Time .35 _____
PEEP of 5 cm H_20 _____
Alarms set _____
Rate of 30 bpm _____
Flow 10 L _____
FiO_2 100% _____
Pop Off Set 5 cm H_20 above PIP _____
Low pressure 5 below PIP _____

Date: _____

Name: _____

Problems / Comments: _____