

Hi-VNI[®] Technology

PRECISION FLOW Hi-VNI[™]

Precision Flow[®] Hi-VNI Nurse Call and EMR Installation Instructions



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Nurse Call Installation Instructions

1 Introduction

This document describes the Nurse Call communication interface of the Precision Flow® Hi-VNI device. This document is intended for use by hospital IT, biomedical engineering or other experts who wish to connect the Precision Flow® Hi-VNI into a Nurse Call system.

2 Scope

This document applies to the current design and embedded firmware version of the Precision Flow® Hi-VNI unit. The current software version is 4.4.1. This document does not cover any earlier versions of Precision Flow® Hi-VNI embedded firmware and will require a review and update for future versions of the firmware.

3 Hardware Interface Description

3.1 Nurse Call Interface

The Nurse Call / EMR Communication Cable (Part No. 3100897) contains a 3 pin 3.5 mm Stereo Audio Jack (See P2 in Figure 1) for indicating an alarm condition on a hospital nurse call system and a DB9 female Data Jack for interfacing Electronic Medical Record capable technologies.

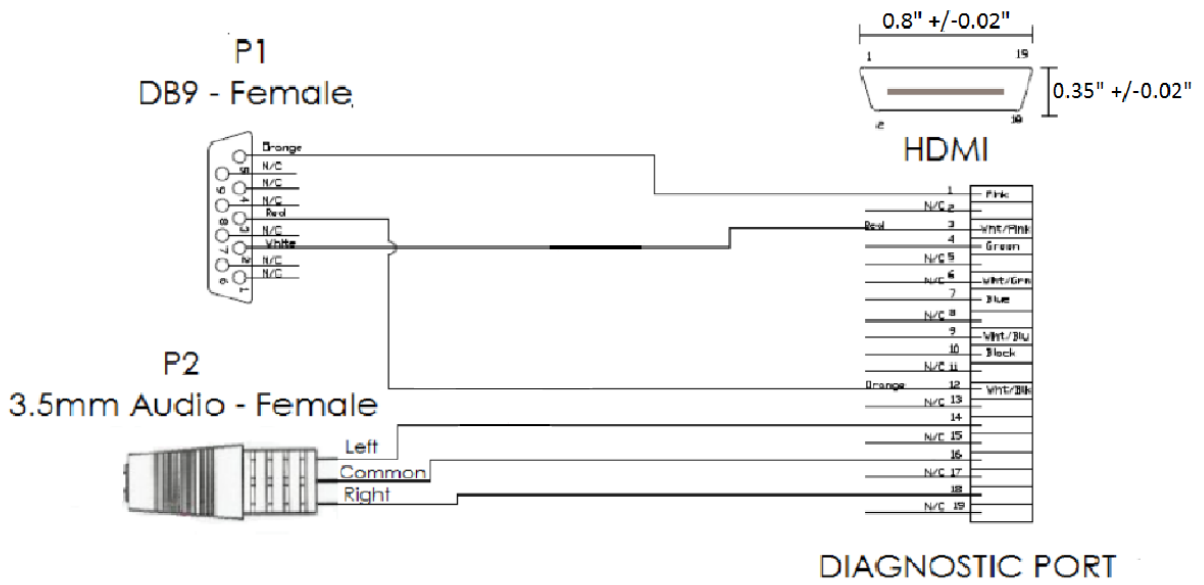
An adapter or re-termination of the cable's 1/8 in. (3.5 mm) stereo audio jack connection will be necessary and shall be supplied by the user to connect the Nurse Call Interface Adapter to the hospital's nurse call system.

4 Wiring Guide: Connecting the Nurse Call Cable

The cable's 3.5mm stereo jack supports "Normally Open" and/or "Normally Closed" Nurse Call system connections. The signals on the 3 connector contacts are (see P2 in Figure 1 and Figure 1A):

- Normally Closed (pin 18 of HDMI connector) Ring or Right Channel of 3.5mm audio Jack (See Figure 1A)
- Normally Open (pin 14 of HDI connector) Tip or Left channel of 3.5mm audio Jack (See Figure 1A)
- Common (pin 16 of HDMI connector) Sleeve or common channel of 3.5mm audio Jack (See Figure 1A)

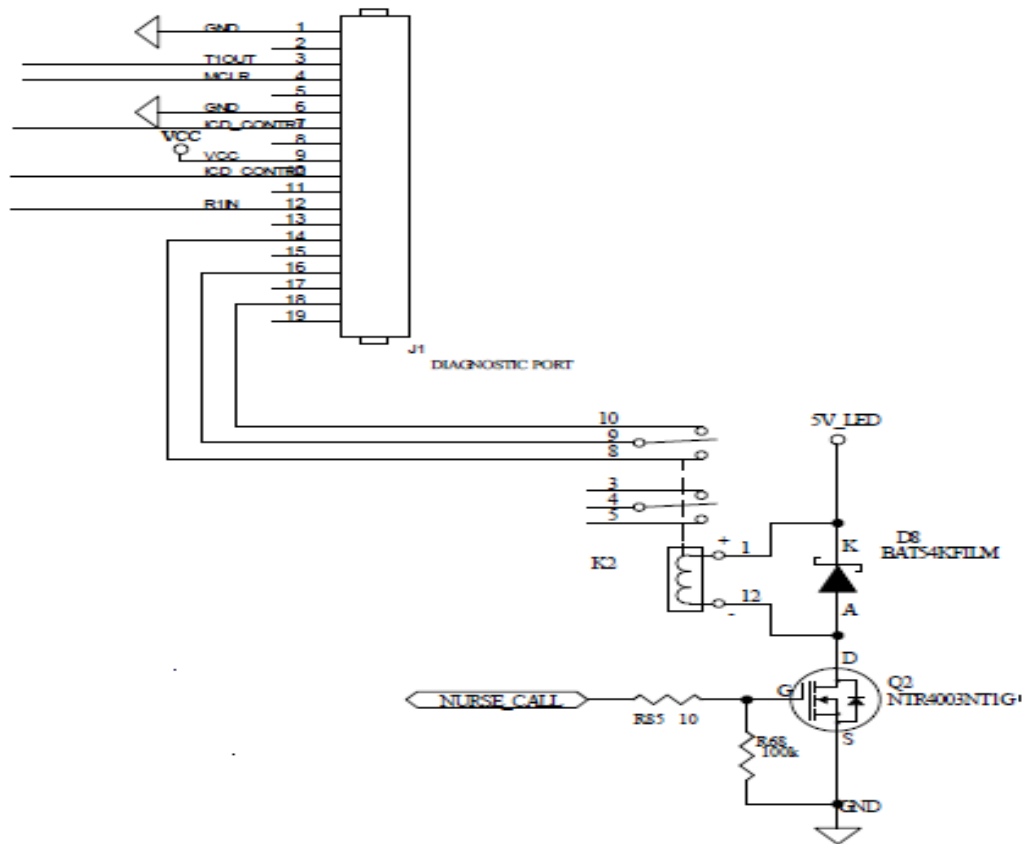
4.1 Figure 1: Nurse Call & EMR Cable Schematic



4.2 Figure 1A: 3.5mm Stereo Audio Jack Male Pinout



4.3 Figure 2: System Schematic














5 Installation Instructions

Remove the silicone plug in the oxygen sensor cover on the back of the Precision Flow[®] Hi-VNI and plug in the HDMI connector of 3100897 into the HDMI port of the Precision Flow[®] Hi-VNI. Connect the other end of the properly terminated cable to the hospital Nurse Call system. Refer to figures 1, 1A and 2 for circuit diagram and schematic reference.

6 Alarms

Precision Flow[®] Hi-VNI Alarms that signal the Nurse call station are defined in Table 1. Also, embedded software shall detect a control system fault if any of the Precision Flow[®] Hi-VNI sensor count values are out of range for more the 5 seconds. These control system faults shall illuminate the General Fault Alarm, sound the medium priority alarm and will display a numeric fault code (50 through 83) in the temperature display on the LED display. These control system faults shall also trigger the nurse call station.

6.1 Table 1: Alarms that signal Nurse Call

Alarm icon	Audio Signal	Indicates
General fault (flashing) 	Medium Priority Cannot be muted	Malfunction of sensor or control system
General fault (flashing) % O ₂ displays dashes (- -) 	Medium Priority Cannot be muted	O ₂ sensor fault
Blocked tube (flashing) 	Medium Priority Mutes only during brief reset period	High back pressure
Water out (flashing) 	Medium Priority	No water in disposable water path. Gas flow continues without heating or water circulation.
Disposable water path (flashing) 	Medium Priority	Disposable water path faulty or not detected. Unit will not run.
Battery (flashing) 	Medium Priority	The unit is running in BATTERY mode. Gas flow and blending continue without heat or water circulation.
Cartridge fault 	Medium Priority	Cartridge and/ or DPC not detected. Unit will not run
Cartridge Fault 	Low Priority	Gas bubbles in water circulation. Unit continues to operate.
Gas supply (flashing) Gas supply (continuous and flow rate numeric display flashes) 	Medium Priority	Gas supply pressure outside 4-85 psi (28-586 KPa) range. Unit will not operate.
Gas supply (flashing) Gas supply (continuous and flow rate numeric display flashes) 	Medium Priority	Selected flow cannot be provided from current gas supply.
Temperature display shows dashes (- -) flashing, & General Fault icon 	Medium Priority Can- not be muted	Temperature out of range.

7 Installation Verification Procedure

Verify that the complete system is functioning by creating a test alarm and checking that the correct result has been received.

1. Connect and turn on the Precision Flow[®] Hi-VNI. Refer to Section 7 of the Precision Flow[®] Hi-VNI Instruction for Use (3101477-01-EN)
2. Force an alarm occurrence, by placing your thumb over the distal end of the delivery tube to simulate a blocked tube condition.
3. Confirm that you receive the result you expect in the system according to the hospital standard for that alarm, such as a warning light is turned on or an audio signal is received.
4. Release your thumb from over the distal end of the delivery tube to clear the blocked tube condition and confirm that the nurse call alarm condition clears.

After the test has been successfully concluded, the Nurse Call is ready for use.

EMR Installation Instructions

8 Introduction

This document describes the serial communication interface of the Precision Flow[®] Hi-VNI device for use with EMR Systems. This document is intended for use by computer programmers and other experts who wish to implement an EMR system with the Precision Flow[®] Hi-VNI.

Data transfer uses a physical RS-232 connection and a communication protocol described in this document.

9 Scope

This document applies to the current design and embedded firmware version of the Precision Flow[®] Hi-VNI unit. This document does not apply to firmware versions prior to 4.4.1. This document only applies to EMR implementations.

10 Hardware Interface Description

10.1 Hardware

The Precision Flow[®] Hi-VNI has an HDMI style connector on the back of the unit. The Vapotherm **Nurse Call / EMR Communication Cable (Part No. 3100897)** has an HDMI connector on one end and a DB9 Female RS-232 connector on the other end. This cable can be used to connect the PF Hi-VNI to standard RS-232 port on a EMR system. The pin out of this cable is shown in Figure 1

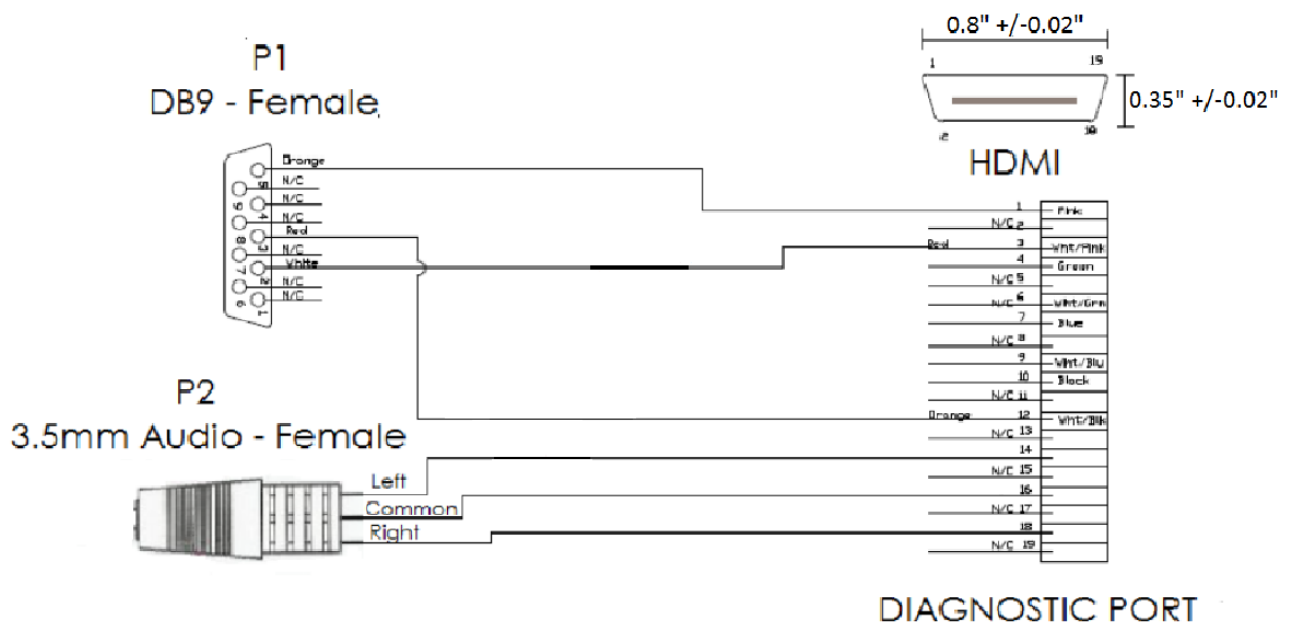


Figure 1: Nurse Call / EMR Communication Cable

10.2 Serial Port Configuration / Parameters

The serial communication configuration is:

- 38,400 baud rate
- 8 data bits per word
- 1 Stop bit
- No parity
- No hardware flow control

All data transmitted and received are in ASCII format.

11 Communication Interface Description

11.1 Introduction

The communication protocol is a command/response system. The EMR system will send a request for data and the Precision Flow[®] Hi-VNI will respond.

In addition, the Precision Flow[®] Hi-VNI will transmit certain messages without a request from the EMR system (asynchronous messages). These messages can be ignored by the EMR system and are typically sent when certain events or conditions change on the Precision Flow[®]. For example, when air supply gas is connected to the Precision Flow[®] the embedded firmware will send a status message, an example is shown below:

```
User flow rate changed from 0.5 to 5.0  
OpMode=Single_Gas:Air
```

11.2 EMR Data Acquisition General Description

EMR systems may acquire the current therapy delivery status and parameters by sending a single carriage return character (<CR>, ASCII code 13 dec, 0x0D hex) to the Precision Flow[®]. This is a status request.

The Precision Flow[®] will respond with an ASCII text formatted message (status message) that will include the follow items of information:

- Temperature (User Selection and Current Temperature)
- Flow Rate (User Selection and Effective Flow Rate)
- FiO₂ (User Selection and measured concentration)
- Operating Mode

All messages sent from the PF Hi-VNI unit are terminated with a carriage return character and a line feed character (<CR><LF>) sequence.

The Precision Flow[®] Hi-VNI will respond to each status request with current data. The EMR can send status requests as frequently as required to meet data acquisition requirements.

However, the EMR system should not send a new request before the Precision Flow[®] Hi-VNI has responded to a previous request. In other words, the EMR system cannot send 5 carriage return characters in rapid sequence and expect the Precision Flow[®] Hi-VNI to output 5 status messages; send one carriage return, get one response, repeat.

11.3 Null Byte in message

The Precision Flow[®] Hi-VNI will occasionally insert a ‘null’ (ASCII code 0) byte in a message. The software in the EMR system must remove this byte from the received message to accurately parse the message. Note: The null byte is an extra character, removing this byte will yield a complete message line from the Precision Flow[®] Hi-VNI .

11.4 EMR Data Format Specifics

When the EMR sends a <CR> byte the Precision Flow[®] Hi-VNI will respond with two lines of data (each terminated with <CR><LF> characters). Example output is shown below:

```
Temp=33(22) Flow=5.0(5.0) O2%=021(18.2) Mode=Standby OpMode=Single_Gas:Air
water=out Faults: 0x00000000 = None.
```

Each of the three user selectable parameters are shown with corresponding current data. The user setting is the number that follows the ‘=’ character, and the current data is the number in the parentheses. Current data values are detailed below:

Temperature: Current water temperature as measured in the water return path.

Flow Rate: The number in the parentheses is the effective flow rate. The effective flow rate is determined from the FiO₂ setting and the current gas supply pressures. The effective flow rate will be lower than the user selected flow rate if there is not sufficient gas supply pressure to reach the user desired flow rate.

O₂%: The current O₂ concentration as measured by the O₂ sensor. Note: The O₂ sensor requires periodic calibration that is initiated automatically by the Precision Flow[®] Hi-VNI system. In addition, when the Precision Flow[®] Hi-VNI is not in run mode, there will not be a continuous gas flow at the O₂ sensor, therefore this value will not always match expected values. The Precision Flow[®] Hi-VNI system is designed to handle O₂ sensor re-calibration and sensor accuracy when appropriate based on operating conditions. In terms of EMR data acquisition and therapy delivered to the patient, the user setting value should always be used and indicates the FiO₂ percentage delivered.

In addition to the user selectable parameters the status message includes the current operating mode, supply mode status, DPC water status, and current fault conditions.

Mode: This is current operating mode of the Precision Flow[®] Hi-VNI ; possible values are:
“Standby”: The Precision Flow[®] Hi-VNI is not delivering therapy.
“Run”: The Precision Flow[®] Hi-VNI is currently delivering therapy.
“Run(warm)”: The Precision Flow[®] Hi-VNI is delivering therapy, but the water temperature has not yet reached the user selection.

“Battery”: The Precision Flow[®] Hi-VNI is flowing and metering gas, but the AC power has been lost and the Precision Flow[®] Hi-VNI has turned off the heater to conserve energy.

“Fault”: The Precision Flow[®] Hi-VNI has detected a fault condition and is not delivering therapy.

OpMode: This indicates the gas supply status. Possible values are:

“No_Gas”: Neither the O₂ or Air supplies are connected.

“Single_Gas:O₂”: Only the O₂ supply is connected.

“Single_Gas:Air”: Only the Air supply is connected.

“Dual_Gas”: Both O₂ and Air supplies are connected.

Water: Indicates presence of water in the DPC water path.

Faults: If there are no faults detected, this value will be zero formatted as a hexadecimal number. It is beyond the scope of this document to describe the faults and it is not necessary for EMR implementation. The EMR system should always use the mode information described above to determine when therapy is being delivered to the patient.

Example data parsing:

```
Temp=33(22) Flow=5.0(5.0) O2%=021(18.2) Mode=Standby OpMode=Single_Gas:Air  
water=out Faults: 0x00000000 = None.
```

The user selected temperature is 33 degrees and the temperature as measured by the sensor at the water return path is 22 degrees.

The user selected flow rate is 5.0 LPM and there is sufficient supply pressure to reach 5.0 LPM at the current FiO₂ setting.

The user selected FiO₂ percentage is 21%. The O₂ sensor is currently reading 18.2%, however since the Precision Flow[®] Hi-VNI is not currently flowing gas, this reading is likely not accurate.

The Precision Flow[®] Hi-VNI is in standby mode and is not flowing gas or delivering therapy.

Only the Air supply is connected.

The water sensor is not detecting water in the DPC (note: the DPC may not be inserted).

There are no fault conditions detected.

12 Installation Instructions

Remove the silicone plug in the oxygen sensor cover on the back of the Precision Flow[®] Hi-VNI and plug in the HDMI connector of 3100897 into the HDMI port of the Precision Flow[®] Hi-VNI.

Connect the other end of the properly terminated cable to the hospital EMR System. Refer to figures 1 for circuit diagram and schematic reference.

13 Installation Verification Procedure

Verify that the complete system is functioning by placing the Precision Flow[®] Hi-VNI in run mode and checking that the correct status has been received.

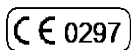
1. Connect and turn on the Precision Flow[®] Hi-VNI. Refer to Section 7 of the Precision Flow[®] Hi-VNI Instruction for Use (3101477-01-EN).
2. Initiate connection between the Precision Flow[®] Hi-VNI and the hospital EMR system.
3. Initiate a response at the EMR system from the Precision Flow[®] Hi-VNI and confirm the received data is correctly represented at the EMR system.

After the test has been successfully concluded, the Precision Flow[®] Hi-VNI EMR System is ready for use.



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