DT-7000
OPERATOR'S MANUAL

Software Version 1.01

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INTRODUCTION

System Overview

Wireless **M**edical **T**elemetry **S**ervices (WMTS) Remote Transceivers provide the link between the patient and the Central Station through the newly approved 608 - 614 MHz Medical Telemetry frequency band. The ambulatory and bedside device transceivers communicate data to the Central Station through the Access Point transceiver. In addition, the transceivers are capable of receiving control commands for self-use or connection transfer.

The PatientNet ambulatory transceiver is the DT-4500. This transceiver is worn by the patient and usually carried in a gown pocket or paper pouch, and used with a 6-wire leadset connected to the electrodes on the patient.

The DT-7000 and 7001 are the PatientNet bedside-device transceivers and are physically connected to bedside monitors (other manufacturers' bedside monitors and ventilators).

The DR-10000 Access Point transceiver collects data from the ambulatory and bedside transceivers, sends that data to the Central Station, and transmits control data to the transceiver devices.

Equipment Site Selection/Location

The DT-7000 transceiver is attached to a bedside device through the use of the adhesive strip or screws.

Clinical Use and Responsibility

CAUTION: United States Federal law restricts this device to sale by, or on the order of, a physician or properly licensed practitioner.

The PatientNet System provides the technology to monitor cardiac rhythms, vital signs, and equipment alarms for patients with various levels of acuity in multiple patient care settings.

The monitoring system does not replace physicians, caregivers or system operators. We recognize that machines are not capable of replacing human judgment, and emphasizes the importance of the human element in the determination of any patient care interventions.

Implementation of clearly documented and communicated patient care guidelines and protocols accepted by the healthcare team is essential to the optimal use of the PatientNet System.

The following list is intended to provide guidance in determining potential high risk patients, but the actual definition for risk is a clinical judgment reserved for the care-givers.

- clinically unstable patients
- patients who require frequent intervention
- patients with pacemakers
- patients with a history of rapid or frequent rate and/or rhythm changes
- patients who experience dramatic changes in their QRS complexes
- patients receiving medications that could result in rapid or frequent rate and/or rhythm changes
- ventilator-dependent patients

User Warnings, Cautions, and Notes

Before operating the WMTS transceivers, read and follow all warnings and cautions presented in this section.

Warnings

1. **Do not operate this device in the presence of flammable anesthetics. Such an environment presents the risk of explosion.**
2. **Do not use transceivers that have been dropped, or damaged due to severe impact, until a biomedical engineer has inspected them. Cracks, openings, or other damage to the transmitters/transceivers can compromise the electrical safety features of the transmitters/transceivers.**

Cautions

1. **Any changes or modifications to the device that are not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.**
2. **Do not open or modify this device, including the antenna, without approval by the manufacturer, or an authorized service agreement. Doing so will result in violation of FCC compliance.**
3. **Electromagnetic interference or power overload, due to electrosurgical or diathermy instruments, may damage the device.**
4. **The transceiver is an intentional radiator of RF energy that may interfere with the operation of electronic/electrical equipment not associated with the attached system. Maintain a minimum 4-inch separation between the remote antenna and other electronic/electrical equipment.**
5. **For optimum transceiver reception, you must carefully select the transceiver frequencies that avoid interference.**
6. **The chassis is equipped with male and female AC sockets to accommodate various UL approved AC line cords. UL approval prohibits the simultaneous use of both AC sockets.**

Notes

1. This equipment has been tested and found to comply with the limits for a CLASS B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and possibly radiates radio frequency energy, and, if not installed and used in accordance with the instructions contained in this manual, may cause harmful interference to radio and television communications. However, there is no guarantee that interference will not occur in a particular installation.

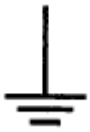
   If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, then the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate the receiving antenna
   - Increase the separation between the equipment and the receiver
   - Connect the equipment into an outlet on a circuit different from that of the receiver
   - Consult the dealer or an experienced audio television technician

2. To ensure that the use of this product does not contribute to interference, it is necessary to use shielded I/O cables. Connecting this device to peripheral devices that do not comply with the CLASS B requirement or using an unshielded peripheral data cable could result in harmful interference to radio or television reception.
3. The DT-4500, DT-7000, and DT-7001 should be disposed of at the end of their useful life per applicable regulations.

Definitions of International Symbols

The following table defines the international symbols that appear on the PatientNet Wireless Network™

Symbol	Name	Definition
	**Attention**	Consult accompanying documents
	**Hazardous Voltage**	Caution: Dangerous Voltages. Do not remove cover or back. Refer servicing to qualified service personnel.
	**Off**	Power is disconnected from main source
	On	Power is connected to main source
	**Button**	System on/off

	**Earth Ground**	Functional. The device is electrically grounded.
	**Defib Protection**	This is a type BF equipment with Defibrillator protection
	**UL Mark**	Underwriters Laboratory classification mark
	**Fragile: Handle with Care**	Storage / Transportation Packaging
	**Keep Dry**	Storage / Transportation Packaging
	**Temperature Limitation**	Storage / Transportation Packaging

	**Humidity Limitation**	Storage / Transportation Packaging
IPX7	**IPX7**	This device can be immersed in 1m of water for 30min.
IPX1	**IPX1**	This device is protected against vertically falling water drops.
V	**Volts**	The practical m/kg/sec unit of electrical potential difference and electromotive force that is equal to the difference of the potential between two points in a conducting wire that is carrying a constant current of one ampere, when the power dissipated between these two points is equal to one watt, and is equivalent to the potential difference across a resistance of one ohm when one ampere is flowing through it.
A	**Amperes**	The practical m/kg/sec unit of electric current that is equivalent to a flow of one coulomb per second or to the steady current produced by one volt applied across a resistance of one ohm.
VA	**Volt Amperes**	A unit of electric measurement that is equal to the product of a volt and an ampere that for direct current constitutes a measure of power equivalent to a watt.
Hz	**Hertz**	A unit of frequency that is equal to one cycle per second.

USE AND MAINTENANCE

The DT-7000 and DT-7001 send data and alarm information from bedside monitors and ventilators to the Central Station.

The transceivers support the bedside monitors shown in “Appendix A” on page 167.

Power to the DT-7000 is provided through one of the following:

- the AC power adapter, which provides continuous power
- the bedside monitor, which provides continuous power

Power to the DT-7001 is provided through one of the following:

- the AC power adapter, which provides continuous power
- the bedside monitor, which provides continuous power
- the internal battery, which is replaceable by qualified service technicians

Note: See your hospital’s Service Department for battery replacement.

Operating Instructions

The DT-7000 and DT-7001 appearance and functionality are equivalent; however, only the DT-7001 is capable of using an internal battery as a power source.

Push Button Function and Use

See Figure 1 on page 15 for an image of the DT-7000/DT-7001 controls and LED indicators.

External Serial Devices (I/O) Ports

The External Serial Device (I/O) ports allow external serial devices or programming cables to connect and maintain logical communication links between the DT-7000/DT-7001 and the Central Station.

Note: *External Serial Device (I/O) Port 1 is currently functional. I/O Ports 2, 3 and 4 will be functional in future product releases.

Remote Record

When depressed, the Remote Record function button will initiate a strip chart recording at the Central Station.

Nurse Call

When depressed, the Nurse Call function button will initiate a Nurse Call Alarm at the Central Station.

Power Button

Pressing the Power button either places the transceiver in or out of Standby Mode.

Attendant Present / Procedure Alarm Silence (PAS) Unlock Button

The Attendant Present push button has three functions. Each function is initiated based on how long the button is pressed.

1. **Exiting the Standby Mode**

   DT-7001 - If the transceiver is powered by battery only, then pressing the Attendant Present button will take the transceiver out of Standby Mode and all LEDs will illuminate for a few seconds.
   DT-7000 - If the transceiver is powered by an external power source, then pressing the Attendant Present button will take the transceiver out of Standby Mode.

Note: The LEDs are constantly illuminated when powered by an external source.

2. **Initiating an Attendant Present Alarm**

   Once the transceiver is out of the Standby Mode, pressing the Attendant Present button will activate the **Attendant Present** function and initiate an Attendant Present Alarm at the Central Station.

3. **Unlocking the PAS button**

   The PAS button must be disabled prior to initiating the Procedure Alarm Silence alarm. In the “locked” position, the PAS button is disabled.

   To “unlock” the PAS key, press, and hold (for about two seconds), the Attendant Present button until the Procedure Alarm Silence Status Indicator LED begins flashing. Once the LED indicator starts flashing, the PAS button is in the “unlocked mode” and functional.

Note: The PAS button must be pressed while the LED is still flashing. If it is pressed after the LED has stopped flashing, then the PAS button will automatically be “re-locked”.

Procedure Alarm Silence (PAS) Button

Depressing the PAS button, while the PAS Status Indicator LED is flashing, informs the clinicians at the Central Station area that the attending nurse will be performing a procedure to the patient that may cause inadvertent false alarms at the Central Station (i.e. changing lead wires, electrodes, etc.)

Once the PAS button is pressed, the following events occur at the Central Station.

1. A timer is displayed in the fourth patient block configurable field that displays the length of Procedural Alarm Silence time remaining on the transceiver.

CAUTION: All non-level one alarms are ignored while the PAS alarm is active.

2. "PA SILENCE" is denoted in Full Disclosure for the duration of the PAS period.

Once the PAS button is pressed, the DT-4500 enters the PAS Mode with the following indications:

1. The active time is set for 120 seconds and begins counting down.
2. The active time is transmitted to the Central Station.
3. The PAS Status LED indicates the time remaining through its flash speed. The LED flash speed increases as the PAS time remaining decreases from 120 seconds to 0 seconds.
4. The attendant can reset the PAS active time to 120 seconds by pressing both Attendant Present buttons again.

The Procedure Alarm Silence alarm remains active until one of the following conditions occur:

1. The transceiver no longer sends the procedure alarm silence indicator to the Central Station.
2. A level one alarm is detected and triggered at the Central Station
3. The patient tile alarm text area is clicked on. All alarms are set to ON once this area is clicked.
4. The attendant presses the PAS button while PAS is active. This will automatically cancel the 120 second PAS at the Central Station, and will re-enable the audible alarm tone.

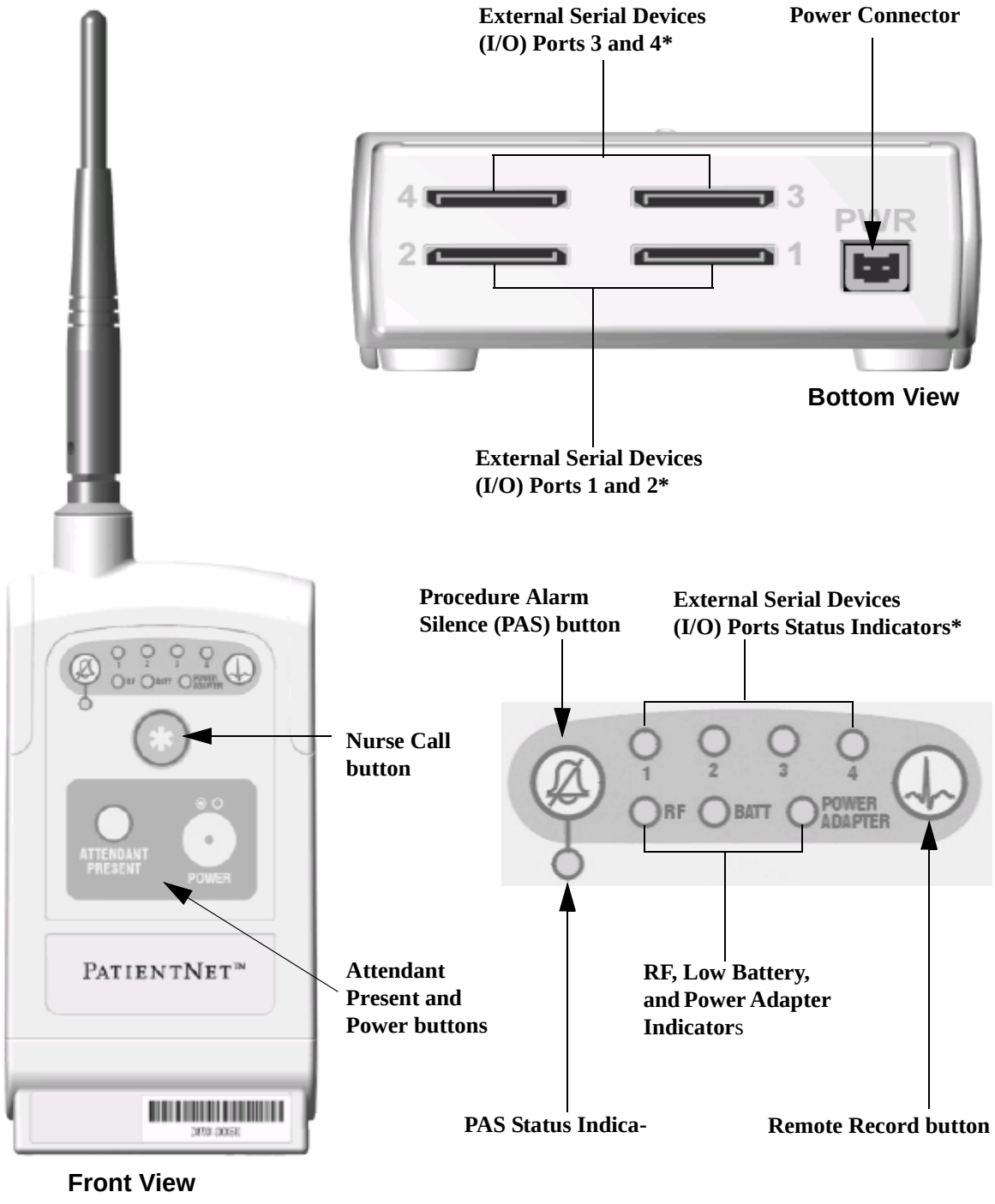


Fig. 1. DT-7000/DT-7001 Controls, I/O Ports, and LED Indicators

Note: *External Serial Device (I/O) Port 1 is currently functional. I/O Ports 2, 3 and 4 will be functional in future product releases.

LED Indicators Function

Once the transceivers exit Standby Mode, either by pressing the Attendant Present or Power buttons, all LED indicators are illuminated for a brief period. After the specified time period, only those LEDs displaying positive (or negative) transceiver functions, as described in each section below, remain illuminated.

Procedure Alarm Silence Status Indicator

The Procedure Alarm Silence Status Indicator is illuminated when the PAS function is active. The LED flashes while the Procedure Alarm Silence Key is unlocked or the PAS active time is running low. The PAS key can only be pressed and activated during this unlocked phase. Refer to the section on “Procedure Alarm Silence (PAS) Button” on page 14 for more information.

External Serial Devices (I/O)

The External Serial Device (I/O) LEDs are labeled 1-4 and are each illuminated when there is an external serial device connected, detected, and maintaining a logical communication link to the corresponding I/O data port (fig. 1).

Low Battery (BATT)

The Low Battery (BATT) LED is illuminated while the battery voltage remains good; however, the LED flashes when the battery voltage falls below a predetermined value. When the battery power falls below a predetermined value, then the transceiver will automatically power itself off.

RF link (RF)

The RF link indicator is illuminated while there is RF communication between the DT-7000 and DT-7001 transceivers and the Central Station. The LED flashes if there is communication between the transceivers and the Access point, but not the Central Station.

Power Adapter

The Power Adapter LED is illuminated when the transceiver is powered from an external power source that is connected to the Power Connector (fig. 1), and not one of the I/O ports.

Cleaning

This section provides cleaning and maintenance instructions for DT-7000 and DT-7001 transceivers.

Read and follow all precautions when cleaning transceivers.

WARNING: VitalCom makes no claims concerning the sterilization of the DT-4500 Ambulatory, DT-7000, and DT-7001 Instrument Transceivers.

CAUTION: Do not gas sterilize or AUTOCLAVE any part of the monitoring system, transmitters, or transceivers.

Note: DO NOT use abrasive cleaners.

Cleaning the Chassis

1. Transceivers can be cleaned with a gauze pad or cloth moistened with one of the following agents:.
   - Soap and Water
   - Quaternary Ammonium
   - Glutaraldehyde 2%
   - Dilute Chlorine Bleach (Sodium hypochlorite), 10% solution, freshly made in past 24 hours
   - Isopropyl Alcohol 70%
   - Ethyl Alcohol
2. Use a cloth moistened with distilled water to rinse away the cleaning solution.
3. Dry thoroughly with a lint-free cloth.

Connecting to the Bedside Monitor

See Figure 1 on page 15 for an image of the DT-7000/DT-7001 controls and LED indicators.

Note: Before the transceiver is connected to the bedside monitor, the system administrator must program it with the bedside device specific software module.

1. Attach the transceiver to the bedside monitor by sliding the Device Hook over the Mounting Disk until the transceiver snaps into place. The Mounting Disk is provided with the transceiver and is attached to the bedside device through adhesive or hardware tools.
2. Connect the AC power adapter into the power port located on the bottom of the transmitter.
3. Plug the AC power adapter into the wall electrical outlet. If the AC power adapter is not used, the transmitter will operate either from its internal battery (DT-7001 models) or from connection to the bedside device.
4. Attach the host end of the I/O cable to I/O port 1 (Ports 2, 3 and 4 will be functional in future releases).
5. Attach the other end of the I/O cable to the bedside monitor.

SPECIFICATIONS

Specifications are approximate and may change with the actual unit shipped. Call VitalCom Customer Support 800.955.2424 if precise specifications are required.

The DT-7000 is an externally powered Class 1 device and is suitable for continuous operation.

The DT-7001 is an internally powered Class 1 device and is suitable for continuous operation.

Both devices are intended for non-patient connection use.

Table 1 DT-7000/7001 Environmental Specifications

	Operating	Storage
Temperature	+41° F to +104° F +5° C to +40° C	-4° F to +158° F -20° C to +70° C
Humidity	15% to 95% non-condensing	10% to 95% non-condensing
Pressure/Altitude	1060 hPa to 700 hPa -1,252’ to 9,840’	1060 hPa to 500 hPa -1,252’ to 18,280’

Table 2 DT-7000/7001 Device Specifications

Component	Requirements
Environmental Protection	IPX1
Power Supply	input 120V, 60Hz, 35 VA Output 6VOC @ 1.6 A
Frequency Range Programmable	608 - 614 MHz
Modulation	Digital Encoded FM (FSK)
Dimensions	3.0 in. x 1.25 in. x 7.0 in. (11.0 in. tall with antenna up)

STATEMENT OF COMPLIANCE

UL Classification

DT-700x
WITH RESPECT TO ELECTRIC SHOCK, FIRE,
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL2601-1/CAN/CSA
C22.2 NO. 601.1
79VK

The DT-7000/7001 transceiver is classified in accordance with UL 2601-1 and IPX1 (according to IEC 529-1989) on non-patient equipment. The DT-7000/7001 has been designed to withstand the effects of EMI and meets the EMC requirements of EN60601-1-2 (April 1993) and CISPR 11. However, extremely high levels of electro-magnetic energy (above the levels of EN60601-1-2) may still produce interference.