GE Healthcare

ApexPro™ Telemetry System

Operator's Manual

Software Version 4

CARESCAPE® Telemetry T14 Transmitter

ApexPro™
English
2028341-012 (CD)
2028340-030A (paper)

NOTE

Due to continuing product innovation, specifications in this manual are subject to change without notice. The information in this manual applies to ApexPro software version 4 or later and the CARESCAPE Telemetry T14 transmitter.

NOTE

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Contents

1 Introduction

Manual information

Purpose

This manual contains the instructions necessary to operate the ApexPro telemetry system safely and in accordance with its function and intended use.

It also contains limited instructions necessary to operate the telemetry system when used with the CIC Pro Clinical Information Center. For more information, refer to Related documents on page 1-2.

Intended audience

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices, and terminology, as required for monitoring of critically ill patients.

Related documents

This manual is intended to be used in conjunction with the CIC Pro Clinical Information Center Operator's Manual (PN 2026421-001) and the CIC Pro Clinical Information Center Bedrock Hardware Platform Service Manual (PN 2026421-002).

This manual assumes that you are familiar with the operating procedures of the CIC Pro Clinical Information Center. It uses the CIC Pro software version 5 (or later) user interface for procedures, navigation and illustration purposes.

If your system uses an earlier CIC Pro software version, you may notice minor discrepancies between what you see on the equipment and the information presented in this manual. Refer to the documentation provided with your system for the most accurate operator's and service instructions.

Conventions used

Equipment terms

This manual uses the following terms to simplify common equipment names.

Term	Description
ATS	Refers to the ApexPro Telemetry Server.
CIC Pro center	Refers to the CIC Pro Clinical Information Center.
Monitor	Refers to a bedside monitor, transport monitor, blood pressure monitor, or a wireless monitor on the Unity Network.
Printer	Refers generically to a direct digital writer or a laser printer.
Server	Refers to the ApexPro Telemetry Server (ATS) or a CIC Pro center with a BCM or Nightshade server.

Term	Description
Transmitter	Refers to the CARESCAPE Telemetry T14 transmitter.
Writer	Refers to the PRN 50-M digital writer.

Text styles

This manual uses the following text styles to identify hardware terms, software terms and the correct way to enter data.

Style	Definition
Bold	Indicates hardware items, such as keys, labels or connectors.
Bold and italicized	Indicates software items, such as menus, menu options or screen text.
Italics	Emphasizes a word.
>	Indicates menu options or control settings to select consecutively.
+	Indicates keyboard keys to select simultaneously.

Illustrations and names

In this manual, all illustrations are provided as examples only. They may not necessarily reflect your monitoring setup or data viewed on your monitoring device.

All names appearing in examples and illustrations are fictitious. The use of any real person's name is purely coincidental.

Ordering manuals

A paper copy of this manual will be provided upon request. Contact your local GE representative and request the part number on the first page of the manual.

Revision history

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter changes whenever the document is updated.

Revision	Comments
A	Initial release.

Equipment information

Intended use of this equipment

The ApexPro telemetry system is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro telemetry system is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure and SpO2. The ApexPro telemetry system is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro is also intended to provide physiologic data over the Unity network to clinical information systems for display.

Safety statements

The safety statements presented in this chapter refer to the equipment in general and, in most cases, apply to all aspects of the device. There are additional safety statements in other chapters which are specific to that chapter content.

The order in which safety statements are presented in no way implies the order of importance.

Dangers

Danger statements identify an imminent hazard which, if not avoided, will result in death or serious injury. No danger statements apply to this system.

Warnings

Warning statements identify a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

The following warning statements apply to this system.

WARNING
Do not monitor patients with a 3-leadwire set when reliable pacer detection is required. Pacer pulse detection can be erratic when only a single vector is monitored. Always use a 5- or 6-leadwire set when reliable pacer detection is required.

WARNING
ACCESSORIES (SUPPLIES) — To ensure patient safety, use only parts and accessories manufactured or recommended by GE.

Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

WARNING
ACCESSORIES (EQUIPMENT) — The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity; and
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

WARNING
ACCIDENTAL SPILLS — To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.

WARNING
ACCURACY — If the accuracy of any value displayed on the monitor, central station, or printed on a graph strip is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

WARNING
ADJUSTING SYSTEM ALARM LEVELS — The ***Leads Fail*** alarm indicates that one or more electrodes are not connected to the patient and, as a result, there is loss of all waveforms and arrhythmia analysis. The ***ARR SUSPEND*** alarm indicates that arrhythmia conditions are not being detected and therefore alarms associated with arrhythmias will not occur. The ***Leads Fail*** and ***ARR SUSPEND*** alarms should be adjusted to a lower priority level only by experienced qualified personnel and with great caution. Adjusting these alarms to a lower priority level may result in reduced awareness of conditions that indicate the loss of patient monitoring.

WARNING
ALARMS — Do *not* rely exclusively on the audible alarm system for patient monitoring. Adjustment of ***Alarm Volume*** to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

After connecting the monitor to the central station, nurse-call system, and/or network, verify the function of the alarm system.

The functions of the alarm system for monitoring of the patient must be verified at regular intervals.

Do not rely exclusively on the ***Alarm Pause Breakthrough*** feature for alarm notification during an alarm pause. This may result in a hazard to the patient. Only crisis alarms break through an alarm pause.

WARNING
BEFORE INSTALLATION — Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

WARNING
BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

Before using the system, the operator must verify that it is in correct working order and operating condition.

Periodically, and whenever the integrity of the product is in doubt, test all functions.

WARNING
CABLES — Route all cables away from patient's throat to avoid possible strangulation.

WARNING
CONDUCTIVE CONNECTIONS — Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

WARNING
DEFIBRILLATION — Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.

WARNING
DISCONNECTION FROM MAINS — When disconnecting the system from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device. If you do not observe this sequence, there is a risk of coming into contact with line voltage by inserting metal objects, such as the pins of leadwires, into the sockets of the power cord by mistake.

WARNING
DISPOSAL — Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

WARNING
DUST COVERS — If the dust covers for the interface connectors become detached from the transmitter, they may pose a choking hazard for pediatric patients. Inspect the dust covers before each use to verify that they are securely attached. If the dust covers become detached and cannot be reinserted into their retaining slot, do not use them on the transmitter, and keep them out of pediatric patients' reach.

WARNING
ELECTRODES — Whenever patient defibrillation is a possibility, use non-polarizing (silver/silver chloride construction) electrodes for ECG monitoring. Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal.

WARNING
ELECTROMAGNETIC INTERFERENCE — Operation of transmitters outside the designated WMTS frequency band is at increased risk for electromagnetic interference. WMTS is protected in the U.S. only. This interference could lead to lapses in patient monitoring and missed alarm events, putting the patient at risk and compromising patient safety.

WARNING
EMC— Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitoring system comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

Changes or modifications to this device/system not expressly approved by GE may cause EMC issues with this or other equipment. This device/system is designed and tested to comply with applicable standards and regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows:

Use of known RF sources, such as cell/portable phones, or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation of this device/system. Consult qualified personnel regarding device/system configuration.

The device/system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device/system should be tested to verify normal operation in the configuration in which it is being used. Consult qualified personnel regarding device/system configuration.

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the device/system.

This device/system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Mains power should be that of a typical commercial or hospital environment. Device is compliant to Class A.

WARNING
EXPLOSION HAZARD — Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

WARNING
IMPROPER TRANSMITTER/LEADWIRE APPLICATION — Applying a transmitter and/or leadwire that is not thoroughly dry to a patient can result in an electrically conductive path being established and a ***Leads Fail*** alarm not being provided if leadwires come off the patient.

WARNING
INCORRECT ALGORITHMS, ARRHYTHMIA PROCESSING AND CALCULATIONS BASED ON PATIENT AGE — After manually updating or automatically retrieving patient demographic information from a network database, *always* confirm that the entered patient's date of birth matches the patient's actual date of birth. Otherwise the appropriate age-related algorithms, arrhythmia detection, and calculations will not be applied.

WARNING
INTERFACING OTHER EQUIPMENT — Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.

WARNING
LEAKAGE CURRENT TEST — When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.

WARNING
LOSS OF DATA — Should the monitor at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until monitor function is restored.

If the monitor does not automatically resume operation within 60 seconds, power cycle the monitor using the power on/off switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

WARNING
LOSS OF DATA —Caregivers and telemetry patients should be made aware of antenna coverage areas. Movement outside of the coverage area may result in loss of patient monitoring.

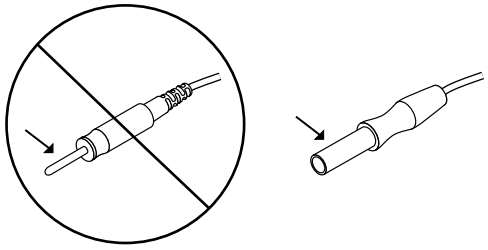
WARNING
NETWORK INTEGRITY — The ApexPro server resides on the Unity network. It is possible that inadvertent or malicious network activity could adversely affect patient monitoring. The integrity of the Unity network is the responsibility of the hospital.

WARNING
OPERATOR — Medical technical equipment such as this monitor/ monitoring system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

WARNING
POWER SUPPLY — All devices must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect the device from the power line and operate it on battery power, if possible.

All devices of a system must be connected to the same power supply circuit. Devices which are not connected to the same circuit must be electrically isolated when operated (electrically isolated EIA232 interface).

WARNING
PROTECTED LEADWIRES — Only use protected leadwires and patient cables with this device. The use of unprotected leadwires and patient cables creates the potential for making an electrical connection to ground or to a high voltage power source which can cause serious injury or death to the patient.



Unprotected Leadwire Protected Leadwire

322C

WARNING
RATE METERS — Keep pacemaker patients under close observation. Rate meters may continue to count the pacemaker rate during cardiac arrest and some arrhythmias. Therefore, do not rely entirely on rate meter alarms.

WARNING
SINGLE PATIENT USE —This transmitter is designed for use on one patient at a time. Using this equipment to monitor different parameters on different patients at the same time compromises the accuracy of data acquired.

WARNING
SITE REQUIREMENTS — For safety reasons, all connectors for patient cables and sensor leads are designed to prevent inadvertent disconnection, should someone pull on them. Do not route cables in a way that they may present a stumbling hazard. For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient.

Cautions

Caution statements identify a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

The following caution statements apply to this system.

CAUTION
DEFIBRILLATOR PRECAUTIONS — Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and leadwires.

Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

CAUTION
DISPOSABLES — Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

CAUTION

DISPOSAL — At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact GE or its representatives.

CAUTION

ELECTROCAUTERY PRECAUTIONS — To prevent unwanted skin burns, apply electrocautery electrodes as far as possible from all other electrodes, a distance of at least 15 cm/6 in. is recommended.

CAUTION

INSTRUCTIONS FOR USE — For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

CAUTION

MAINTENANCE — Regular preventive maintenance should be carried out annually. You are responsible for any requirements specific to your country.

CAUTION

MPSO — Do not use a multiple portable socket outlet (MPSO) for a system because it could result in unacceptable enclosure leakage currents.

CAUTION

NEGLIGENCE — GE does not assume responsibility for damage to the equipment caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support equipment mounted on such walls.

CAUTION

POWER REQUIREMENTS — Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source.

In the U.S.A., if the installation of this equipment will use 240 V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

This equipment is suitable for connection to public mains as defines in CISPR 11.

CAUTION

RESTRICTED SALE — U.S. federal law restricts this device to sale by or on the order of a physician.

CAUTION

SECURITY — The web browser which runs in conjunction with the ApexPro server is intended for hospital INTRANET use only. If confidential patient information is made available from the hospital intranet, the security of the data is the responsibility of the hospital.

CAUTION

SUPERVISED USE — This equipment is intended for use under the direct supervision of a licensed health care practitioner.

CAUTION

UNINTENTIONAL RADIO FREQUENCY (RF) INTERFERENCE — Unintentional RF interference could degrade the reliability and performance of the wireless data link. The facility must maintain an RF environment free from unintentional interference. Refer to the service manuals for more information.

CAUTION

VENTILATION REQUIREMENTS — Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

Notes

Note statements provide application tips or other useful information.

The following note statements apply to this system.

- Put the CIC Pro center in a location where you can easily see the screen and access the operating controls.
- This product is not likely to cause abnormal operation of other patient-connected equipment such as cardiac pacemakers or other electrical stimulators. Exceptions are noted in the pacemaker monitoring section, if applicable.
- This product is protected against the effects of cardiac defibrillator discharges to ensure proper recovery, as required by test standards.
- This equipment is suitable for use in the presence of electrosurgery.

Equipment symbols

NOTE

Some symbols may not appear on all equipment.

	ATTENTION: Consult accompanying documents.
	TYPE B APPLIED PART: Non-isolated applied part suitable for intentional external and internal application to the patient excluding direct cardiac application. [Medical Standard Definition:] Applied part complying with the specified requirements of IEC/EN/UL 60601-1 Medical Standards to provide protection against electric shock, particularly regarding allowable leakage current.
	TYPE CF APPLIED PART: Isolated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application. “Paddles” outside the box indicate the applied part is defibrillator proof. [Medical Standard Definition:] F-type applied part (floating/isolated) complying with the specified requirements of IEC/EN/UL 60601-1 Medical Standards to provide a higher degree of protection against electric shock than that provided by Type BF applied parts.
	Interface connector(s)
IPX3	Complies with IPX3 standards (IEC 60529) for protection against water ingress under test conditions; water sprayed at an angle up to 60 degrees on either side of the vertical axis shall have no harmful effects, with device not in actual use.
IPX7	Complies with IPX7 standards (IEC 60529) for protection against water ingress under test conditions; immersion in one meter of water for 30 minutes, with device not in actual use.
	Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.
	Non-ionizing electromagnetic radiation: To indicate elevated, potentially dangerous, levels of non-ionizing radiation. Note - In case of application in a warning sign the rules according to ISO 3864-1 shall be adhered to. IEC 60878 note: See safety sign ISO 7010 - W005 "Warning, non-ionizing radiation".

	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	This symbol indicates the date of manufacture of this device. The first four digits identify the year and the last two digits identify the month.
	Medical Equipment With respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO. 601.1, IEC 60601-1, IEC 60601-1-1, IEC 60601-2-27 and IEC 60601-2-49.
	Manufacturer name and address.
	European authorized representative.

Equipment compliance

IEC, UL, and EN 60601-1 device classification

Type of protection against electrical shock	Transmitter — Internally powered Receiver system — Class I
Degree of protection against electrical shock	T14 transmitter — Type CF Defibrillation proof applied part
Degree of protection against harmful ingress of water	T14 transmitter — IPX7 (IEC 60529)[1] Receiver system — Ordinary Equipment (enclosed equipment without protection against ingress of water)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

[1]The T14 transmitter is designed to be IPX7 compliant, so it can withstand inadvertent submersion. The transmitter should not be exposed to spray or shower during patient monitoring.

FCC compliance information statement

The CARESCAPE Telemetry T14 transmitter complies with Part 95 Subpart H of the FCC rules to be used in wireless medical telemetry service. Operation of this equipment requires prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

Installation and maintenance of this transmitter should be performed by a person certified as technically qualified to perform such operations. Replacement of any transmitter component or modifications to the transmitter could result in a violation of the rules. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. Use only GE approved replacement parts, non-approved parts may result in a violation of the FCC rules.

RF Exposure

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. The RF transmission power from the antenna conforms to the general public FCC limit of Specific Absorption Rate (SAR) 1.6 W/kg. The maximum SAR value measured from this device was 0.1200 W/kg. This device must not be co-located or operating in conjunction with any other antenna or transmitter.