2 Safety

For your notes

For Your Safety

Intended Use

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.

Definitions

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness. Familiarize yourself with their definitions and significance.

Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

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

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

System Safety

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

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

Dangers

There are no dangers that refer to the equipment in general. Specific "Danger" statements may be given in the respective sections of this manual.

Warnings

WARNINGS

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.

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.

WARNINGS

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.

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.

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 alert 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.

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.

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

WARNINGS

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.

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

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.

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

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

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.

WARNINGS

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.

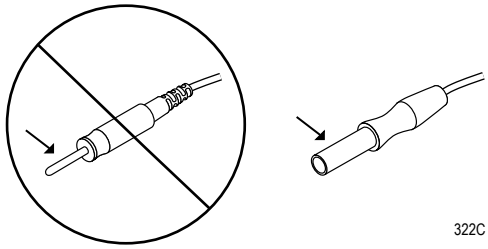
NETWORK INTEGRITY — The clinical information center resides on the hospital's computer network, and it is possible that inadvertent or malicious network activity could adversely affect patient monitoring. The integrity of the computer network is the responsibility of the hospital.

POWER SUPPLY — The device must be connected to a properly installed power outlet with protective earth contacts only.

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 RS232 interface).

Do not use this power unit in the presence of flammable anesthetics.

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**

WARNINGS

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.

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

CAUTIONS

ACCESSORIES (SUPPLIES) — To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems *Information Technologies*.

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.

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.

CAUTIONS

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.

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.

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

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 Medical Systems *Information Technologies* or its representatives.

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.

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.

CAUTIONS

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.

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.

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.

Once monitoring is restored, you should verify correct monitoring state and alarm function.

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

MPSO — The use of a multiple portable socket outlet (MPSO) for a system will result in an enclosure leakage current equal to the sum of all individual earth leakage currents of the system if there is an interruption of the MPSO protective earth conductor. Do not use an additional extension cable with the MPSO as it will increase the chance of the single protective earth conductor interruption.

NEGLIGENCE — GE Medical Systems *Information Technologies* 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.

CAUTIONS

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.

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.

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

SECURITY — The web browser which runs in conjunction with the clinical information center 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.

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

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.

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

- Put the system 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 connection to public mains as defined in CISPR 11.
- This equipment is suitable for use in the presence of electrosurgery.

Reference Literature

Medical Device Directive 93/42/EEC.

EN 60601-1/1990 + A1: 1993 + A2: 1995: Medical electrical equipment. General requirements for safety.

EN 60601-1-1:2001: General requirements for safety. Safety requirements for medical electrical systems.

IEC Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

ROY, O.Z.: Summary of cardiac fibrillation thresholds for 60-Hz currents and voltages applied directly to the heart. Med. & Biol. Engn. & Computing 18: 657...659 (1980).

Classification

The telemetry system is classified, according to IEC 60601-1, as:

Type of protection against electrical shock	Transmitter — Internally powered Receiver system — Class I
Degree of protection against electrical shock	ApexPro Transmitter — Type B applied part ApexPro CH Transmitter—Type CF Defibrillation proof applied part (not for sale outside of the U.S.)
Degree of protection against harmful ingress of water	ApexPro Transmitter — IPX3 (IEC 60529) ApexPro CH Transmitter — IPX7 (IEC 60529)-not for sale outside of the U.S. 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

Underwriters Laboratories, Inc.

Medical Equipment
With respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1, and CAN/CSA C22.2 NO. 601.1 and if applicable, IEC 60601-2-27, IEC 60601-2-30, and IEC 60601-2-49.

FCC Compliance Information Statement

This equipment 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. This device is also certified for RSS-210 of Industry Canada.

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 Medical Systems 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 0.01 W/kg. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Equipment Symbols

NOTE
Some symbols may not appear on all equipment.

ATTENTION: Consult accompanying documents.

CAUTION: To reduce the risk of electric shock, do NOT remove cover. Refer servicing to qualified service personnel.

NOTE
The rating of protection against electric shock (indicated by symbol for CF or BF) is achieved only when used with patient applied parts recommended by GE Medical Systems *Information Technologies*.

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.

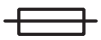
[Medical Standard Definition:] F-type applied part (floating/isolated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock than that provided by type BF applied parts.

TYPE BF APPLIED PART: Isolated (floating) applied part suitable for intentional external and internal application to the patient excluding 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 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock than that provided by type B applied parts.

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 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide protection against electric shock, particularly regarding allowable leakage current.



Fuse

Equipotentiality

Alternating current (AC)

Power; I = ON; O = OFF

Indicates where to press to open the door on the 7160 DDW.

Silence Alarms keyboard key.