

RTX3320:

The RTX3320 device is for use by patients at home. It is intended to be used in combination with a variety of patient monitors upon the prescription of a licensed physician or other authorized healthcare provider. RTX3320 serves as the remote communication link between compatible patient monitors, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center, or with the healthcare/wellness provider or other out-of-hospital caregivers.

The purpose is to transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.

RTX3320 is a "black box" device – it is not connected to the patient and not operated by the patient. The installation must be performed by or under supervision of an authorized professional healthcare company.

This device does not measure, interpret or make any decisions on the vital data that it conveys.

Precautions and warnings

This device is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data.

Clinical judgement and experience are required to check and interpret the measurements collected and transmitted.

This device is not for use in systems which substitute for medical care. This device is not intended for patients requiring direct medical supervision or emergency intervention.

IMPORTANT:

Use only the original power supply adapter which comes with the device

TECHNICAL SPECIFICATIONS

- This device is for use at home.
- Power requirements
 - Mains: 100-240 VAC, 50-60Hz, 200 mA, Class II, No applied part. Only use the original power supply adapter with the type designation FW7333M/06.
- Range of temperatures
 - Operating: 10° C to 40° C / 50° to 104° F.
 - Storage: -10° C to +45° C / 14° to 114° F.
 - Transport: -20° C to +60° C / -4° to 140° F.
- Relative humidity
 - Operating: 10% to 90% non-condensing.
 - Storage/Transport: 10% to 95% non-condensing.
- Barometric pressure
 - Operating: 700 –1060 hPa.
 - Storage/Transport: 700 –1060 hPa.
- Dimensions: Ø140 x 35 mm / Ø5.5 x 1.4 inches.
- Weight: 280 g / 10 oz including power supply adapter.
- Radio Transmitter: Bluetooth compliance: Version 1.1.
 - Operating frequency: 2.402 to 2.480 GHz.
 - Output power: 1 to 100 mW / Bandwidth: <1MHz.
 - Antenna type: Internal, omni directional / Antenna gain: -0.8 dBi.
 - Operational range: Up to 100 meters (indoor) depending of surroundings.
- ⓘ The frequency band is not harmonized. Use of wireless Bluetooth technology can be restricted in some countries. Contact local authorities for more information.
- ⓘ The internal antenna used for this mobile transmitter must provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.
- CE RTX Healthcare declares that this device is in compliance with the essential requirements and other relevant provisions of Directive 93/42/ECC. A copy of the declaration of conformity may be found at the RTX website: www.rtx.dk.
- This device has been tested and found to comply with FCC Part 68. Please read the "US telephone network customer information" in this manual.
- This device has been tested and found to comply with TBR21.
- This device, including the power supply adapter, is certified to comply with EN60601-1.
- This device, including the power supply adapter, is tested according to EN60601-1-2.
- Data integrity and security: The privacy of data transmission with this device is secured by data encryption and authentication (SSL), and meets authorized standards under the HIPAA.

RTX3320:

The RTX3320 Wireless Telehealth Gateway is used for wireless reception of measurements taken by on-site patient monitors such as a wireless blood pressure monitor or a wireless personal weight scale.

When the Gateway has received the measured values, it generates a call and conveys the data to a remote facility via a public telephone line. In some cases the Gateway is programmed to deliver data at a specific time of day.

The delivery of data will automatically be repeated if the attempt to deliver data fails. The Gateway works in fully automatic mode, and requires no user action.

Cleaning and Maintenance

The Gateway may be cleaned with a soft, dry cloth or a cloth dampened with tap water and a mild detergent. A household glass cleaner on a soft, dry cloth may be used to clean off smudges. Never use any solvent, thinner, lighter fluid, alcohol, wet wipes or similar products on the Gateway.

NOTE

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 can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio 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, 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 receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by this company could void the user's authority to operate the equipment.

Part# 96100805 US/UK



WIRELESS TELEHEALTH GATEWAY
RTX3320



USERS MANUAL

HOW TO INSTALL AND INSTRUCTIONS FOR USE
RTX3320 for PSTN

CALL FOR SERVICE:



INSTALLATION STEP BY STEP

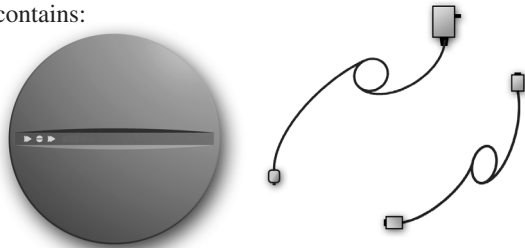
PARTS IDENTIFICATION

1 IMPORTANT
Before installation, please read all the information on both sides of this sheet!

2 UNPACKING
Inspect the package for any damage. In the event of damage, please call for service.

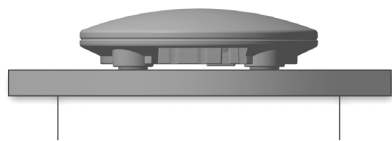
Ensure that the package contains:

- Gateway
- Power supply adapter
- Telephone cable
- Country-specific telephone plug converter
- This manual



IMPORTANT: Always keep the original package for return shipment.

3 PLACING THE GATEWAY



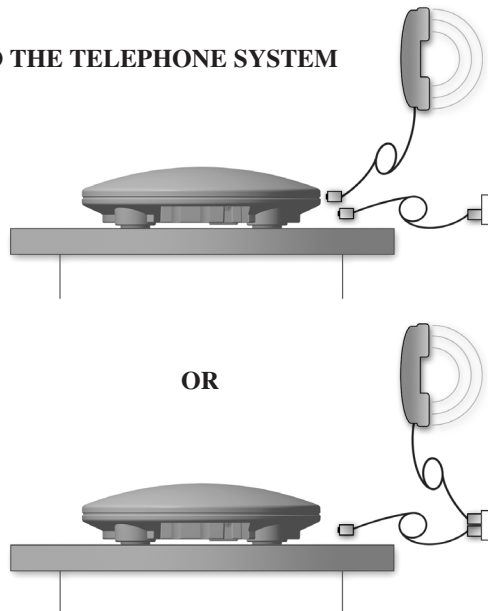
Place the Gateway in a level position.

It is important that the cables be carefully arranged and secured to avoid unintended disconnection, or the possibility of tripping or blocking the path of a wheelchair or other moving object. Be careful not to use a power socket which may be switched off unnoticed. Do not install or service the device, power adapter or cables during an electrical storm.

Do not place the Gateway in extreme climatic conditions (excessive heat or humidity, in direct sunlight or where it may be exposed to large amounts of dust). Do not set beverages near the equipment as spills may easily result in serious damage.

Protect the device and cables from damage. Keep pets and small children away from the area where the Gateway and cables are located.

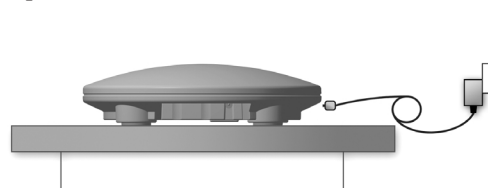
4 CONNECT TO THE TELEPHONE SYSTEM



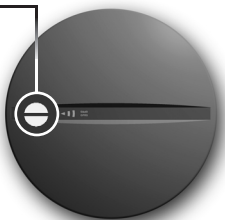
OR

5 CONNECT THE POWER SUPPLY ADAPTER TO AN ELECTRICAL OUTLET

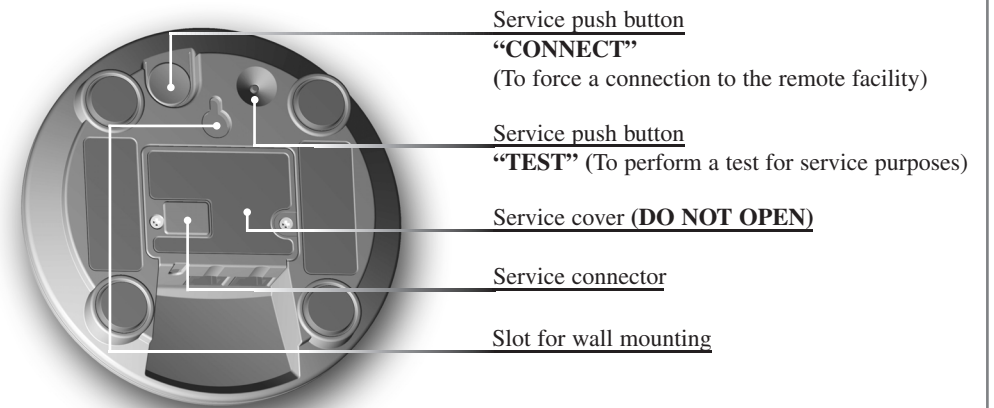
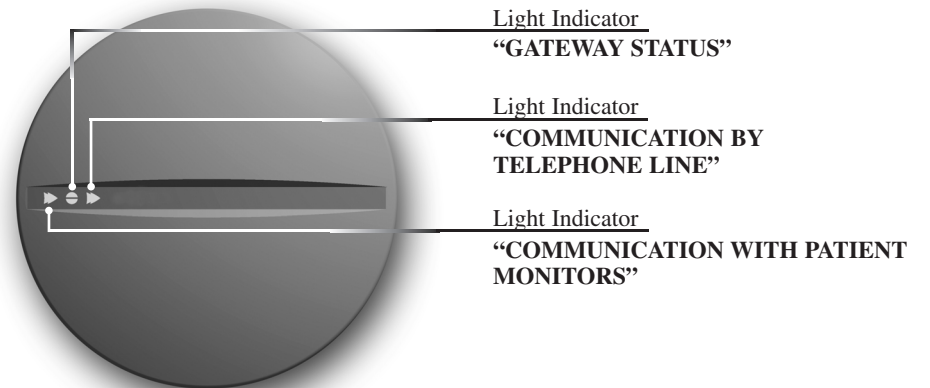
IMPORTANT: Never disconnect the power supply adapter from the Gateway. Make sure that the power source cannot be switched off unnoticed.



6 CHECK THAT THE GATEWAY STATUS INDICATOR IS GREEN

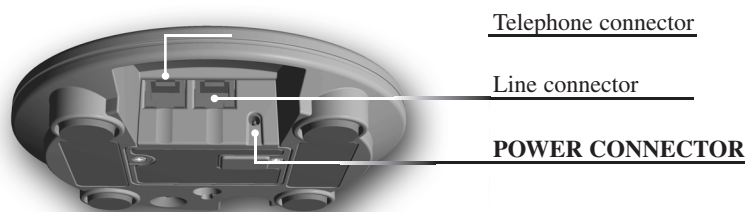


The Gateway is now ready for use with compatible patient monitors.



SERVICE PUSH BUTTONS:

IMPORTANT: Only use these push buttons under the supervision of service personnel



SIGNALING:

SYMBOL	SIGNAL	GREEN	AMBER
▶ ● ▶	Gateway Status		
	On	Power on – Gateway ready	System initiating – not ready
▶ ● ▶	Communication with patient monitors		
	Flashing (– – – –)		Gateway waiting for uninstalled patient monitor to appear
	On	Communication with patient monitor	
▶ ● ▶	Communication via telephone line		
	Flashing (– – – –)	Dialing	Error related to dialing (no dial tone or line is busy)
	Quick flashing (– – – – –)	Initiating transmission of data	Error related to data transmission
	On	Transmitting data	

The green light indicator on the power supply adapter indicates that power is connected.

US telephone network customer Information

This equipment complies with Part 68 of the rules and requirements adopted by ACTA. On the bottom side of this equipment is a label that contains, among other information, a product identifier in the format US:RTXMM00B3320. If requested, this number must be provided to the telephone company. The registration jack USOC for the equipment is RJ11C. A plug and jack used to connect this equipment to the premises wiring and telephone network must comply with the applicable FCC Part 68 rules and requirements adopted by the ACTA. A compliant telephone cord and modular plug is provided with this product. It is designed to be connected to a compatible modular jack that is also compliant. See installation instructions for details. The REN is used to determine the number of devices that may be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most but not all areas, the sum of RENs should not exceed five (5.0).

To be certain of the number of devices that may be connected to a line, as determined by total RENs, contact the local telephone company. For products approved after July 23, 2001, the REN for this product is part of the product identifier that has the format US:AAAEQ##TXXXX. The digits represented by ## are the REN without a decimal point (e.g., 03 is a REN of 0.3). For earlier products the REN is separately shown on the label.

If this equipment US:RTX3320 causes harm to the network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice is not practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary. The telephone company may make changes in its facilities, equipment, operations or procedures that could affect the operation of the equipment. If this happens the telephone company will provide advance notice in order for you to make necessary modifications to maintain uninterrupted service. If trouble is experienced with this equipment US:RTX3320, for repair or warranty information, please contact RTX America, Inc., 2099 Gateway Place, Suite 310, San Jose, California 95110. If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved. Connection to party line service is subject to state tariffs. Contact the state public utility commission, public service commission or corporation commission for information.

If your home has specially wired alarm equipment connected to the telephone line, ensure the installation of this equipment US:RTX3320 does not disable your alarm equipment. If you have questions about what will disable alarm equipment, consult your telephone company or a qualified installer.