

FRESENIUS MEDICAL CARE

Kinexus[®] Gateway User's Guide

For use with the Liberty[®] Select Cycler

P/N 480114 Rev E | March 2024

Legal

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Fresenius Medical Care only distributes the Gateway for use with the Liberty Select Cyclor. For more information, contact:

Fresenius USA, Inc.
Waltham, MA 02451
(800) 227-2572

This document provides overview, installation instructions, specifications, and troubleshooting for the Gateway. For more information about the Liberty Select Cyclor, refer to the *Liberty Select Cyclor User's Guide*, P/N 480165.

Intended Use: The Kinexus Portal is intended to allow clinicians to review patient data collected from the patient’s home dialysis device(s) and to enable physicians to manage patients’ home dialysis therapies for certain Fresenius Medical Care products, including peritoneal dialysis cyclor(s). The Kinexus Portal does not provide medical diagnosis or recommendations regarding medical treatment. The Kinexus Portal and the content appearing on this site are not substitutes for professional medical advice, diagnosis, or treatment.

The Kinexus Gateway is intended for transmission of home dialysis therapy data and patient data for patients using certain Fresenius Medical Care products, including peritoneal dialysis cyclor(s).

Kinexus is not an electronic health record (EHR) or billing solution.

Indications for Use: The Fresenius Medical Care Liberty Select Cyclor is indicated for acute and chronic peritoneal dialysis.

Patents apply, see www.fmcna.com/patents

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Glossary

Cellular connection: What cell phones communicate over. AT&T and Verizon are two common cellular providers.

Cloud: A place on the internet where your Gateway and your healthcare team can exchange information. Data on the cloud is kept secure.

Ethernet Cable: A type of cable that connects two devices through a local area network (LAN).

LAN: A type of port connected by an Ethernet cable. Ethernet cables connect devices to each other or connect a device to the internet. Stands for *Local Area Network*.

LED: A small light on the top of the Gateway. Stands for *Light Emitting Diode*.

RS-232: A type of port used to send data between two devices. The RS-232 port on the Liberty Select Cyclor connects to a USB port on the Gateway. Stands for *Recommended Standard 232*.

USB: A type of port and cord. USB cords connect devices to each other. Stands for *Universal Serial Bus*.

END OF CHAPTER



Chapter 1: Introduction

Introduction

Communication between you and your health care team is essential to making sure you get the most out of your dialysis treatments. The Kinexus Gateway for the Liberty Select Cycler ("Gateway") is a new accessory made to assist your healthcare team in keeping track of your Peritoneal Dialysis (PD) therapy. The Gateway transfers treatment and alarm history data at the end of each treatment to your care team. Depending on the configuration, some versions of the Gateway are also able to send updated programs to the cycler. A cellular connection is required to use the Gateway.

The Gateway may receive therapy parameters from your healthcare team. The Gateway is not intended to upload any software or treatments to the Liberty Select Cycler and is not a treatment monitoring device.

About this Guide - Call-outs

You should read this guide before using the Gateway with your cycler. The guide has several helpful call-outs within to help you use the Gateway correctly.



WARNING

Warnings warn against actions that could hurt you. If you do not follow these directions, it can lead to serious injury or death.



WARNING - SHOCK HAZARD

Shock Hazard means that you could get a severe electrical shock if you do not use the equipment the right way.

**CAUTION**

Cautions warn against actions that could harm you or your machine.

**NOTE:**

Notes mark extra information about Gateway features. Notes have helpful information. They may also have information about unique cases.

Using this Guide

This user's guide is designed to walk you through the process of setting up your Gateway to work with your cyclor. Look through the Table of Contents to quickly find a section, or search the Index to find a specific topic. Pages are also labeled on the sides to help you keep track of what section you are reading.

**NOTE:**

The Gateway is not in use during the treatment. Some wireless transmissions from the Gateway may be actively emitted during treatment or device functions. The associated hazards should be minimal.

**NOTE:**

If the treatment data transfer is not successful, your cyclor will retry the transfer at the end of next treatment.

**NOTE:**

Do not connect any other accessories to your cyclor that are not approved by Fresenius Medical Care.

**NOTE:**

Do not modify the Gateway provided to you by Fresenius Medical Care.

**NOTE:**

Do not connect or disconnect the Gateway from your cyclor when the cyclor is powered ON.

What's Included

When you receive your Gateway, you will find the following items:

- The Gateway
- One (1) 100-240V AC wall power adapter
- Two (2) cellular antennas
- One (1) RS-232 to USB cable
- Kinexus Gateway User's Guide (this document)
- SysLINK™/SysCoRE™ Gateway User Manual and Installation Guide

**NOTE:**

Images may differ from actual items.

**NOTE:**

For all inquiries and questions, call Fresenius Medical Care Technical Support at **(800) 227-2572**.

**NOTE:**

It is recommended to place the Gateway approximately three (3) feet (one [1] meter) away from the cyclor.

END OF CHAPTER



Chapter 2: Gateway Overview

Overview

The Gateway is a small device that uses cellular networks to communicate with your healthcare team through the cloud. The Gateway communicates with the cloud to transfer treatment and alarm history data at the end of each treatment. The Gateway has ports to connect the device. There are several LED lights on top of the Gateway. These lights help show you what the device is doing or if there is a problem with the Gateway.



CAUTION

Do not share your Gateway or give your Gateway to others to use. The Gateway must be distributed to and used only by the person it is prescribed for.

Front View

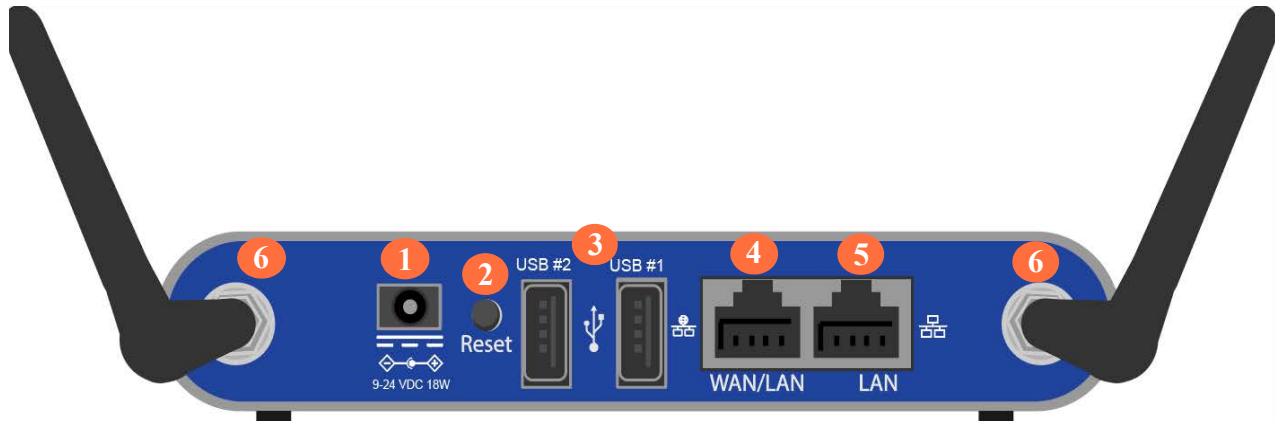


Front View

The front of the Gateway is a blue plate with the Fresenius Medical Care logo on the left. There are no LEDs or ports on the front.

The left side of the Gateway is a heat vent. The right side is a speaker. The Gateway lets you know about its status with voice responses. See [Gateway Commands](#) on [page 3-9](#) for a list of the possible responses you may hear.

Back View



Back View

The back of the Gateway is where you power on the Gateway and where you connect the Gateway to your cyclor. The back of the Gateway includes:

- 1 Power Cord Inlet:** This is where you plug in the power cord. Plugging in the power cord turns the Gateway ON. Unplugging the power cord turns the Gateway OFF.
- 2 Reset button:** The Reset button is located on the back panel of the gateway. To reset the gateway, press the Reset button momentarily (less than one second). Use a paper clip, or similar object, to press. The Status light will turn orange initially during the reset.

To reset the Gateway back to factory defaults, press and hold the Reset button until the status light alternates between red and green. This will occur in about 10 seconds. Then release the Reset button.



CAUTION

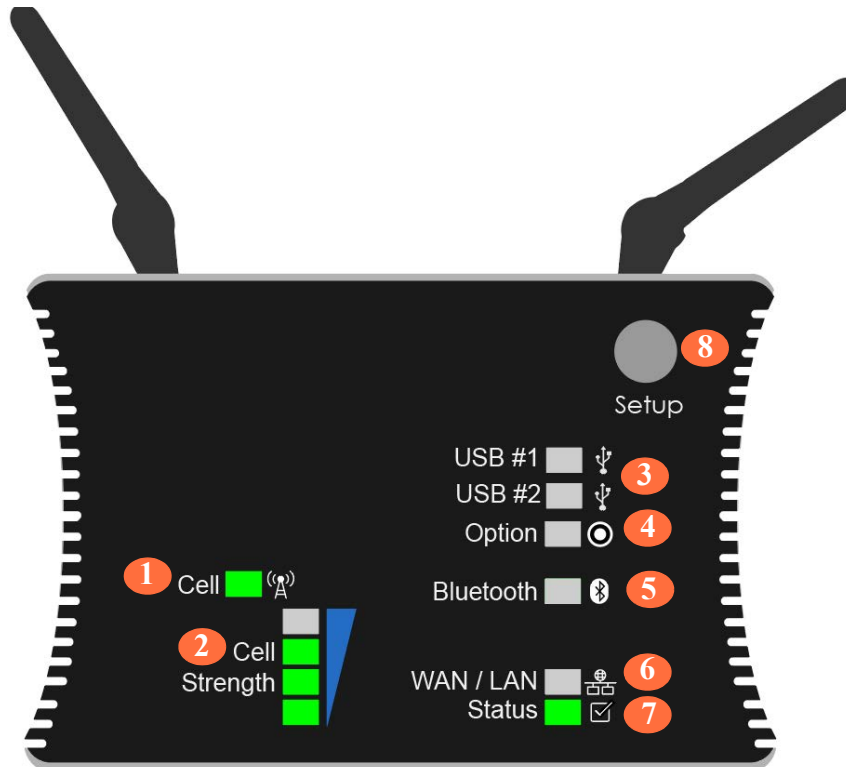
Do not press reset your Gateway without guidance from Technical Services support. Pressing this button will reset your Gateway and your Gateway will no longer function.

- 3 USB 1 & 2 Port:** This is where you plug in the USB-to-RS232 cable that connects the Gateway to the cyclor. Kinexus Gateways have either (1) or (2) USB ports. Either port may be used to connect your Liberty Select cyclor.

- 4 **WAN/LAN Port:** The WAN/LAN Port is not used.
- 5 **LAN Port:** The LAN Port is not used.
- 6 **Antennas:** The two ports at the far left and right sides of the Gateway are made to plug in antennas. These antennas help the Gateway connect to a cellular network.

Top View

The top of the Gateway displays several LEDs. These LEDs show the power status, if the Gateway is communicating with the cyclor, and if the cellular connection to the internet is working.



Top View

The top parts of the Gateway, include:

- 1 Cell:** Within two minutes of powering up, the *Cell* LED will turn green. If the light remains dark, there is no cellular connection.
- 2 Cell Strength:** These LEDs show the strength of the cell signal.
 - One (1) LED means that you have poor reception.
 - Four (4) LEDs means that you are getting strong reception.
 - You may be able to improve cellular strength by rotating the antennas on the back of the Gateway.

- 3 **USB 1 & 2:** The USB1 and USB2 LED lights are green when connected; red when a fault has occurred, amber/orange when disabled, and off when not in use.
- 4 **Option:** No function.
- 5 **Bluetooth:** The *Bluetooth* LED will be solid green or flicker green during normal operation. The light is off if the Bluetooth is not connected or not functioning. If DISABLED (amber/orange color), the feature must be enabled within the *Setup* Menu.
- 6 **WAN/LAN:** No function.
- 7 **Status light:** The *Status* LED indicates current gateway status. It will be solid amber/orange at initial power up. The light will blink green at one second intervals during normal operation. Should the status light stop blinking, remaining in the solid OFF or ON state for more than 60 seconds, remove power supply from the wall plate power outlet, wait 30 seconds and then restore power by plugging the power supply into the wall plate power outlet. Wait until the status light begins blinking again before using the Gateway.

These LEDs show the status of the connection.

- Solid green means that the Gateway is ON.
- Flashing green means that the Gateway is receiving or transmitting data.
- Flashing red and green means that the Gateway is not connected to the internet.

- 8 **Setup:** No function.

Bottom View



Bottom View

The bottom panel of the Gateway is labeled with the marker plate. The marker plate lists the manufacturer name, model number, part number, serial number, and any cautions or warnings associated with the device. Some of the information on the bottom of the Gateway is unique to each Gateway and your Gateway will not exactly match the image above.

For more information, see [Marker Plate Symbols](#) on page 5-6.

Power Supply



Plug the round power supply connector to the Gateway. Then plug the power supply directly into a wall plate power outlet.



WARNING - SHOCK HAZARD

To power on the gateway, always insert the round power supply connector to the gateway first. Then insert or plug in the power supply to the wall plate power outlet.



WARNING - SHOCK HAZARD

To power off the Gateway, always remove the power supply from the wall plate power outlet first. Then remove the round power supply connector from the Gateway.

END OF CHAPTER

Chapter 3: Gateway Setup

Gateway Setup

Before setting up your Gateway, you should find a flat, dry surface near your cyclor to set it up. Make sure the Gateway is at least eight (8) inches away from your body during your dialysis treatment.

**NOTE:**

Avoid placing the Gateway near your bedside if at all possible. Electromagnetic (EM) radiation may interfere with your other medical devices.

**CAUTION**

Pacemaker devices, implanted neurostimulators, and implanted defibrillators may be affected by EM radiation. If you wear a pacemaker, implanted neurostimulator, or implanted defibrillator, you should avoid contact with the Gateway and stay further away from the Gateway than the recommended eight inches. You should also avoid installing the Gateway yourself.

**CAUTION**

Position the power cord and RS232 to USB cable so they will not be tripped over by you or others living in your home.

**CAUTION**

Do not let the Gateway come into contact with blood or bodily fluids, i.e., dialysate from your abdomen.

**CAUTION**

Place the Gateway on a flat, dry surface, away from any potential fluid spills or splatter.

**NOTE:**

The Gateway may transmit during treatment or other cyclor functions.

**NOTE:**

The wall plate power outlet should be near to the Gateway and easily accessible.

**NOTE:**

Physical placement of the Gateway near a bedside should be avoided where possible due to EMC radiation.

**CAUTION**

Pacemaker devices may be affected by EMC in several ways and wearers should avoid contact with the Gateway. All persons should remain at least 20 cm (8 inches) from the transmitter's antenna. Pacemaker wearers should try to increase this distance where possible for general safety margins of operation and avoid self-installation of the Gateway.

Your Gateway may communicate with other devices using wireless radio, Ethernet, or a serial/USB cable. Your device supplier will furnish you with installation instructions specific to your devices.

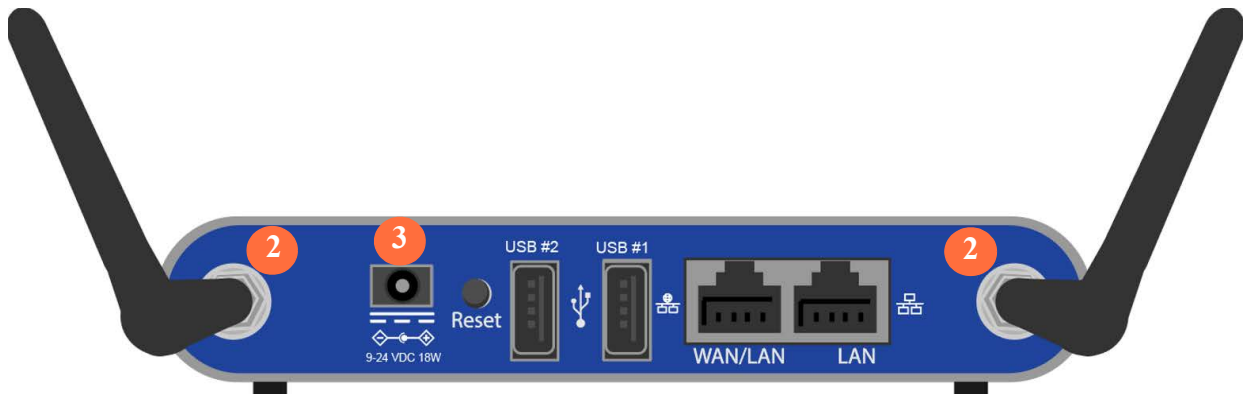
Generally, your additionally supplied devices will be either for medical or information technology applications. In some cases, the two applications can be combined. When that occurs, follow the medical application instructions where applicable.

**WARNING - SHOCK HAZARD**

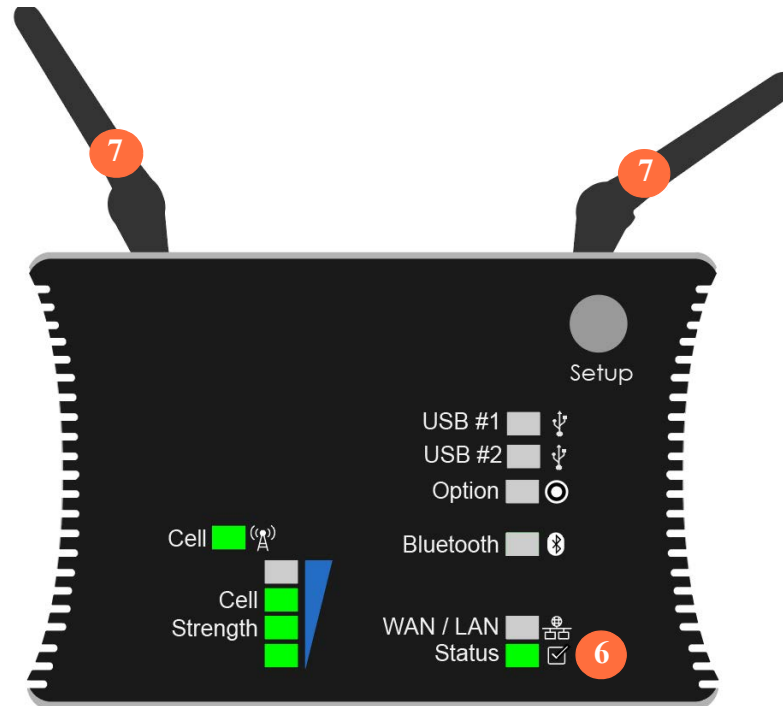
If your Gateway is being used around medical patients, the Gateway must be out of reach by the patient. Some patients may have a weakened immune system.

Connect Gateway to Internet

- 1 Remove your Gateway from the packaging. Inspect the Gateway for signs of damage such as breaks or cracks.
- 2 Unwrap the antennas. Fasten them to the ports at the back of the Gateway and screw them in using the thumb nuts at the ends of each antenna, **2**.



- 3 Plug the round end of the power cord into the power cord inlet in the back of the Gateway, **3**.
- 4 Plug the power adapter directly into a 120v wall outlet.
- 5 Kinexus Gateways have either (1) or (2) USB ports. Either port may be used to connect your Liberty Select cyclor.
- 6 Once the Gateway has been plugged in the Status LED will turn orange. Wait until the LED turns green to continue, **6**.



- 7 Rotate the antennas on the back of the Gateway back and forth. Watch the Cellular Strength LEDs while you do this. You want the strongest signal possible, **7**.

**NOTE:**

Green LED lights show cellular strength. If there are no lights illuminated, a signal is not present. If all four green lights are illuminated, signal strength is strong. Aim for at least two green lights to appear.

Connect Gateway to Cycler

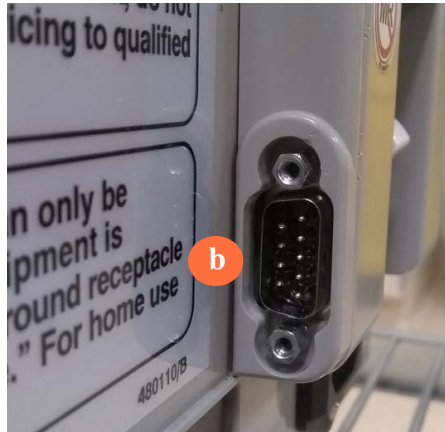
**NOTE:**

Do not connect or disconnect the Gateway from your cycler while the cycler is powered ON.

- 1 With the Power Switch on your Liberty Select Cycler set to OFF, connect the USB-to-RS-232 cable to your Liberty Select Cycler, **a**.
 - a. If your Liberty Select Cycler has a cap over the RS-232 port, remove the RS-232 cap using a screwdriver.



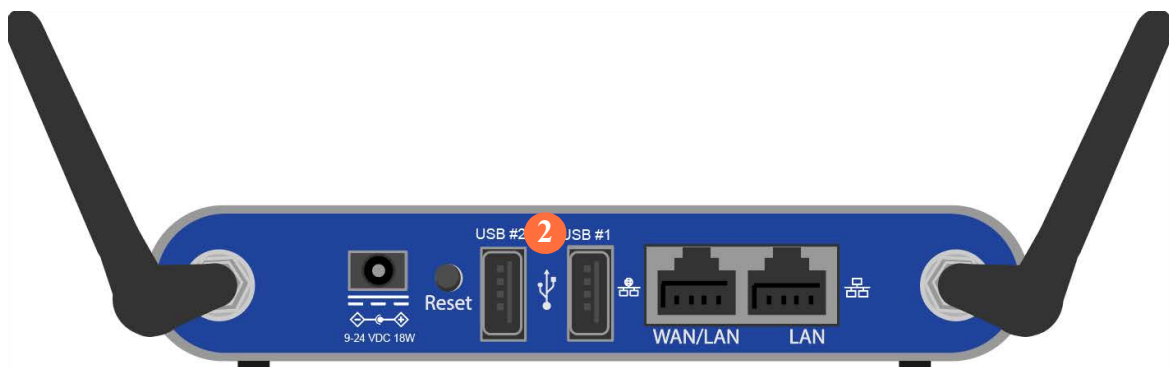
- b. If your Liberty Select Cyclor does not have a cap over the RS-232 port, proceed to step 1c. b



- c. Connect the RS-232 end of the RS-232 to USB cable to the RS-232 port on your Liberty Select Cycler, **c**.



- 2 Plug the USB end of the RS-232 to USB cable into the USB port on the back of the Gateway, **2**. Kinexus Gateways have either (1) or (2) USB ports. Either port may be used to connect your Liberty Select cycler.



Gateway Commands

Failed to upload your treatment data – The Gateway was unable to upload your treatment information to the cloud. It will re-try automatically at the end of your next treatment.

Gateway is ON – Confirms the Gateway is powered ON.

Sending your treatment information to your clinic, please wait – Confirms the Gateway successfully received your treatment information from your cyclor and is transmitting data to the cloud.

There seems to be a connectivity issue with your Gateway. Please contact technical support using the number found on your cyclor – Your Gateway does not have an internet connection.

Treatment data uploaded successfully – Confirms the Gateway successfully uploaded your treatment information to the cloud.

END OF CHAPTER

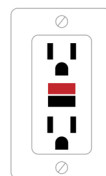
Chapter 4: Troubleshooting

**NOTE:**

The Gateway is non-user-serviceable and must be replaced by Fresenius Medical Care. Call Fresenius Medical Care Technical Support at **(800) 227-2572** for questions regarding set-up, troubleshooting, or assistance in returning or replacing your Gateway.

If no LEDs light up on your Gateway:

- 1 Unplug the power cord from the Gateway and the wall outlet. Plug the power cord back into the Gateway, and then plug the cord back into the wall outlet.
- 2 If the outlet is connected to a power switch, ensure that the switch is set to ON.
- 3 Check to make sure the power to the wall outlet is working.
 - a. Unplug the Gateway from the wall outlet and plug another device, like a lamp, into the same outlet.
 - If device works, unplug it and plug the Gateway back into the wall outlet.
 - If the device doesn't work, use a different outlet to test the Gateway.
- 4 If the outlet is a GFI (ground-fault interrupter):
 - a. Check to see if the Reset button is popped out on the outlet. Reset buttons are usually the large button in the middle of the wall outlet, and are often colored red. See the diagram on the right for an example of a GFI outlet.
 - b. If the Reset button is popped out, unplug the Gateway from the wall outlet, press the Reset button back in, and plug the Gateway back into the outlet.
- 5 Check your fuse box to see if a circuit breaker needs to be reset.



If none of these steps work, call Fresenius Medical Care Technical Support at **(800) 227-2572**.

END OF CHAPTER



Chapter 5: Appendix

Device Specifications

Dimensions

Floor space: 5.5 inches (13.97 cm) wide by 4 inches (10.16 cm) deep

Height: 1 inch (2.54 cm)

Weight: 1 lb/0.45 kg

Operating Conditions

Temperatures: 50° — 104° F (10° C — 40° C) with provided power supply. For use at environments below 10°C or above 60°C, use a power source rated for 60°C, 9-24VDC, minimum 12W, tip positive, listed to UL/ANSI 60601-1 and UL/ANSI 60950-1

Relative Humidity: 10% — 85% (non-condensing)

Storage Conditions

Temperatures: -22° — 149° F (-30° C — 70° C)

Relative Humidity: 5% — 90% (non-condensing)

Maximum Altitude

9842ft/3000m

Electrical

Power Supply: Positive polarity Direct Current at 9-24V and minimum 18W input capacity connected to a circuit equipped with a hospital grade receptacle

External Connections: Ethernet ports; USB port; cellular antennas

Regulatory

Your Gateway was tested for operation in an environment such that medical devices and other medical equipment can be used. Your Gateway meets IEC 60601-1-2 and FCC Class B requirements for use in business, industrial, commercial, and residential environments. In addition, your Gateway meets the safety standards for IEC 62368-1.

The Marker Plate located on the bottom of Gateway will contain regulatory information about radios installed.

The Gateway complies to:

Colocation – FCC 15.247 (FCC Part 15 Subpart C)

Transmitters Colocation Evaluation Applicable to

USA & Canada

EU

Australia/New Zealand

FCC15B (FCC Part 15 Subpart B)

IEC 62368-1, second and third edition

IEC 60601-1-2, 4th edition

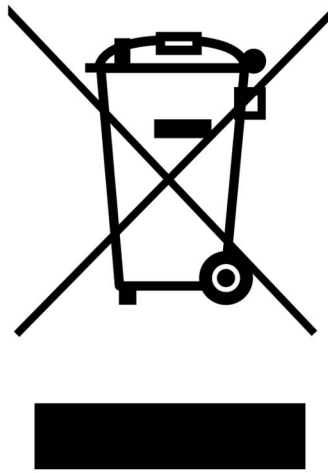
FCC Information

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:

- 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.

WEE Information

This is important information for users with regards to the proper disposal and recycling of your Gateway. You are required to comply with this notice for all electronic products bearing the following symbol:



Radio Bands and Frequencies

North America Modem & Wireless

Module Quectel SC20-AL / WL

Modem

Frequencies:

Marker Plate Symbols

Your Marker Plate is the label located on the bottom of your Gateway. The Marker Plate contains important information as to the environmental conditions for usage. The symbols below define the conditions of usage required for the gateway and the patient.



This symbol indicates that accompanying documentation with the Gateway must be read prior to installation.



This symbol indicates the temperature range.



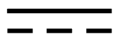
This symbol indicates the humidity range.



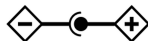
This symbol indicates the elevation range.



This symbol indicates the weight of the Gateway.



This symbol indicates the power input to the gateway is DC power at the defined voltage and a minimum watt input capability.



This symbol indicates positive polarity for the DC power input to the Gateway.

Cleaning Your Gateway

The Gateway is not sterile equipment; however, you should keep your Gateway clean and dry at all times. Clean the **exterior surface** of your Gateway using a damp cloth and a diluted (1:100) bleach solution or other suitable hospital disinfectant.

Use surface cleaner in **small amounts** to avoid excess cleaner from entering the interior of your Gateway. Rinse off cleaning solutions with a water-dampened cloth, especially if a corrosive cleaner such as bleach is used.



CAUTION

Do not allow any fluid to drip into your Gateway. The Gateway must be OFF when you are cleaning it. If any fluid gets inside your Gateway, you must contact a Fresenius Medical Care Technical Support immediately at **(800) 227-2572**. Clean fluid spills immediately to prevent moisture from possibly damaging your Gateway. Your Gateway should be placed on a water-tolerant surface, and spills should be cleaned up immediately.



CAUTION

Do not use foaming type cleansers or disinfectants containing alcohol or quaternary ammonium compounds like N-alkyl (C12-C18) dimethyl benzyl ammonium chloride (benzalkonium chloride). These chemicals attack the polycarbonate plastics used in your machine. Read the product labels and follow the instructions. Do not use spray bottles.

Any service must be performed by a Fresenius Medical Care technician. If your Gateway needs service, call Fresenius Medical Care Technical Support at **(800) 227-2572**.

END OF CHAPTER



Chapter 6: Gateway Information

Gateway Information

Please complete the following information for future reference. You will find most of this information on the bottom label of your Gateway and your power supply.

Serial Number: _ _ _ _ _

Model Number: SL-600 IP22/ SC-600 IP22

MEID: _____

Internet Connection: Cellular

END OF CHAPTER

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