

Kinexus[®] Gateway User's Guide

For use with the Liberty[®] Select Cycler

P/N 480114 Rev D | Oct 2023

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Legal

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

Fresenius USA, Inc. 4040 Nelson Ave. Concord, CA 94520 (800) 227-2572

This document provides overview, installation instructions, specifications, and troubleshooting for the Gateway. For more information about the Liberty Select Cycler, refer to the *Liberty Select Cycler 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 products, including peritoneal dialysis cycler(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 products, including peritoneal dialysis cycler(s).

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

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

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Chapter 6: Information About Your Gateway





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 Cycler 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.

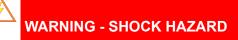
The Gateway may receive therapy parameters from your healthcare team. The Gateway is not intended to upload any software or treatments to the Liberty Select Cycler and is not a treatment monitoring device.

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.



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



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 your machine.

NOTE:

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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 cycler. 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:

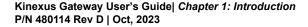
The Gateway is not in use during the treatment. Some wireless transmissions from the Gateway may be actively emitted during treatment or device functions. The associated hazards should be minimal.

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NOTE:

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





1 - 3 Introduction > Using this Guide

NOTE:

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Do not connect any other accessories to your cycler 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 cycler when the cycler 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[™] Gateway User Manual and Installation Guide

NOTE:

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

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NOTE:

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

END OF CHAPTER





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 a number of 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 3-8 for a list of the possible responses you may hear.

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Back View



Back View

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



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 Port:** This is where you plug in the USB-to-RS232 cable that connects the Gateway to the cycler.
- 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 cycler, and if the cellular connection to the internet is working.



Top View

The top parts of the Gateway, from left to right, include:

- **1 Cell**: This LED is green if you are connected to a cellular network.
- 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 Option:** No function.
- 4 Bluetooth: No function.
- **5 Status:** 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.
- 6 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 5-3.







Chapter 3: Gateway Setup

Gateway Setup

Before setting up your Gateway, you should find a flat, dry surface near your cycler 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.



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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 cycler functions.



NOTE:

Before starting, take the USB-to-RS-232 cable out of the Gateway packaging.

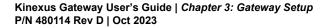


Connect Gateway to Internet

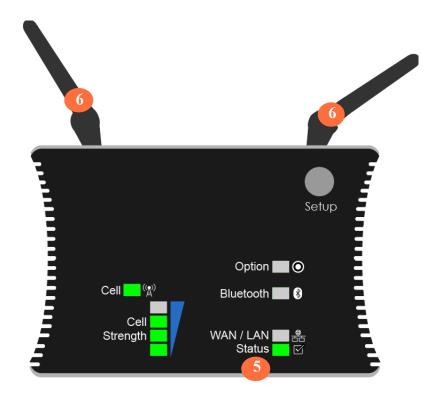
- 1 Remove your Gateway from the packaging. Inspect the Gateway for signs of damage such as breaks or cracks.
- 2 Unwrap the antennas. Fasten them to the ports at the back of the Gateway and screw them in using the thumb nuts at the ends of each antenna, 2.



- 3 Plug the round end of the power cord into the power cord inlet in the back of the Gateway,
- 4 Plug the power adapter directly into a 120v wall outlet.
- 5 Once the Gateway has been plugged in the Status LED will turn orange. Wait until the LED turns green to continue,





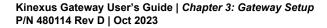


6 Rotate the antennas on the back of the Gateway back and forth. Watch the Cellular Strength LEDs while you do this. You want the strongest signal possible, 6

NOTE:

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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

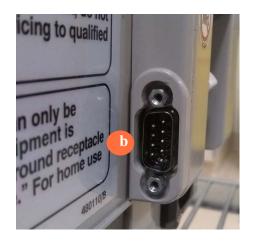
NOTE: Do not connect or disconnect the Gateway from your cycler while the cycler is powered ON.

- 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 Cycler does not have a cap over the RS-232 port, proceed to step 1c.





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



2 Plug the USB end of the RS-232 to USB cable into the USB port on the back of the Gateway, 2



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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 cycler 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 cycler – 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

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.

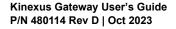


b. If the Reset button is popped out, unplug the Gateway from the wall outlet, press the Reset button back in, and plug the Gateway back into the outlet.

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







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: $50^{\circ} - 104^{\circ}$ F ($10^{\circ} - 40^{\circ}$ C) with included power supply **Relative Humidity:** 10% - 85%, non-condensing

Storage Conditions

Temperatures: $-22^{\circ} - 149^{\circ}$ F ($-30^{\circ} - 65^{\circ}$ C) Relative Humidity: 5% - 90%, non-condensing

Maximum Altitude

8500 feet (2591 meters)

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



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Regulatory

The Gateway has been tested to the medical standard IEC 60601-1-2 with the Liberty Select Cycler. In addition, your Gateway meets the safety standards for IEC 60950-1 commonly found with Information Technology devices.

Ingress Rating: IP22

Standards Compliance: IEC 60601-1-2, 4th Edition

IEC 60950-1 FCC Part 15 Subpart B Colocation FCC 15.247



Marker Plate Symbols

| | Read the accompanying documentation, such as this guide, before installing the Gateway. |
|-----------------|--|
| | Temperature range. |
| \mathcal{N} | Humidity range. |
| | Elevation range. |
| O kg | The weight of the Gateway. |
| | The DC power input to the Gateway at the defined voltage and minimum watts input capacity. |
| \$- • -* | 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**.



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Gateway

Gateway Information About Your Gateway

To find information about your Gateway, read the label on the bottom of the Gateway. See *Bottom View* on page 2-4.

Serial Number: ___ __ __ __ __

Model Number: SL-600 IP22

MEID:

Internet Connection: Cellular

END OF CHAPTER





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