

Gateway 2 Technical Manual

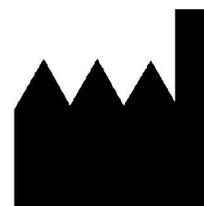
for use with NorthEast Monitoring's
DR400 Wireless Recorders
version 1.001



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1. Introduction to Wireless Event

The NorthEast Monitoring patch-style DR400 recorders come with a Wireless feature that uses wireless technology to communicate with a paired device. For event transmission, the communication occurs between the recorder and a paired NorthEast Monitoring Gateway 2. Wireless transmission is initiated when the DR400 is in Event recording mode and there is event data to transmit.

For event recording, the patient is given a paired DR400 and Gateway 2. The Gateway 2 can be carried on the person and/or be placed in a location in the home or another location. Once an event is recorded, the DR400 will attempt to locate the Gateway 2 to transmit the event.

If the patient is away from the Gateway 2 for an extended period of time, the recorder will continue to try to transmit at regular intervals. Once the patient is back in close proximity to the Gateway 2, and a transmission is successful, all events in memory will be sent at that time starting with the oldest.

During a successful wireless transmission, encrypted event data is sent via the airways through a cell phone signal to an FTP site identified on the recorder. When an event file is successfully received at the FTP site, the DR400 reads the file back, checks it, confirm it for accuracy and deletes the event(s) from its memory.

Once on the FTP site, the event files are copied to a temporary local location, and are then deleted from the FTP site. Each file is then decrypted and placed in a designated location on a local PC. Once the data is saved on PC, you are able to access this data via the Incoming Files screen in LX Event.

2. The Gateway 2 Transceiver

The Gateway 2 Kit includes:

- Gateway 2 (part number NEMP00539)
- AC Power Adapter (NEMP00571)

Gateway 2 Specifications

- Voltage: 90-264 volts
- Frequency: 47 to 63 Hz.
- Maximum current: 2A at 5V DC
- Weight: 150 gms.
- Dimensions: 111.81mm x18.01mm x73.08mm (4.402" x 0.709" x 2.877")
- Operating temperature: 0 to 40 C

AC Power Adapter Specifications:

- Maximum current: .5A

FCC Class B digital device notice

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 and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this

device must accept any interference, including interference that may cause undesired operation of the device.

Symbols

Please note that the recorder is labeled with the following symbols:



Refer to instruction manual/ booklet. Follow instructions for use



This device contains an internal lithium battery that may be recycled at end of life. This device and all other accessories should be disposed of according to local ordinances.



This product does not contain lead.



This device has wireless capabilities.

Data Security

For Wireless transmission via the Gateway 2, data is encrypted using symmetric 256-bit encryption key on the recorder and is sent in data block. One or more blocks can be sent at a time. Once the data is received via the Event Decoder, the encryption key will be used to decrypt the data into a readable format. The Key ID is visible on the both the recorder and the Event Decoder. The two Key IDs must match in order for files to be transferred and decryption to take place.

3. The Gateway 2



The Gateway 2 is a transceiver (transmitter + receiver) that communicates with the wireless recorder. The Gateway 2 sends the encrypted event data via a wireless phone network to the receiving location. Both the recorder and the Gateway 2 are able to transmit and receive data to ensure that encrypted data arrives at its desired location.

The button does the following:

- short press causes a display refresh.
- 3-second press to turn on. Be sure to keep pressing until “HOLD BUTTON” switches to “Booting”.
- 5-second press to turn off. Keep pressing until large X appears on screen to ensure that it turned off.
- 30-second press for forced shut down.

Turn on the Gateway 2

To start, plug in the Gateway 2 to ensure it has power.

The, press the button down until the “HOLD BUTTON” message switches to “Booting”, for approximately 3 seconds. Once the Gateway 2 is started you will see:

```
NEMON
Gateway 2
Firmware version number
Booting
```

At this point, the Gateway 2 is searching for a local cell network.. If there is a lack of cell signal upon startup, you may see two Xs appear on the LED screen. If you see an error such as 000008, this is also a sign that a cell signal cannot be found. Try moving your Gateway 2 to a better location where a signal may be found and the device can connect to a network.



When the Gateway is ready, you should see battery and signal strength (triangle) graphics at top of screen.

4. Pair DR400 with Gateway 2

For DR400 recorders to transmit event data, the DR400 must first be paired with a Gateway.

URL-key file and the Pairing Process

In order to pair a DR400 with a Gateway 2, your organization must obtain a urlkey.dat file from NorthEast Monitoring, and the urlkey.dat file must be placed in the directory where the PCPatch utility exists. You can right-click on your PCPatch desktop shortcut to identify the location of where to put the urlkey.dat file.

Pairing the Gateway with DR400

A URLKEY.dat file must exist in the bin directory with the PCPatch.exe file in order to pair with a Gateway. If the file does not exist, the Pair Gateway button will not be enabled.

Refer to the DR400 manual for the pairing procedure.

Once paired, the wireless settings that are programmed into your site's urlkey file, are visible on the PCPatch Settings screen. All of the settings must match the settings in the FTP receiving location in order for wireless transmission to take place.

Gateway	00043e08ce24
Service URL key	nemon
Remote Server URL	nemondb.dyndns.org
Remote Server Port	8000
Carrier APN	11583.mcs
Key ID	4047

- Service URL key - Your unique identifier
- Remote Server URL- FTP Server's fixed IP-address or domain name.
- Remote Server Port - defaults to 21 or as required
- Carrier APN
- KEY ID - The receiving center identifier, which is an ID for the actual unique 256-bit encryption key for files sent via the Gateway.

If the data is incorrect or you do not have a urlkey.dat file, contact NorthEast Monitoring or your distributor for assistance.

5. Power the Gateway 2

The Gateway 2 can be operated while plugged in or on battery power. To ensure best performance, patient should plug in Gateway when there is no need to transport it.

In locations with ideal cell signal, the Gateway 2 can run on battery power for over 16 hours, but in all cases, it is recommended that the Gateway 2 be plugged in overnight and at any time the patient is not ambulatory.

To power or charge Gateway 2, connect device to approved USB-C AC power adapter (this connector is not polarized, so can be connected in either direction). The device will charge whether turned on or not. When turned on, the top line of the Gateway 2 screen will display its power status:



When connected to power, a plug symbol will appear to the right of the battery status indicator.



While charging, the battery status indicator will have a lightning bolt within the outline of the battery. The battery should fully charge in approximately 3 hours.



Once fully charged, the full battery indicator will appear. The Gateway 2 can remain plugged in once fully charged, but if the cable is removed and then re-connected, it may take several minutes to indicate full charge again as the internal battery charger must go through its top off cycle to indicate it is fully charged.



Low Battery Warning. If the Gateway 2 is not plugged in, the battery indicator will show battery capacity that is left. Once the battery starts flashing (at 30% capacity), you should plug in the Gateway 2 as soon as possible to ensure that it continues to function for the short-term.



If a large empty battery appears on the screen, the battery is at or below 5% and the Gateway 2 is no longer functioning. Plug in Gateway 2 to reboot and charge battery.

Alternatively, if the Gateway 2 screen is blank, it is turned off. Hold the button down to start. If nothing happens, the battery is low, and therefore you need to plug in Gateway 2 before pressing the button to start.

DR400 status

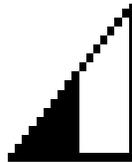
During an event procedure, the second row of the screen displays the charging status and SN of the paired DR400 when in operation using the same symbols as above.

If the Gateway 2 and a DR400 have no communication for 4 hours, the DR400 status will no longer appear.

More about the Gateway 2 screen

The network signal strength graphic appears at the top right of the screen.

Any signal without an X indicates that there is a connection to the network. If only a small portion of the triangle is filled in black, it is best to move the Gateway 2 to another location that has better service such as near a window.



The bottom row of the Gateway 2 screen shows communications and diagnostic data:

- When present, the left side of the bottom of the screen are numbers that will appear when the DR400 and Gateway 2 are communicating and transmitting. These numbers have no relevance to you or the patient, however, their appearance on the screen means that a transmission is occurring and that is good.
- The right side of the screen has two indicators. The first is the wireless network that the Gateway 2 is connected to. You may see: A for A&T, T for T-mobile and V for Verizon, or other.
- To the right of the network, is the number of minutes since the last transaction - either when the last event was sent, or if MCT is turned on, the last time the DR400 looked for an ETel request.

If neither have occurred in the past 4 hours (240 minutes), an asterisk “*” will appear in the bottom-right. Otherwise the number of minutes since the last communication appears.

6. Receiving Events via FTP

System Requirements

The computer at the Service/institute where the events are to be received, must have the following minimal capabilities:

- Windows 10 or Windows 11 Operating System
- Eight (8) GB of RAM memory
- Twenty (20) GB of available disk storage
- Broadband Internet connection
- Access to Port 21
- FTP server capability - Internal or commercially hosted FTP site

Overview of the Transmitting Process

1. The DR400 records an event
2. The DR400 is ready to send an event and attempts to connect to the paired Gateway 2
3. If paired Gateway 2 is found, the decrypted event is transmitted via the wireless network
4. The FTP site receives two files for each event file
5. The Event Decoder utility that is running the background uses WinSCP to move the file to the local PC and decrypts the file
6. The event file is placed in a designation location where the LX Event Incoming screen can access it
7. User opens LX Event Incoming files screen and assigns event to active patient

The ETel Installer

The ETel utility must be installed on the local PC. The ETel Installer includes 3 pieces of software that support the Event process:

1. The Event Decoder - the Event Decoder runs in the background and will restart when you reboot your PC. The Event decoder calls WinSCP download the event files from the FTP site, and then decrypts the files using your unique urlkey.dat file, and places the files into the Incoming Files folder for LX Event to retrieve.
2. WinSCP, and FTP client, runs in the background. The Event Decoder uses them to move files from the FTP site to the local PC.

3. The ETel utility is used for the MCT process. Once an event procedure has been started, it can be used to update settings, request MCT ECG data or to view settings of the recorder.

Installing the Utilities

Contact Northeast Monitoring Support to get a copy of the ETel installer. You should install the utility on a PC where the LX Event software resides. By default, the installer will create and be installed in the C:\nm\eventpgm directory.

The installer will put a shortcut in the startup list so it will start on booting the computer. It assumes that xx\ftp\event is the location where the “incoming files” go and that the program will be in xx\eventpgm. Further one has to put the urlkey.dat file in xx\eventpgm. xx\ is by default c:\nm\

Note: *You must put a copy of your urlkey.dat file into the directory with the Event Decoder Utility in order for it to run*

FTP user name and password

Once the urlkey.dat file is in the directory, run eventcode with the argument “user password” to identify your FTP site’s logon credentials. You will then need to use these to set up the FTP site that you will be using to transmit event.

To do this, open the Command prompt, go to c:\nm\eventpgm and run:

```
c:\nm\eventpgm>eventdecode user password
```

Your response will look something like this:

```
NorthEast Monitoring EventDecode version 1.00
Jul 12 2021
service url: ABCDE
urlkey Key ID 1234
ftp server ftp.ftpnemon.com port 21
user ufr2xrnd@ftpabcde.com
password AFRSD9eZ
```

The user name that you use to access your FTP site may incorporate the user identified by the decoder utility, and may not be the same exact string.

7. Set up and test the Process

Before your first event procedure, you will need to set up the system and then test to ensure that everything is working correctly. We also recommend that you do a quick test at the start of every procedure to ensure that the DR400 and Gateway 2 are communicating as required.

Set up the system as follows:

1. Get a preconfigured urlkey.dat file, password and username from NorthEast Monitoring.
2. Set up your FTP site using the username and password.
3. Install the PCPatch and copy the urlkey.dat file into the installation directory. The default location is c:\nm\bin.
4. Install the ETel utility, which includes WinSCP and Event Decoder, and copy the urlkey.dat file into that directory. The default location is c:\nm\eventpgm.
5. Reboot your PC to start the Event Decoder utility, which runs in the background
6. Install LX Event.

Test the set up and/or procedure start up:

1. Fully charge both the DR400 and Gateway 2.
2. Turn on the Gateway 2 by holding down the button for about 3 seconds. When the Gateway 2 starts up and successfully finds a network, both battery and signal strength graphics will appear on the screen. If there is an X instead, you may need to move to a location with better service such as near a window, an exterior room of the building, or an above ground floor.
3. Using the docking station, attach the DR400 to the PC via a USB port, and start the PC Patch utility.
4. On the PC Patch window, click on “Erase DR400”.
5. Use the PCPatch to pair the DR400 with Gateway 2. Do this by going to the Settings screen and clicking on the “Pair Gateway” button. Once pairing is confirmed, compare the S/N on the Gateway 2 with the Gateway value in PC Patch.
6. While still on the Settings screen, confirm that the DR400 recording mode is set to Event and the Event settings are what you prefer. If using MCT, be sure that MCT check time is set to “20” or more.

Click “Update Recorder and Close” to save all of the settings to the DR400.

7. On the main screen, enter the new Patient ID by clicking on the “New patient” button.
8. Click on “Start DR400” and follow the prompts. Once completed, remove the DR400 from the docking station. The DR400 starts flashing green at startup.

Confirm proper set up by recording & sending event

This process should be completed at the start of each new procedure to ensure that the DR400 and Gateway 2 are paired and that events can be received.

1. If not running, start the ETel utility so that you can verify that the files are downloading to your local system.
2. With Gateway 2 turned on and in room, create a manual event by quickly pressing the “PRESS” button on the DR400. Once the green light stops flashing on the DR400 (about 90 seconds), the recorder will attempt to transmit the manual event.
3. The Gateway 2 will indicate if a transmission has taken place in the lower-right side of the screen. A number denotes the time, in minutes, an event was last sent. Alternatively, if there is an asterisk “*” in that location, that means that no transmission has taken place.
4. After a minute, the ETel process will decrypt and move the event file to the LX Event folder. Open the LX Event utility and go to the Incoming Files window to view the file.
5. If you do not see a file in the Incoming Files window in LX Event, go to `c:\nm\ftp\event` to see the event file is there. If it is there, the LX Event may be looking for incoming files in a different location.
3. Does the Gateway s have enough signal strength? If there is one or more Xs on the screen, this may be the case. You should move the Gateway 2 to a location with better service such as near a window, an exterior room of the building, or an above ground floor.
4. Is the DR400 recording? If it is recording, you should see green flashing for about a minute after quickly pressing the “PRESS” button to record and event. If you are able to hold down the “PRESS” button until the green light goes out, that means that the DR400 had not been started initially.
5. Is the DR400 recording in Event mode? Check the DR400 using PCPatch. If you go to Preview you can see when the recording was last started (is that correct) and in Settings, you can see what recording mode it is in. If the Preview screen is not available, that means that the recording has not been started.
6. The DR400 and the Gateway 2 are not paired. You can confirm the Gateway SN on the DR400 by using the PCPatch. Also, during a successful transmission, numbers should appear on the lower-left side of the Gateway 2. If there is no change, the Gateway 2 and DR400 may not be paired.
7. The FTP site is not set up properly.
8. Login to your FTP site to view the files. There will be 2 files for each event. One file ends in “dat” and the other “cmd”. (You may need to “refresh” to see the files once they appear.) If they are there, ETel may not be running. Contact NorthEast Monitoring support.

Troubleshooting

If the test did not work the first time, try transmitting again by recording a second manual event. If the second time does not work, there may be a problem, such as:

1. Is the Event Decoder running in the background? Start Task Manager to confirm.
2. Is the Gateway 2 turned on? The battery indicator and signal strength should be visible on the screen.

8. Maintenance and Care

Care for the Gateway 2 as you do the DR400 recorder. Clean the outside of the device with a damp soft cloth between uses; use water and a non-abrasive liquid soap, as required. DO NOT use any abrasive cleaners, such as acetone, on the outside of the recorder.

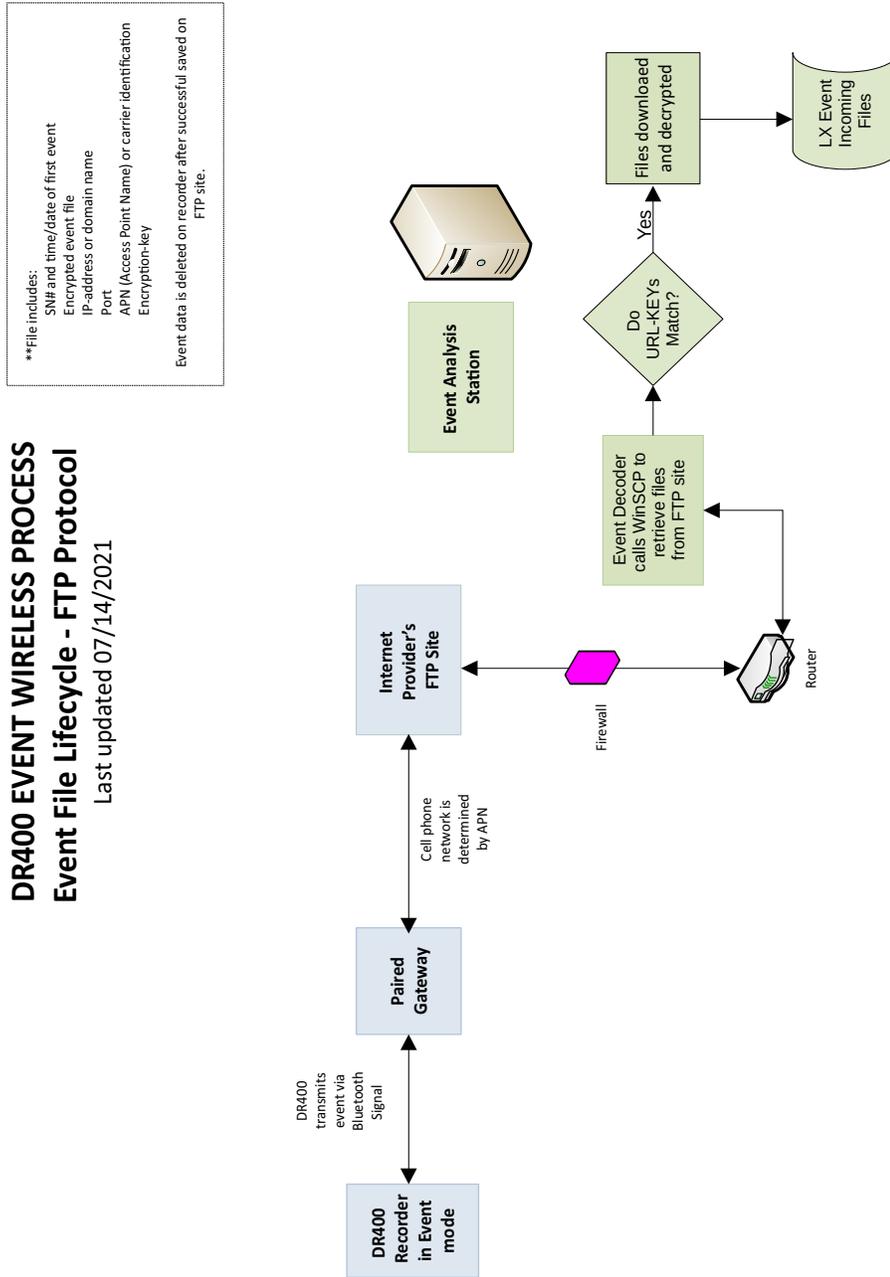
Disinfect as needed, following instructions from your infection control department. Sani-Cloth germicidal surface wipes are recommended. Sterilization is not needed.

Warning: The product cannot be exposed to Ethylene Oxide (EtO) sterilization processes as it may negatively impact the device and/or battery.

Do not submerge in water.

At the end of their useful lives, all NorthEast Monitoring Inc. products should be disposed of following local ordinances.

Appendix A: Event Wireless Process Flow-chart



Wireless_Flow_2021_07_ftp.odg