# DR400 User Manual

*patch style Holter recorder with event capabilities*


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Part number: NEMM048-Rev-A
Revision: July 22, 2019

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# Chapter 1 -About the DR400

The NorthEast Monitoring DR400 patch style recorder can be used as either a Holter monitor and/or a looping Event recorder. The DR400 is designed to facilitate ambulatory cardiac monitoring, on order of a physician, of those patients (including infants weighing less than 10 kg.) who may benefit from such monitoring, including but not limited to those with complaints of palpitations, syncope, chest pains, shortness of breath, or those who need to be monitored to judge their current cardiac function, such as patients who have recently received pacemakers.

The data obtained by monitoring is not analyzed at the time of recording. After the recording is complete, the data must be downloaded to a compatible version of NorthEast Monitoring HE/LX (Holter) Analysis or LX Event software to be analyzed.

The DR400 recorder is compatible with 5.2 or newer versions of HE/LX Analysis. The DR400 recorder in wireless mode for event recording, is compatible with LX Event version 2.11 or newer.

## *Specifications*

***The DR400 recorder is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias and is not for In Vitro diagnostic use.***

### Physical Specifications

The DR400 recorder meets the following physical specifications:

- Size: 6.8 cm (length) x 3.9 cm (width) x 1.3 cm (depth)
- Weight: 34 grams (1.2 oz.) with battery

### Electrical Specifications

The DR400 recorder electrical specifications are:

- Recording bandwidth: 0.05 to 70 hertz in 180 samples/sec. mode*
- Operation duty cycle: Continuous
- Data storage format: Sample difference
- Pacemaker sensitivity: 2 millivolts
- Pacemaker pulse duration: 150 to 2,500 microseconds
- Resettable fuses: 0.5 amp

* When measuring millivolts, results should be within 5% of expected results.

### Environmental Specifications

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

The operating range of the device is between 10 and 45 degrees C, between 10 and 95% humidity, and between 500 and 1060 hPa pressure.

Store and/or transport the recorder at temperatures between -20 and 60 degrees C for up to 1 month, and -20 to 30 degrees C for long term; and between 10 and 95% relative humidity, and 500 and 1060 hPa pressure.

### IP44 Ingress Protection

The DR400 recorder has an Ingress Protection Marking of IP44. Dust will not enter device in sufficient quantities to interfere with satisfactory operation. Water jets will not have harmful effect.

### Wireless Specifications

The DR400 recorder is equipped with wireless Bluetooth transmitter. A NorthEast Monitoring Gateway is able to receive the encrypted Event and Holter data. The Bluetooth specifications for the DR400 are:

- Receive Sensitivity: 95 dBm
- Output Power: 10.5 dBm max
- Link Budget: Up to 105.5 dB
- RX/TX Turnaround: 150 us
- Frequency: 2402 – 2480 MHz in 1 Mhz steps
- Data Rate and Modulation:
  BR:1 Mbps,
  GFSK / EDR: 2-3 Mbps PSK
- Number of Channels: 79

## Intended Use

- **Holter Mode:** Detection of Arrhythmias, Efficacy of Pharmacological Treatment, and Pacemaker Evaluation.
- **Event Mode:** The event recorder module is a patient activated device designed to record and for diagnostic evaluation of transient symptoms (such as dizziness, palpitations, syncope, and chest pain).

## Indications for Use

1. **Detection of Arrhythmias:** The DR400 recorder is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.
2. **Efficacy of Treatment:** DR400 recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.
3. **Pacemaker Evaluation:** The DR400 recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.
4. The DR400 recorder is to be used only on the order of a physician.

## Device Charging

The DR400 recorder has an internal rechargeable Lithium battery that is not user replaceable. The recorder comes with a USB cable that attaches to any USB charging source (power plug) for recharging. The battery will take at most, 2 hours to fully recharge between uses.

**Warning: A UL 60950-1 certified charger is recommended for use with the recorder. A non-certified charger may not be safe to use.**

## LED Display

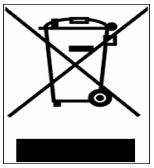
The DR400 recorder has an LED display which consists of a single light that indicates various modes and conditions.

## Warning Symbols

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

Refer to instruction manual/ booklet. Follow instructions for use

Type BF device.



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.


Caution: Federal law restricts this device to sale by or on the order of a physician

This device has Bluetooth capabilities.

**Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**

## Instructions to the User About Electrical Interference

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.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment has been certified to comply with the limits for a Class-B computing device, pursuant to FCC Rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

## Patient Leads

The DR400 recorder is used exclusively with NorthEast Monitoring patch electrodes which are available in 1- and 3-lead configurations.

## Storage Capacity

The patient's ECG data is stored on non-volatile memory internal to the recorder. The internal memory can store up to 470 MB of data.

## Warranty Repairs

The warranty for NorthEast Monitoring products can be found on our web-site at www.nemon.com. Contact your dealer or NorthEast Monitoring prior to returning a recorder for repair to determine the warranty period, conditions and exclusions. If your dealer is unavailable, contact NorthEast Monitoring directly.

The recorder can only be serviced or repaired by NorthEast Monitoring or a NorthEast Monitoring authorized representative.

Prior to returning a recorder, you must obtain a return merchandise authorization (RMA) number. This RMA number must be visible on the outside of the packing carton, otherwise, NorthEast Monitoring will refuse delivery. The usable life of the device and accessories are at least long as the warranty period.

## Operating the Recorder

If you require training, such as assistance in setting up, using, or maintaining your recorder, contact NorthEast Monitoring or your dealer. Should the recorder fail to work properly during its useful life or changes its performance, stop using immediately and contact NorthEast Monitoring or your dealer.

**Warning: The recorder cannot be serviced while in use on patient.**

**The DR400 recorder contains no user-serviceable parts. Removing the label or opening the recorder voids the warranty.**

NorthEast Monitoring can be contacted at: [+1]978-461-3992, toll-free in the U.S.A. at 866-346-5837, or email support@nemon.com.

The patient is not the primary operator, but may be asked to press the EVENT button or transmit events.

Care should be taken when this device is used, especially with infants or small children, as it includes small internal parts that could be a choking hazard. Additionally, the leads could become entangled and could be a strangulation hazard.

## Online help

In addition to the information in this manual, more information and help can be found at our web site, www.nemon.com or by emailing technical support at support@nemon.com.

Our “Technical Support” page on the web-site includes Frequently Asked Questions.

The most current version of this manual, the warranty and our software can always be found on our web-site on the “Downloads & Documents” page.

## Getting Started

The DR400 recorder comes with a Quick Start Guide, a USB cable and power plug, and a reusable patient lead. A supply of disposable electrodes may also have been included with your recorder.


Before recording, you should charge your DR400 and download and install the PCPatch utility. More information about installing and using the PCPatch utility can be found in the next chapter and on the DR400 Quick Start Guide.

The PCPatch utility download, a copy of the current manual, the DR400 Quick Start Guide and technical support can be found at www.nemon.com.

# Chapter 2 -Recording Holter

The DR400 recorder has an internal battery and memory. Battery charging is done via a USB cable attached to the power plug.

The NorthEast Monitoring PCPatch Utility is used to update settings and download data. In order to do this, the DR400 will be attached to the PC using a USB cable.

## Step 1: Fully charge the DR400

**You must fully charge your recorder before its first use.**

To charge the internal lithium battery, plug the DR400 recorder into a USB charger (not a PC). While charging, the DR400's LED light will flash orange. Once fully charged, the LED light will turn a solid orange. At this point, detach the DR400 from the charger and the recorder will go into standby mode.

It will take, at most, 2 hours to fully charge the battery. A fully charged battery will record for up to 40 days, but we highly recommend that you charge the DR400 between patients. For 24 hour recordings, this will take only about 10 minutes.

If the DR400 is used frequently, for example, not left in the charger for more than a day or two, it is fine to keep it plugged in between uses. If you use your DR400 less frequently, for example it might be left in the charger for more than a few days, it is best to remove the DR400 from the charger once full charged. You will then want to plug it in again to ensure it is fully charged before your next study, but that should only take a few minutes.

## Step 2: Enter Patient ID using PCPatch utility

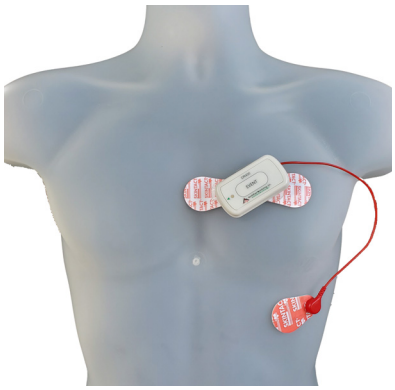
After charging, but before starting a new recording, plug one end of the USB cable into the DR400 and the other into the PC. Start the PCPatch utility to:

1. SAVE the previous patient's file (if not saved previously)
2. ERASE the file from the DR400 recorder (erasing the data on the recorder will also update date and time)
3. Enter the NEW Patient ID for the next recording.

## Step 3: Prepare patient

Patient preparation and patch placement is critical to obtain a quality ECG signal. To ensure proper hook-up, follow these steps:

1. Select either a 1-lead electrode patch (1CH), a 1-lead electrode with the addition of a ECG lead wire (3CH).
2. Determine the best location to attach the electrode patch and optional lead wire onto the patient, but do not attach at this time.
3. Prepare the patient's skin. If the patient has hair in any of the site, shave it with a safety razor. Use an alcohol pad and rub the sites briskly until the skin reddens. Let the skin air dry before proceeding.



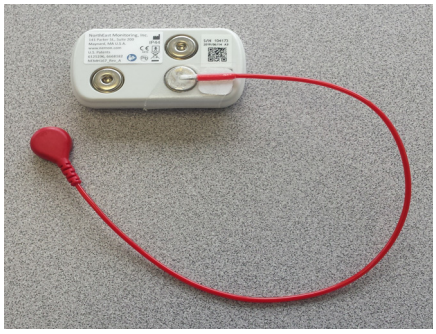
*1-lead electrode patch with optional lead wire (3CH)*

## Step 4: Prepare DR400

1. **First, you may want to test the DR400 to ensure it is ready for the next patient.** Do this by removing the DR400 from the USB cable, wait for the flashing to stop, and then quickly pressing the EVENT button. If the light immediately turns orange, this means one of two things: 1) the previous patient's data has not been erased or 2) it has been erased and there is no new Patient ID. You will need to plug the recorder back into the USB and use the PCPatch utility to delete the file and/or enter a new Patient ID.

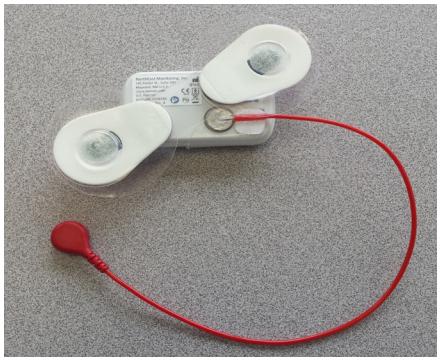
   Now you can begin preparing the recorder:

2. If using the 1-lead electrode patch with the optional ECG lead, attach the ECG lead wire first. The ECG lead attaches to the snap closest to the USB port. Once attached, the clear plastic piece will cover the USB port and be aimed to the right as pictured below:



*DR400 with lead wire attached*

Next, attach the 1-lead electrode patch diagonally on the other 2 snaps. Press down firmly so that all snaps are locked in place.



*DR400 with lead wire and adapter for 3CH*

## Step 5: Start Recording

1. Once the electrode patch and optional lead wire are attached to the DR400, remove paper backing from electrodes and press firmly on to patient to attach. Attach the optional lead to the patient once the patch is in place.
2. If you want to observe lead quality at hook-up, start the PCPatch utility now. Once the PCPatch utility finds the Bluetooth USB, the utility is ready for you to start the DR400 recorder.

   More information about installing and using this feature can be found later in this chapter.
3. To start the DR400 recorder, hold the "EVENT" button down firmly for 3 seconds. While pressing the button, the DR400 first shows a solid green light which goes off when recording has started. You can tell it has started when:
   - The DR400 will then flash for about 30 seconds at the start of recording.
   - View the ECG on the PCPatch viewer to ensure that the recorder is running and hook-up is good.

   ***Warning: If the light on the DR400 turns a solid orange, this means that the previous patient's data is still on the DR400 or the DR400 does not have a Patient ID. When this occurs, you must plug the DR400 into the PC and use the PCPatch utility to save and/or delete the previous patient's data and/or enter a new Patient ID.***
4. Advise the patient that showering is allowed with the DR400 and patch attached, we do not recommend that the patient go swimming while wearing either.
5. Instruct the patient on how to use the EVENT button to indicate symptomatic events or activities of interest during the Holter test. Advise them to push the EVENT button briefly.
6. Provide the patient with instructions on how to use and change the patch, if required.

## Step 6: Copy data for analysis

1. After recording is finished and the patient and patch have been removed from the DR400, plug the recorder into the USB cable that is attached to the PC where the PCPatch utility is installed.

   ***Note: Recording stops once the DR400 is plugged into the USB cable for 2 minutes.***
2. Start the PCPatch utility and copy the flash.dat file (ECG data file). When doing a copy, the utility will automatically find the next open patient directory in HE/LX Analysis.
3. Once copied, you may want to erase the file from the recorder.
4. Remove the DR400 from the PC USB. At this point you may want to plug the DR400 into a power source to recharge the battery for its next use.

## The DR400 PCPatch Utility

The DR400 uses the PCPatch utility to save ECG patient data to HE/LX Analysis, enter patient IDs, and update settings on the recorder. The utility can also be used to view your patients ECG data live via a Bluetooth USB that is attached to the computer.

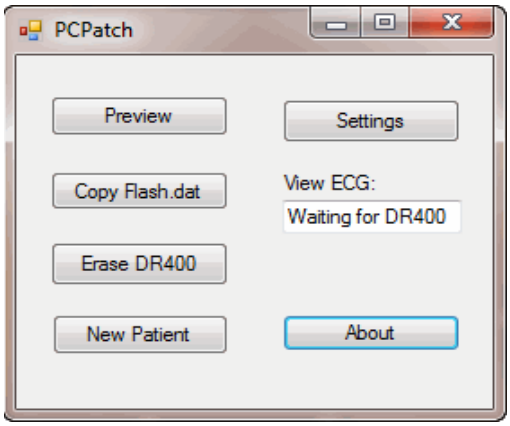
### Download and Install the utility

Go to the NorthEast Monitoring web-site at www.nemon.com to download the PCPatch utility. Install the PCPatch on the computer where the HE/LX Analysis software resides. Once installed, you should see a short-cut on your desktop. Click on the shortcut to run the PCPatch utility.

The default directory "c:\nm\bin" is where the PCPatch utility will be installed. If your analysis software is located elsewhere, you will need to override the "nm" directory at install. In addition to pcpatch.exe, debpatch.txt and pat_template.001 are necessary to run the PCPatch utility.

### Using the PC Patch Utility

Plug the DR400 into the USB on the same PC where the PCPatch utility is running. When the recorder shows a solid green light, it is ready to communicate with the PC. If the PCPatch is running you should see the following:




*PCPatch main screen with Bluetooth available*

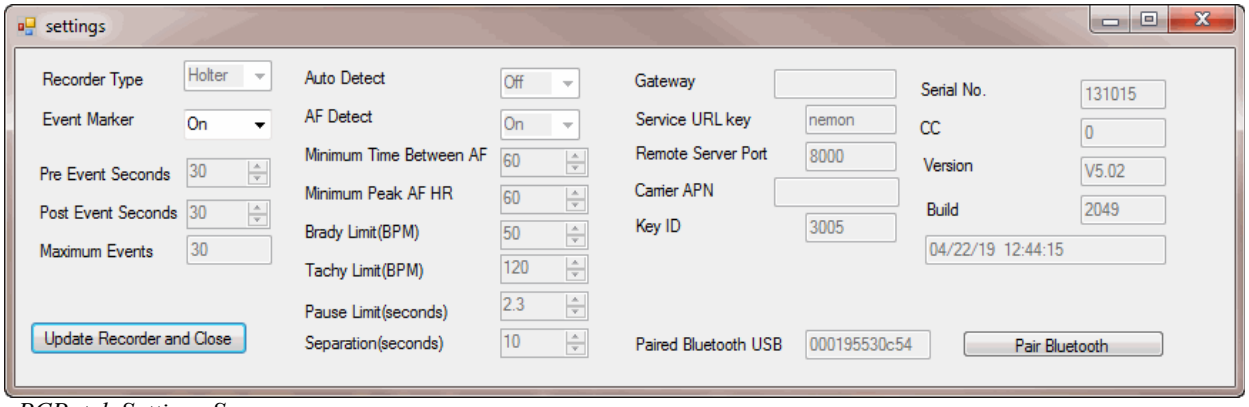
Once the DR400 is found, you can do the following:

- Preview - When a patient file is on the DR400, you can view the Recorder S/N, the Patient ID and the date and start time of the recording
- Copy Flash.dat - When recording complete, save the patient file to the HE/LX patient directory. The PCPatch will automatically select the next empty patient directory to save the file to.
- Erase DR400 - After the patient file is saved, use this to erase the patient file from the recorder. You will need to do this before you can start a new recording
- New Patient - After erasing previous patient, enter the Patient ID for the next recording
- Settings - Allows you to update the Recorder settings such as Type (Holter vs. Event) and turn On or Off the Event Marker

**DR400 Date and Time.** When the data on the DR400 is erased using the PCPatch utility, the date and time on the recorder will be updated to match the date and time on the PC. After erasing, you can view the date/time on the right-hand side of the PCPatch Settings screen.

### Using HE/LX Analysis with the PCPatch

You can use HE/LX Analysis to analyze existing or newly saved patient files while you are copying and previewing files using the PCPatch. Once you save a file using PCPatch, use HE/LX to update the patient information before analysis.




*PCPatch Settings Screen*

## *DR400 Settings*

Use the PCPatch utility to update the settings on the DR400.

**Update Recorder and Close.** Press "Update Recorder and Close" to save changes. Close the window to make no changes.

**Recorder Type.** Choose from Holter or Event

**Event Marker .** When "On", the ECG will be labeled with one second of 6-cycle square wave where the event took place.

### Event Recording Specific Settings:

**Pre Event Seconds.** The number of seconds saved before the EVENT button is pressed by the patient.

**Post Event Seconds.** The number of seconds saved after the EVENT button is pressed by the patient. If this number is set to 15 seconds, the user will not be asked to select a diary entry after pressing the record button.

**Maximum Events.** Limits the number of events that are saved at any one time. A total of 90 minutes can be saved on the recorder. The maximum number of events may be automatically adjusted by the recorder based on the number of seconds saved for each event as well as the number of channels.

### Auto Detect Settings for Event

**Auto Detect.** Turns auto detection On/Off for all event types, including AF.

**AF Detect.** Only turns Atrial Fibrillation detection On/Off.

**Minimum Time Between AF.** The second "Min AF time", applies to AF events only. The range of 2 - 90 minutes..

**Minimum Peak AF HR.** The minimum HR that at least 3 beats of the previous 20 must exceed, in order for an event to be called AF. The range is 60 - 120 BPM.

**Brady Limit.** If a heart rate on or below this number is detected, an event will be recorded. The range is 20 - 100 BPM.

**Tachy Limit.** If a heart rate on or above this number is detected, an event will be recorded. The range is 50 - 300 BPM.

**Pause Limit.** If no heart beat is detected for at least the pause length in seconds, an event will be recorded. The range is1.0 to 10.0 seconds.

**Separation.** Limits the number of events by type by requiring a minimum amount of time between the same type of event. Applies to all events, except AF. The range is 2 - 20 minutes.

### Wireless Settings for Event

When the DR400 is set to Event recording, wireless is automatically turned on. This means that if the DR400 has been paired with a NorthEast Monitoring Gateway, the recorder will attempt to transmit any saved events.

On the Settings screen, you can see if the DR400 has been paired with a Gateway and find other important settings that are required to allow the Wireless feature to work. They are:

**Gateway.** the Serial Number of the paired Gateway

**The Service URL key, Remote Server Port, Carrier APN, and Key ID** are all required for Wireless Event to function. These settings are entered at NorthEast and cannot be changed by the technician. Contact NorthEast Monitoring for more information about using the Gateway for Event recording.

Please refer to the Gateway and Socket Technical Manual, NEMM046, for information on how to set up and run the Wireless feature.

### About the DR400:

- Serial No. of DR400 recorder
- CC (Customer Code)
- Version number of firmware on DR400
- Build number of firmware on DR400

**Date and Time .** on recorder. Automatically updated when the DR400 is erased using the PCPatch utility.

## Pair Bluetooth

**Pairing the DR400 with a Bluetooth USB.**

You must have a NorthEast Monitoring Bluetooth USB adapter to view the patient hook-up on the PC.

**Install Bluetooth USB First.** Do this by plugging the Bluetooth into the same PC where the PCPatch utility is installed. The first time the PCPatch utility runs, it will set up the Bluetooth USB. Once functional, the mode button on the Bluetooth USB will flash green.

**Pair DR400 with Bluetooth.** Once the Bluetooth USB is installed, attach the DR400 to the PC via the USB cable and start the PCPatch utility. From the PCPatch main screen, open the Settings screen and click on Pair Bluetooth. Once the DR400 is paired with the Bluetooth, you can now use it for ECG viewing moving forward. You will not need to pair it again.

## To View Live Patient ECG

For 10 seconds at start up and after pressing the EVENT button, the DR400 will transmit a Bluetooth signal for ECG viewing. When the PCPatch is running and receives the Bluetooth signal, it will open the screen and allow you to view the patient's ECG.

First, start the PCPatch application and allow it to find the Bluetooth USB. At that point, hold down the EVENT button to start the recording or if already recording, press quickly to record an event.

If you are not seeing ECG data, there may be one or more issues that is visible on the PCPatch screen. You will see one of two messages under "View ECG":

- "No BT" - the Bluetooth USB cannot be found on the PC where the PCPatch utility is installed. The DR400 will only pair with one of the Bluetooth USB adapters pictured above.
- If the Bluetooth USB is installed on the same computer, and the PCPatch fails to see it, just restart the PCPatch again so that it will search.

  It is best to restart the PCP Utility between recorders so that it can reconnect with the Bluetooth on startup. Sometimes the Bluetooth USB needs a moment to compose itself.
- "Waiting for DR400" - If the DR400 appears to be transmitting, perhaps it is not paired with the Bluetooth USB that is plugged into the PC. If you want to fix this now, you will need to remove the DR400 from the patch electrode and plug it into the USB cable to pair it with the Bluetooth USB from the Settings screen.

# Technical Considerations

## LX Remote Installations

The PCPatch utility must be used with LX Remote to copy the patient files. You must install the PCPatch Utility on the PC where the LX Remote desktop application exists, mostly likely the c:\nm\Remote directory.

Once files are copied to the LX Remote directory, you can open the Patient Information record in LX Remote and enter the patient information before sending the file.

## Network Installations

For Holter, if the PCPatch utility is being installed on a PC that does not have HE/LX Analysis installed, you will need to do the following to allow the user to save patient files to HE/LX Analysis:

1. Ensure that the local PC has read/write access to the HE/LX Analysis patient directory on the server
2. On the local PC, create a directory labeled “c:\nm\bin”

- Copy the h4w.ini file from a PC that has HE/LX Analysis installed and paste it into the local directory. (The h4w.ini file most likely can be found in the c:\nm\bin directory.)
- Using Windows, test to ensure that the path to the Patient Directory works for the PC where PCPatch is installed.

# Chapter 3 -Appendices

## Appendix A: Maintenance and Care of the Recorder

Clean the outside of the recorder 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.

Do not submerge the recorder in water.

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

## Appendix B: Pacemaker Detection

The recorder has a built-in pacemaker detection capability. This was designed to overcome the problems inherent with the analysis of Holter recordings from patients with pacemakers.

A pacemaker is designed to initiate cardiac conduction by stimulating a spot on the myocardium with a pulse of 1-4 volts and a duration of typically 250 to 2,000 microseconds. When this pulse is seen at the surface recording electrodes it is significantly attenuated. For patients with a unipolar electrode configuration, the signal at the surface may range from under 50 to over 200 millivolts. When a bipolar lead configuration is used, the signal is typically much lower and is in the range of 3 to 50 millivolts. Especially with the bipolar leads, the signal size is dependent on the positions of the pacemaker lead and the surface electrodes.

The amplitude of the signal being referred to here is not the size of the "spike" commonly seen on an ECG cart or bedside monitor. Since the duration of the pulse is short compared to a QRS complex, normal ECG recorders will greatly attenuate the signal; in some cases it cannot be seen at all. Also, some ECG recorders have devices which enhance the pace pulse to insure that it will be displayed. Only very wide bandwidth recorders as are sometimes used in an electrophysiology study will show the unmodified full amplitude of the pulse.

The recorder has the wide bandwidth ECG amplifiers necessary to pass the pacemaker pulse. Since the pulse would still be too short to be recorded in a reliable manner at any practical sampling rate for Holter recording, the pulse is detected by the recorder. The time of the pulse is then digitally stored along with the Holter ECG data. When the data is analyzed, the pacemaker pulse is displayed and used for the analysis.

At recording time, it is desirable to have the recorder be as sensitive to the pacemaker pulse as possible so pulses will not be missed. A conflicting requirement is that there should be as few false pacemaker detections as possible.

False pacemaker detections are primarily caused by electrical events. Any external electrical signal that is coupled to the patient electrodes which looks like a pacemaker pulse will of necessity be stored by the recorder. The most common form of electrical signal that can look like a pacemaker signal is an electrostatic discharge (ESD) or "spark." These happen very frequently in dry weather but also occur, at a lower rate, under humid conditions.

Fortunately most ESD spikes as seen at the patient electrodes are of shorter duration or of lower amplitude than the real pacemaker pulses. While there is no absolute limit to the size or duration of the ESD pulses, the recorder ignores all pulses that are less than 150 micro-seconds long or are less than two millivolts in size.

As pacemakers are normally programmed to a pulse width greater than 200 microseconds, this does not cause a loss of detection. The requirement that the pacemaker pulse be at least two millivolts in size is not a common problem.

## Appendix C: Accessories

Contact your distributor to purchase accessories for the DR400.

**NEMEL001 .** 3-Channel Hook-Up Kit (Adapter patch with 2 electrodes, plus extra electrode for 1-lead wire)

**NEMCA159 .** Reusable 1-lead wire (for use with NEMEL001 for 3-channel recording)

**NEMP00513.** Sena Parani Mfg PN SD1000U: Bluetooth USB Adapter for Serial Port

## Appendix D: Extraction of ECG data on 3-channel

It is possible to retrieve the raw ECG files from the Holter files. For all 3-channel data, the process results in three files, one for each channel. Each file is then in the form of a binary file consisting of 16-bit words (little endian) with each word representing one sample. The sampling is at 180 samples per second. The data is scaled so that the least significant bit has a value of 12.5 uv. If a pacemaker pulse was detected, the sample at the time of detection will be replaced by the value 0x8000.

To generate these files, first analyze the data (actually the flash.dat) from the recorder using any compatible version of the LX Analysis program. At the completion of this there will be a file "datacard.dat" in the patient directory. The full path is by default:

c:\nm\pat\xx\datacard.dat

where xx is the number of the patient dataset. This can be seen in the "No. and Directory" columns of the "File->open/new" display.

Then, change the directory to c:\nm\bin and on a single command line, run the following command using the following 5 arguments:

**unpackc d1 f1 f2 f3 0**

- where d1 is the path to the source datacard file, for example,
  d1= c:\nm\pat\xx\datacard.dat
- f1, f2 and f3 are the resultant binary destination files, for example:
  f1 = c:\nm\pat\xx\flashc0.dat
  f2 = c:\nm\pat\xx\flashc1.dat
  f3 = c:\nm\pat\xx\flashc2.dat

The result will be the three files in the patient directory xx described previously. The files are flashc0.dat flashc1.dat and flashc2.dat which are for channel 1,2 and 3 respectively. If desired, the destination paths for this command can be any other path but spaces are not allowed in the path or file name.

# Appendix E: EMC Information

**Attention should be paid to the following EMC information prior to installing or using the Northeast Monitoring DR400 Recorder device.**

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the device.
- The device has been tested and found to comply with IEC/EN 60601-1-2.
- Computers, cables and accessories not tested to 60601-1-2 may result in increased emissions or decreased immunity of the device.
- Verify normal operation if utilizing the device adjacent to or stacked with other electrical equipment.

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The Northeast Monitoring DR400 Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Northeast Monitoring DR400 Digital Recorder should ensure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions CISPR 11 | Group 1 | Northeast Monitoring DR400 Digital Recorder uses RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | Northeast Monitoring DR400 Digital Recorder is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage Fluctuations/flicker emissions IEC 61000-3-3 | Not applicable | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Northeast Monitoring DR400 is intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6kV contact<br>± 8kV air | ± 6kV contact<br>± 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/ output lines | Not applicable.<br>No cables exceed 3 meters | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | Not applicable.<br>Northeast Monitoring DR400 Recorder is battery powered. | N/A |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | < 5% $U_T$<br>(>95% dip in $U_T$)<br>For 0,5 cycle<br><br>40% $U_T$<br>(60% dip in $U_T$)<br>For 5 cycles<br><br>70% $U_T$<br>(30% dip in $U_T$)<br>for 25 cycles<br><br>< 5% $U_T$<br>(>95% dip in $U_T$)<br>for 5 s | Not applicable.<br>Northeast Monitoring DR400 Recorder is battery powered. | N/A |
| Power frequency (50/ 60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |
| | | | |

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Northeast Monitoring DR400 Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC 61000-4-3</td><td>3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2,5 GHz</td><td>3 V<br><br>3 V/m</td><td>Portable and mobile communications equipment should be used no closer to any part of the Northeast Monitoring DR400 Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1.2\sqrt{P}$<br><br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  </td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies<br>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td>a</td><td colspan="3">Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the recorder is used exceeds the applicable RF compliance level above, the recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or recorder</td></tr>
<tr><td>b</td><td colspan="3">Over frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

**Recommended separation distances between portable and mobile RF communications equipment and the Northeast Monitoring DR400 Digital Recorder**

The Northeast Monitoring DR400 Digital Recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the recorder as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter m** | | |
|---|---|---|---|
| | **150 KHz to 80 MHz** $d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz** $d = 1.2\sqrt{P}$ | **800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | **0.23** |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## *Appendix F: Test Issues*

None to report.