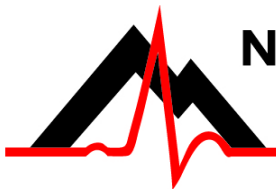


DR400 User Manual

Effective: DR400 v5.29
PCPatch v1.17 / ETel 1.10



NorthEast Monitoring, Inc.

141 Parker Street, Suite 200
Maynard, MA 01754 USA
www.nemon.com

phone: [+1] 978-461-3992
fax: [+1] 978-461-5991
toll free USA: 866-346-5837
email: info@nemon.com

advancing Holter technology



Part number: NEMM048-Rev-L
Last updated: December 19, 2024
Copyright 2019 - 2024
All rights reserved

Table of Contents

About the DR400 ... 3

- Specifications ... 3
- Intended Use ... 4
- Indications for Use ... 4
- Recorder Package Includes: ... 4
- Device Charging ... 4
- LED Display ... 5
- Patient Leads ... 5
- Storage Capacity ... 5
- Symbols ... 5
- The Power Dock ... 5
- Instructions to the User About Electrical Interference ... 5
- Warranty Repairs ... 6
- Operating the Recorder ... 6
- Online help ... 6

Recording ECG ... 7

- Step 1: Fully charge the DR400 ... 7
- Step 2: Start the PCPatch utility ... 7
- Step 3: Prepare patient ... 7
- Step 4: Hook up Patient ... 8
- Step 5: Start Recording ... 9
- Step 6: Copy Holter file ... 9

PCPatch & Wireless ... 10

- DR400 Settings ... 11
- Use Bluetooth for ECG Viewing ... 12
- Wireless Event Recording ... 13
- ETel – Mobile Cardiac Telemetry (MCT) monitoring ... 15

Appendices ... 16

- Appendix A: Maintenance and Care of the Recorder ... 16
- Appendix B: Maintenance and Care of Patient Leads ... 16
- Appendix C: Pacemaker Detection ... 17
- Appendix D: Extraction of ECG data on 3-channel ... 18
- Appendix E: Technical Considerations ... 19
- Appendix F: EMC Information ... 20

Chapter 1 - About the DR400

The NorthEast Monitoring DR400 patch style Holter recorder. Data obtained by monitoring is not analyzed at the time of recording. After recording is complete, Holter data is uploaded to a compatible version of NorthEast Monitoring's Holter Analysis software. The DR400 recorder is compatible with 5.2 or newer versions of HE/LX Analysis software.

The DR400 is also a looping Event recorder. For event recording, data is sent wirelessly to a location where LX Event utility is used to review and report on the recording. The Event function/mode requires LX Event Utility Version 2.11 or newer.

Event recording is not available in the EU.

Clinical Benefits:

The DR400 Holter Recorder is a portable, wearable device that is used to assist in the diagnosis of heart issues that do not show up on an electrocardiogram.

The DR400 is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

The DR400 Recorder is not for In Vitro diagnostic use.

Specifications

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: 33 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 a wireless Bluetooth transmitter. 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

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.

Intended Use

- **Holter Mode:** Detection of Arrhythmias and Efficacy of Pharmacological Treatment.
- **Event Mode:** The recorder captures events automatically or when activated by the patient for diagnostic evaluation of transient symptoms.

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.

Recorder Package Includes:

- DR400 recorder
- Reusable lead wire
- Patch samples
- Docking station
- USB cable & power adapter

Device Charging

The DR400 recorder has an internal rechargeable Lithium battery that is not user replaceable. The recorder comes with a Docking Station and USB cable that attaches to any USB charging source (power adapter) or PC for recharging. The battery will take at most, 3 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.

Patient Leads

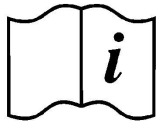
The DR400 recorder is used exclusively with NorthEast Monitoring 1- or 3-lead patch electrodes or a 3-lead adapter.

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.

Symbols

Please note that the recorder is labeled with the following 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 wireless capabilities.



Medical Device



IP44 Ingress Protection

The DR400 Recorder is covered by one or more US patents: D889, 662, D905, 253, 6125296, 6666182.

The Power Dock

The DR400 comes with a docking station that is used for recharging the battery, uploading Holter data and updating the DR400. The docking station can be attached to either a PC for charging and data transfer, or a power adapter for charging only. A cable with a micro-USB connector attaches to the docking station, and the USB end of the cable connects to a PC or power adapter.



Before or after a procedure, firmly attach the DR400 to the docking station via two electrode snaps. When attached via the snaps, a connection is made when the 4 small pads on the recorder coming in contact with the 4 spring pins on the base of the docking station.

Once the DR400 is attached to the docking station, the recorder will recharge automatically. Additionally, after 2 minutes, the DR400 will stop recording Holter data and end the procedure.

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.

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 use the PRESS button to record or transmit events when in Event mode.

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 lead 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.

The [DR400 Technical Support](#) page on the web-site includes Frequently Asked Questions. The most current version of manuals, the warranty and our software can also be found on our web-site on the "Downloads & Documents" page.

Report Serious Incident

The user and/or patient must report any serious incident that has occurred in relation to the Holter Monitor should be reported to North East Monitoring and the applicable competent authority / government agency in the country where the incident occurred.

Chapter 2 -Recording ECG

Below are the steps to complete a procedure using the DR400:

Step 1: Fully charge the DR400

You must fully charge your recorder before its first and every use. To charge the internal lithium battery, place the battery into the docking station, and with the USB cable attached, plug the cable into the power adapter. When plugged in, the DR400 will flash orange while charging, and once fully charged, will flash green every 5 seconds. At this point, you can remove the DR400 from the docking station, and the recorder will stop flashing and go into standby mode.

It takes approximately 2 hours to fully charge the battery from having no charge. A fully charged battery will record Holter for up to 14 days, but we highly recommend that you charge the DR400 between patients. For 24 hour recordings, this will take only about 10 minutes between recordings. For long Event recordings the DR400 should be charged every 14 days.

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 plugged in 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: Start the PCPatch utility

See chapter 3, The PCPatch Utility, for more information on using the PC Patch.



Place the fully charged DR400 into the docking station and attach the docking station to the PC using the USB cable. Start the PCPatch utility and:

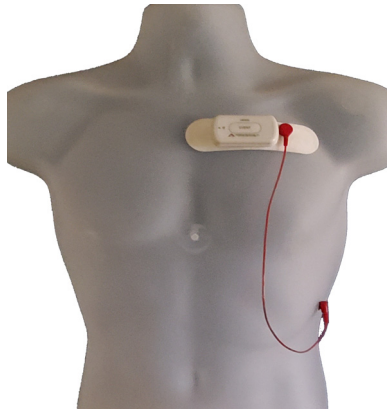
1. ERASE the DR400. This clears all data and updates the DR400 date and time.
2. Enter a New Patient ID for the next recording.
3. For DR400 v5.22 and greater, you can now click on the Start DR400 button in the PCPatch window. If started, you will see a message that the DR400 will start once removed from the docking station.

If you see a message “THIS DR400 CANNOT BE STARTED VIA THIS BUTTON...,” you will need to start the recorder as described in Step 4: Hook up Patient.

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. There are four hook-up options for the DR400:
Select either a 1-lead electrode patch (1CH) for event or Holter, a 1-lead electrode with the addition of a ECG lead wire (3CH), a 3-lead patch (3CH) or the reusable 3-lead adapter.
2. Determine the best location to attach the electrode patch and/or electrodes.
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. For best patch adhesion, allow the skin air dry before proceeding.



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



3-lead patch

Step 4: Hook up Patient

1. **PCPatch Utility.** If you want to observe lead quality at hook-up, start the PCPatch utility if not already running. Once the PCPatch utility finds the Bluetooth USB and is “waiting for DR400”, the utility is ready for you to start the DR400 recorder.
2. **Remove the DR400 from the docking station.** If the DR400 was started via the PCPatch, jump to Step 3.
3. **To otherwise start the DR400, press and hold the DR400 button down until the green light starts flashing.** 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.
4. **Attach electrodes to DR400.** Attach the patch or adapter to the DR400. If you are using the optional lead wire with the 1-lead patch, attach it now. Press down firmly so that all snaps are locked in place. The 3-lead adapter lanyard should be placed around the patient’s neck.
5. **Attach Patch to Patient.** Remove paper backing from patch and press firmly on to patient to attach. If using optional lead wire with patch, attach an electrode to the extension lead wire and attach to the patient in the proper location.
For 3-lead adapter. Attach electrodes to each lead and adhere electrodes as pictured in example.



*3-lead adapter with lanyard placement.
Electrodes required.*

Step 5: Start Recording

1. To start the DR400 recorder, hold the PRESS button down firmly until the green light goes off. At the beginning of a new procedure, 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 flash green for 30 seconds (v5.04) or up to 60 minutes (v5.06).
 - If the PCPatch is on and the DR400 has been paired with the local Bluetooth, the ECG viewer will automatically open and you will be able to view the ECG. Once the viewer window is closed, the DR400 will continue to record but will stop flashing at this time.

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.*

2. Advise the patient that showering is allowed with the DR400 and patch attached, but we do not recommend that the patient go swimming or bathing while wearing either.
3. Instruct the patient on how to use the PRESS button to indicate symptomatic events or activities of interest during the Holter test. Advise them to push the PRESS button briefly.
4. Provide the patient with instructions on how to use and change the patch or electrodes.

Wireless Event

For Event recording, the patient must also be sent home with a wireless Gateway that is paired to the DR400 and chargers for both. The patient should be instructed to charge the Gateway nightly, and the DR400 every 14 days, if required. Let the patient know that the DR400 will flash orange while charging, and then flash green when fully charged.

When the recorder is in Event mode, the recording will stop if the DR400 is erased or the recorder has been plugged in for > 48 hours.

Step 6: Copy Holter file

1. After recording is finished and the patch and lead wire have been removed from the DR400, plug the recorder into the docking station that is attached to the PC where the HE/LX Analysis or LX Remote software is installed.

Note: *For Holter, recording stops once the DR400 is plugged into the PC or power for 2 or more minutes.*
2. Copy the flash.dat file (ECG data file) into the next available patient directory and analyze or send the file as usual.

Chapter 3 - PCPatch & Wireless



The PCPatch utility is used to prepare the DR400 for each procedure. The utility can also be used to view your patient's ECG data live via a Bluetooth USB that is attached to your PC.

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 you prepare the DR400s for the next procedure. The default directory, "c:\nm\bin" is where the PCPatch utility will be installed, unless you specify otherwise. If HE/LX Analysis or LX Remote is located in a different directory, you will need to override the "nm" directory at install. Once installed, you should see a shortcut on your desktop. Click on the shortcut to run the PCPatch utility.

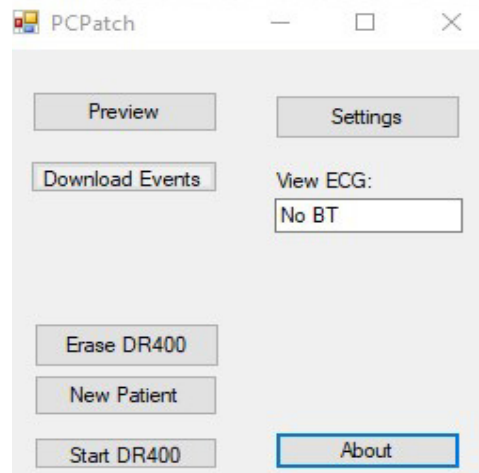
Using the PC Patch Utility

Plug the DR400 into the USB on the same PC where the PCPatch utility is running. When a DR400 is found, you can do the following:

- Preview - When a patient file is on the DR400, you can view the Recorder SN, the Patient ID and the date and start time of the recording
- Download Events - For event recording, use this to copy events to LX Event's Incoming screen. This can only be used when there are events "remaining" on the DR400 when it returns from the field.
- 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 start a new recording.

Note: You will also need to erase the previous file before you can update settings for your next recording.

- New Patient - After erasing previous patient, enter the Patient ID for the next recording
- Settings - Update the Recorder settings and pair with Bluetooth and/or Gateway. The DR400 must be erased before Settings can be updated.
- View ECG: If Bluetooth (BT) is connected, "Waiting for DR400" will be displayed here. If the DR400 is paired with the BT dongle, ECG should automatically become displayed at start up. "No BT" denotes that PC Patch does not currently see the dongle. Details can be found later in this chapter.
- Start DR400 - For DR400 versions 5.22 and greater, this button can be used to start the recorder. The DR400 must be erased and have new Patient ID number to be started.



PCPatch main screen

The screenshot shows the 'settings' window with the following fields and values:

- Recorder Type: Event
- Auto Detect: Off
- Event Marker: On
- AF Detect: On
- Pre Event Seconds: 30
- Minimum Time Between AF: 60
- Post Event Seconds: 30
- Minimum Peak AF HR: 60
- Events to save per day: 24
- Brady Limit(BPM): 50
- Tachy Limit(BPM): 120
- Pause Limit(seconds): 3.0
- Separation(minutes): 10
- MCT check time (minutes): 5
- Gateway: 00043e5c01a9
- Service URL key: fittest2
- Remote Server URL: 18.223.171.10
- Remote Server Port: 21
- Carrier APN: teal
- Key ID: 3334
- Paired Bluetooth USB: (empty)
- Serial No.: 109197
- CC: 0
- Version: V5.29
- Build: 1357
- 2024-09-25 13:16:57
- total events: 0
- remaining: 0

Buttons include 'Update Recorder and Close', 'Pair Gateway', and 'Pair Phone'.

PCPatch Settings Screen

DR400 Settings

DR400 settings are updated via the Settings screen in PCPatch. Except for Pairing the DR400, the recorder must first be erased before Settings can be updated. For Holter, there are only two settings:

- Recorder Type - Holter will record up to 3-channels, Event will record 1-channel. For Holter, the DR400 will record up to 14 days.
- Event Marker - When “On”, the ECG will be labeled with one second of 6-cycle square wave at the event.

Settings for Event only

Pre Event Seconds. Number of seconds saved before an event is detected. Up to 60 seconds allowed.

Post Event Seconds. Number of seconds saved after the event. Up to 60 seconds allowed.

Events to save per day. DR400 will automatically send ECG one or more times per day. For example, if set to 24, events will be sent hourly; if set to 2, events sent every 12 hours. These events will be labeled as “Daily”.

Auto Detect Settings for Event

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

AF Detect. Turn Atrial Fibrillation detection On/Off.

Minimum Time Between AF. For AF events only. The range of 2 - 120 minutes.

Minimum Peak AF HR. 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, a brady event will be recorded. The range is 20 - 100 BPM.

Tachy Limit. If a heart rate on or above this number is detected, a tachy 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, a pause event will be recorded. The range is 1.0 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 - 120 minutes.

MCT Check Time. When ETel-MCT is being used, how frequently the DR400 will check the FTP site for instructions AND how frequently the DR400 will send a status update. When set to OFF, the recorder will not check for ETel messages, however, if a message exists when an event is being transmitted, the message will be received and the DR400 will respond accordingly. Also, if OFF, no statuses will be sent. These events will be labeled as “MCT”.

Update Recorder and Close. Click to save changes. Close window to make no changes.

Use Bluetooth for ECG Viewing

The DR400 transmits a Bluetooth signal for ECG viewing. When the PCPatch is running and receives the Bluetooth signal, it will open an ECG Viewer screen. You must have a the Bluetooth USB adapter pictured below to view the patient ECG on the PC.

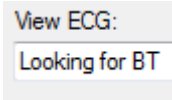


First, install Bluetooth USB. Plug the Bluetooth USB into the same PC where the PCPatch utility is installed. It may take a short time for the Bluetooth USB driver to be installed onto the PC. Once installed and functional, the mode button on the Bluetooth

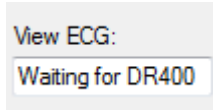
USB will flash green.

Second, start the PCPatch utility.

Upon starting the PCPatch, you will first see “Looking for BT” while the utility searches for a Bluetooth USB that is physically attached to the PC.



When the PCPatch Utility is running and the Bluetooth USB is found and ready to receive a signal, you will see the message, “Waiting for DR400”.



Note: The PCPatch utility only searches for the Bluetooth USB at start up or while attempting to pair with a DR400. If not found, close PCPatch and restart again.

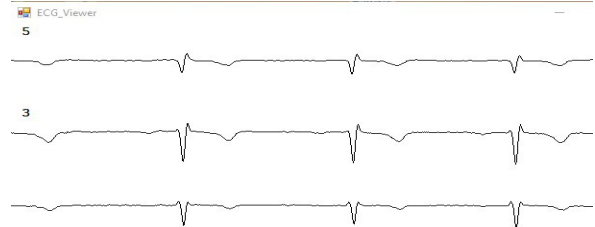
Third, pair the DR400 to Bluetooth USB. Before you can view live ECG with a particular DR400, you will first need to pair the DR400 with your Bluetooth USB. On the PC where the Bluetooth USB is installed, plug in the DR400, open the PCPatch, and go to the Settings screen. Click on the “Pair Bluetooth USB” and the PCPatch will attempt to



pair the two. Once paired, you will see the USB number on the Settings screen. The last 5 numbers should match the Serial Number of your Bluetooth USB. The button is only enabled when a Bluetooth USB was found when the PCPatch utility started.

Using PCPatch to View ECG

With the DR400 ready to record and attached to the patient, start the PCPatch application. Once the utility shows “Waiting for DR400”, hold the PRESS button down until the green light goes out. Once the green light begins flashing, recording has begun and the DR400 transmits Bluetooth for about 15 seconds. After a brief pause, the PCPatch utility should open the window to view ECG.



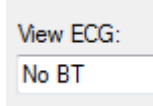
ECG Viewer

If recording has already started and you wish to view the ECG, hold the button down until it starts flashing green rapidly, and then release.

Troubleshooting

No Bluetooth “No BT” message:

- If the Bluetooth USB is installed on the same computer, and the PCPatch fails to see it, you can try to restart the PCPatch so that it searches again. The PCPatch only searches for the Bluetooth USB at start up.
- Unplug and reinsert Bluetooth USB. Check to make sure that the mode light is flashing green. Restart the PCPatch utility to restart the search.
- Drivers for the Bluetooth USB were included with your Windows Operating System. But if you plug in the Bluetooth USB for the first time and the PC is unable to see it at all (the mode light on the USB is not flashing green), you may need to locate and reinstall the device drivers.



“Waiting for DR400” message:

If you see this message and the DR400 appears to be transmitting but you have no ECG screen, perhaps the DR400 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.

Wireless Event Recording

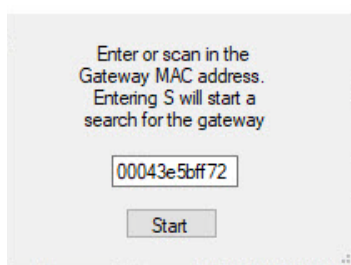
Event recording is performed wirelessly, via a NorthEast Monitoring Gateway 2 or Gateway 3 phone and application. Refer to the Gateway Training Manual, NEMM044, for more information on how to set up and run the Wireless feature.

urlkey.dat file

In order to pair a DR400 with any Gateway, 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 DR400 with Gateway 2

Click on the Pair Gateway button to open the Gateway pairing window. Scan one of the UDI codes on the back of the Gateway to enter the code that



includes the 12-character MAC address. (On the original Gateways, the MAC address is the S/N.) Once scanned and entered, press Start to pair.

Alternatively, you can enter an “S”, to search for a Gateway, but be sure to review the number when paired to ensure that you have paired the DR400 with the intended Gateway 2.

The Gateway 3 and Hexnode Kiosk

A Gateway 3 can only be used with DR400s with v5.29 or later. The Gateway User Manual, NEMM044, instructs you on how to set up and install the Gateway 3 application onto a dedicated cell phone.

The Gateway 3 application is protected by Hexnode. When activated, the Hexnode kiosk prevents the patient from using or updating the phone, except for connecting to the patient’s local wi-fi or making an emergency 911 call.



The password for exiting the Hexnode kiosk is 4615991. For security reasons, do not share this password with the patient.

Pairing the DR400 with Gateway 3 Phone

You will need to pair the phone’s Bluetooth with the recorder before using the Gateway 3 cell phone for the first time. In order to do this, you will need to Exit the Kiosk Mode on the phone.

1. If the phone is in Kiosk Mode, click on the Settings icon on the Gateway 3 screen and you will see the following options:
 - Wi-Fi Settings - This allows you or the patient to connect the cell phone to your local wi-fi. This is especially helpful where cell phone signals are not reliable.
 - Exit Kiosk Lockdown - to Exit Kiosk mode, click on Exit Kiosk Lockdown and enter the password 4615991. Press EXIT, and you will see “Exited Kiosk” appear quickly on the bottom of the screen. From there you can press the back arrow < twice to go to the Home screen, or press the HOME circle in the bottom-center of the screen.
2. From the Home, screen swipe to find and open Settings and continue to Connected devices. There you will see a list of recorders that are already connected.
3. If this DR400 had been paired before and is being re-paired, hit the gear icon next to the recorder SN and click "forget" Confirm.

With the DR400 connected to your PC and PC Patch settings screen open:

4. Click on the Pair Phone button in PC Patch
5. On the phone, click “Pair new device” to begin scanning.
6. When the DR400 SN is found on the phone, click on the SN and confirm “Pair” on the window. (The recorder may be listed as a DR300, and that is fine.)
7. Wait for the PC Patch to confirm the pairing and click OK.
8. Click “Update Recorder and close” in the PC Patch.

9. Once paired, you should see the Recorder SN on the list of Saved devices on the phone.
10. Now that successfully paired, you will need to put the cell phone back into Kiosk Mode which will initiate the Gateway 3 application. You can do this by:
 - Turning off and restarting the cell phone; or
 - by going to the App screen and click on the Hexnode icon. From there you can “ACTIVATE” the Kiosk Mode. This will bring up the Gateway 3 app automatically.

The Gateway Settings

The Gateway field on the Settings screen shows which Gateway has been paired with the DR400. For the Gateway 3, this will be your phone's Bluetooth MAC

address. The Service URL key, Remote Server URL, Remote Server Port, Carrier APN, and Key ID are all required to transmit successfully.

Gateway	00043e9f25a1
Service URL key	nemonid
Remote Server URL	ftp.ftpneumon.com#@ftpneumon.cor
Remote Server Port	21
Carrier APN	iot.kore.com
Key ID	3544

If any of these items are blank or incorrect, you can update these by putting your URLKEY.dat file into the bin directory and pairing the Gateway again. If your URLKEY.dat is incorrect or you do not have a URLKEY.dat file, contact NorthEast Monitoring or your distributor for assistance.

Recording an Event Procedure

Event recording is for channel 1 only, but otherwise the setup and recording procedure are the same as Holter and are described in the previous chapter. While recording in Event mode, the patient should charge the DR400 every 14 days at a minimum. Remind the patient that the recorder will flash orange while charging, and then flash green when fully charged.

As with Holter, the patient can record an event by pressing the PRESS button quickly. The recorder

will flash green when recording an event. Flashing will also occur when the recorder is saving an automatically generated event.

Transmitting Events

Once an event has been saved, the DR400 will attempt to transmit by contacting the Gateway after five minutes. After several tries, and if a Gateway is not found or wireless transmission is not successful, the recorder will then try every two hours to make a connection. Once a transmission is successful, the DR400 will attempt to send events until all are sent.

Transmitting Events Manually

Transmission of events will occur immediately after a manual event is saved. If you want to send a transmission without creating an event, hold the PRESS button down until the DR400 starts flashing orange rapidly. At this point, the DR400 will attempt to connect with its paired Gateway in order to send transmissions.

Download Events on returned DR400

After an event procedure, the Settings screen will show you the total number of events that were saved as well as any

total events	52
remaining	4
<input type="button" value="Update Recorder and Close"/>	

that are still remaining and not transmitted. Use the Download Events button on the main screen to copy the events into the Incoming Files screen within LX Event. After doing this, erase the DR400 so the events cannot be copied over again.

ETel – Mobile Cardiac Telemetry (MCT) monitoring

NorthEast Monitoring’s ETel utility must be installed on your PC in order for you to use the DR400 for Event recording. Additionally, ETel enables Mobile Cardiac Telemetry (MCT), which allows for bidirectional communication between PC and the DR400 without patient interaction.

The ETel MCT feature allows you to request up to 10 minutes of continuous recording for a period of time within the past 72 hours and also allows you to change any or all of the Auto Detect Settings during the event procedure.

The ETel utility runs on your PC and interacts with the server about every 60 seconds to either copy event files from the server to the PC and/or send MCT requests from the PC to the server.

ETel Status

The values at the bottom the screen display the following counts since ETel’s background process, eventdecoder, was last started. The following counts are listed:

Sec since check	Events	Commands	Last transfer
8	457	16	13:00

- Seconds since server and PC last communicated
- Number of Events copied to the PC since the ETel program started
- Number of MCT commands sent since ETel program started, and the
- Time of last event transfer.

ETel Requests

Requests are messages that you send to the DR400 during a procedure. The left-side of the ETel screen is where you generate the requests.

The Recorder Serial Number list at the top is populated by a file coming from LX Event version 3.14 or later. In LXEvent.ini, the RecorderIDFile should point to where your ETel program is installed, which by default is, c:\nm\eventpgm\tmp\openprocedures.txt.

The screen below shows a request that would be used to obtain ECG data. ECG data requests must be within the last 72 hours. Up to 10 minutes at a time can be requested. Multiple requests can be sent during a single procedure, however, only one request at a time can be queued for a single DR400.

MCT Request

Additionally, Auto-event settings can be updated during the procedure. The values for the next setting are put in the New Setting Value field.

Requests will be listed here until they are received and implemented by the DR400.

- None - requesting ECG
- Auto detect on/off
- AF detection on/off
- AF min peak HR
- brady rate
- tachy rate
- pause
- min between AF events
- min time between events
- Events per Day

List of Settings to Change

If you need to delete a command before it is sent, you can click on it while on the list and confirm that you want it removed. Because MCT Requests have to be deleted from the server, you will have to wait three minutes before you can create a new Request after deleting an old one. Once the old request is deleted, you will be able to enter a new request.

The Status Panel

The bottom half of the ETel screen consists of updates from the DR400s that are currently part of an open procedure. If MCT is turned on, the DR400 will send a status update as per the MCT time.

The left-side of the screen includes the status of the DR400 such as lead loss, battery percentage and event counts. The right-side lists the settings that are currently on the DR400.

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.

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 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: Maintenance and Care of Patient Leads

In addition to the one-time use disposable patch, the DR400 can be used with an ECG lead wire (3CH) or the reusable 3-lead adapter.

Intended Use

This cable is intended to be used for the hook-up of a patient to an electronic medical device with the purpose of sensing electrocardiography signals from the human skin using appropriate disposable or reusable ECG electrodes. The application must be performed by a skilled medical professional. The cable is to be used for the specific purpose mentioned on the reverse only.

Instructions for Use

See safety warning on cable

Check the cable integrity before each use. In case of damage of any kind, do not use and do not attempt to repair cable. Consult your biomedical technician. If cable is found to be contaminated, clean it and disinfect it according to instructions below before reusing

Plug equipment connector into its receptacle and connect all patient lead wires to ECG electrodes suitable for your application. Make sure the electrodes and patient connectors are placed correctly following the IEC publications

Tape the patient lead wires to the skin if necessary to avoid movement artefacts. Pay attention to achieve a sensible and ergonomic cable routing

In case you experience disturbance, distortion or interruptions of the signal, stop the procedure and localize the source and, if possible, amend the problem before you continue.

At the end of the procedure, gently disconnect electrode connectors from electrodes. Be aware disconnecting the equipment connector that it could be latched. Unlatch before pulling

Store cable hanging in big loops. Tight coiling must be avoided. Also avoid heat sources and direct sunlight.

Cables are supplied non-sterile and are reusable. For cleaning and disinfection the following substances and procedures must be used:

Cleaning

Patient cables and lead wires can be cleaned with the following: Green soap, green soap tincture (US Pharmacopeia) or alcohol free hand soap, 2% glutaraldehyde solution (such as Cidex), sodium hypochlorite (bleach) solution 10% in water. To clean:

1. Disconnect the patient cable and/or lead wire from recorder.
2. Dampen a clean cloth or gauze pad with an appropriate cleaning solution and wipe all exposed surfaces.
3. Dampen a clean cloth or gauze pad with sterile or distilled water and again wipe all exposed surfaces.
4. Dry all exposed surfaces with a clean, and dry cloth or gauze pad

Adhesive residues can be removed with the alcohols listed below. Never use other organic solvents (e.g. acetone or toluol will damage the cable jacket)!

Disinfection

Clean cable before each disinfection as described above.

Perform wipe disinfection using products with the following substances as active ingredients:

- Ethyl or Isopropyl alcohol 70 – 80%
- Glutaraldehyde 2% (pH 7,5 - 8) (e.g. Cidex®)

- Quaternary ammonium compounds (e.g. Sani-cloth HB wipes)

Remove the disinfectant immediately after the recommended contact time wiping the cable with a cloth moistened in water

Sterilization

Only sterilize when necessary as determined by your hospital's guidelines, to avoid long-term damage of the cables. The cable can withstand standard EO (EtO) sterilization cycles (1 hour, < 57°C, < 75% rel.humidity).

Make sure the correct aeration time has transpired before using the cable.

Caution

- The materials used are not suitable for autoclave or UV sterilization
- Never immerse or soak the cable
- Prolonged alcohol exposure can negatively affect the mechanical properties of the cable jacket

N-propyl alcohol or sodium hypochlorite (bleach, Clorox) should be avoided for the disinfection of the cables

Appendix C: 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 electro-physiology 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 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:

unpackdc 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: Technical Considerations

LX Remote Installations

You may want to install the PCPatch Utility on the PC where the LX Remote desktop application exists. Use the PCPatch to erase, update and to prepare the DR400 for your next patient, however, you should only use the LX Remote software to copy the file off of the DR400 when the procedure is complete.

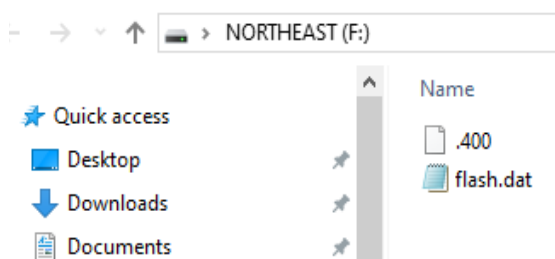
Network Installations

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.

Microsoft File Explorer keeps opening when DR400 plugged in



If the window keeps opening, it may be that your connection is loose. But if you want to prevent the window from opening

when you first plug in or erase your DR400, you can adjust your Windows Settings. Go to Settings > Devices > AutoPlay and for Removable Devices, set it to "Take no action".

AutoPlay

Use AutoPlay for all media and devices



Choose AutoPlay defaults

Removable drive

Take no action


Appendix F: 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 ± 8kV air	± 6kV contact ± 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 ± 1 kV for input/output lines	Not applicable. No cables exceed 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable. Northeast Monitoring DR400 Recorder is battery powered.	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	Not applicable. Northeast Monitoring DR400 Recorder is battery powered.	N/A
Power frequency (50/60 Hz) magnetic field 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>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.</p> <p>Recommended separation distance $d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
NOTE 1: At 80 MHz and 800 MHz, 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.			
a 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			
b Over frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

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.			