

# NorthEast Monitoring, Inc. DR200/HE Digital Recorder for Holter and Event Recording

## *Operator's Manual*



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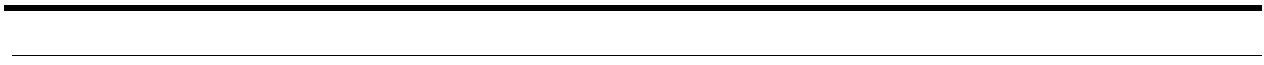
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Part number NEMM019 - Rev-H



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# DR200/HE

## Digital Recorder

# Operator's Manual

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

***Note: For In Vitro Diagnostic Use***

The NorthEast Monitoring, Inc. DR200/HE digital recorder can be used as either a Holter monitor or a looping Event recorder and 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, Inc. Holter LX Analysis software to be analyzed. The DR200 Holter recorder is compatible with 5.2 or newer versions of Holter LX Analysis.

***Note: The DR200/HE is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.***

NorthEast Monitoring, Inc. is an FDA Registered Facility (1224919) that follows all FDA CGMP Manufacturing Practices. The DR200/HE Digital Recorder has FDA 510K Product Classification (K061293 & K070014) and meets the AAMI EC-11/EC-38 standard for frequency response, amplitude accuracy and timing accuracy.

## ***DR200/HE Physical Specifications***

The DR200/HE Digital Recorder meets the following physical specifications:

- 8.6 cm (l) x 6.0 cm (w) x 2.0 cm (d)
- Weight: 70.9 grams (2.5 oz.) without battery; 99.3 grams (3.5 oz.) with battery

## ***Electrical Specifications***

- 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

## ***Power Supply***

The DR200/HE is powered by one 1.5 volt AA alkaline battery (MN1500 or the equivalent), one AA rechargeable NiMH (nickel metal hydride) battery, or one AA Eveready Lithium L91 battery. Although battery life may last longer than a recording, batteries should not be re-used for a second patient. After one use, they should be disposed of following local ordinances.

Do not leave battery in the recorder for extended periods (more than two weeks) when the recorder is not in use.

If you use rechargeable batteries, the battery recharger should be kept out of the patient environment and hook-up area. For details about recommended batteries/chargers, see Appendix B.

## ***Environmental Specifications***

This equipment is not suitable for use in the presence of a flammable anaesthetic 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 700 and 1060 hPa pressure.

Store and/or transport the recorder at temperatures between -40 and 70 degrees C, between 10 and 100% relative humidity, and 500 and 1060 hPa pressure.

The DR200/HE recorder is rated IPX0 and is not for use in wet environments.



## Warning Symbols

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



Attention, consult accompanying document. Refer to documentation for full instructions.

This product is safe for use in the presence of a defibrillator.



## Repairing the Recorder

Should the DR200/HE fail to work properly during its useful life, contact NorthEast Monitoring, Inc. at 866-346-5837 (866-EHOLTER) to arrange for repair and/or replacement. There are no user-serviceable parts.

Removal of the label to open the recorder voids the warranty.

## LCD Screen

The DR200/HE has an LCD screen that is used to display either time-of-day (during the recording), prompts and error messages (during the hookup procedure or during recording), and lead quality (during the Holter hookup procedure). For details about the information displayed on the LCD, refer to the hookup directions that follow.

## Patient Leads

The DR200/HE is compatible with standard single-use silver/silver-chloride ECG electrodes. The DR200/HE uses NorthEast Monitoring, Inc. shielded patient cables with either seven leads or five leads for a 3-channel Holter recording, or three leads for 2-channel Holter recording. For event recording, a 2- or 3-lead shielded patient cable is used. The patient cable connects to the recorder via a 7-pin in-line receptacle.

Patient electrodes should be left sterile in their original packaging until use - following manufacturer's instruction - and then after use, disposed of following local ordinances and the manufacturer's instructions.

Patient lead wires and cables should be cleaned and disinfected as required between uses, with 70 percent isopropol alcohol and a soft cloth to disinfect, and a non-abrasive liquid soap and soft cloth to clean. Sterilization is not required.

**Note: Do not pull on or stretch the patient cables or lead wires when you clean them. This can cause premature failure of the cable. Instead, lay the cable and attached wires on a clean, flat surface, hold them down with one hand, and holding a cloth in the other hand, rub all surfaces of the cable.**

See Appendix A for details about cleaning and disinfecting the DR200/HE recorder as needed.

Patient lead wires and cables should be visually inspected between uses for worn or cracked areas. Frequently used cables should be replaced at least every 6 months. Worn lead wires and cables should be replaced before next use and disposed of following local ordinances and the manufacturer's instructions.

## **Storage Capacity**

The patient's Holter data is stored in the recorder on a removable SD Card. To store 24 hours in normal mode, the minimum capacity of the SD Card should be 28 megabytes; 56 megabytes are required for 24 hours in high resolution mode.

There are some SD Card types that may draw excessive power, and will therefore drain the battery prematurely. If you purchase cards from a supplier other than NorthEast, it is recommended that you first test the SD card for a greater amount of time than the expected use.

The patient's Event data is stored in non-volatile memory internal to the recorder.

## **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.

## **Using the DR200/HE for Holter Recording**

To use the DR200/HE to record a patient's long-term ECG (Holter), follow the appropriate steps listed below:

**Step 1** - Hook up patient;

**Step 2** - Prepare the DR200/HE for recording;

**Step 3** - Set-up patient ID on recorder;

**Step 4** - Start recording.

These steps are described in detail starting with the next section.

If you have a new SD Card that has not been formatted with a flash.dat file, you will need to use your NorthEast Monitoring, Inc. Holter LX Analysis software to initialize the card for the first time. If your software does not refer to the DR200, follow instructions for the SD360.

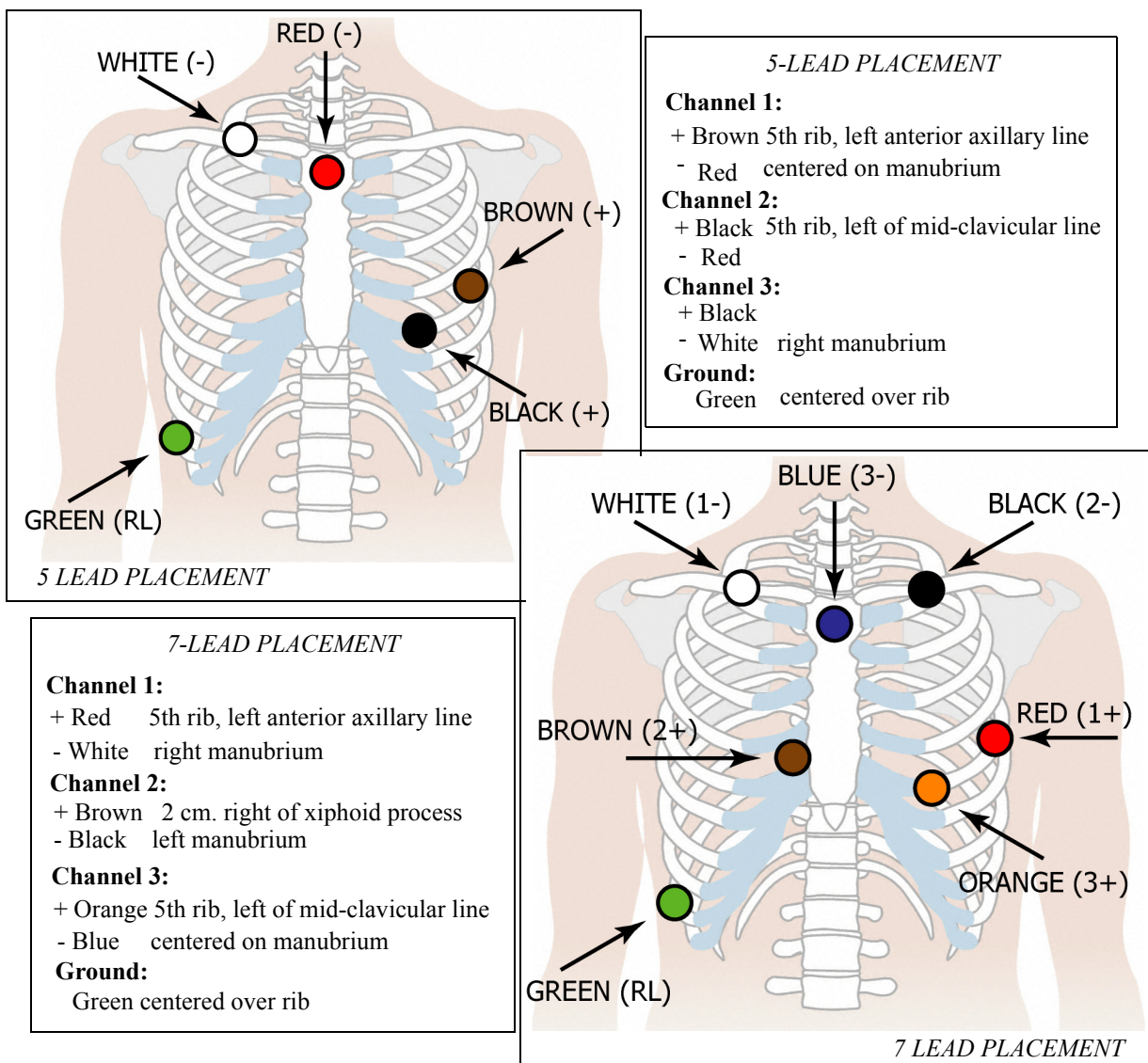
## Step 1: Hook up Patient for Holter

The most important element in Holter monitoring is recording a clean long-term ECG signal. Because a clean signal is directly dependent on the hookup procedure, great care should be taken when hooking up the patient. Poor hookup causes poor signal quality and artifact.

To ensure proper hookup, follow these steps:

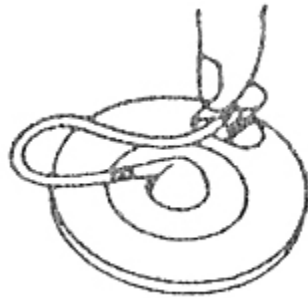
- Using either the 5-Lead (3-channel) or 7-Lead (3-channel) hook-ups shown below, identify sites for the electrodes. You can also choose a 3-Lead hook-up (2-channel) which is shown in the Event section of this manual.

**Note:** The 7-electrode hookup shown below consists of independent bipolar leads and corresponds to IEC60601-2-47 requirements (Code 2). The 5-electrode hookup does not

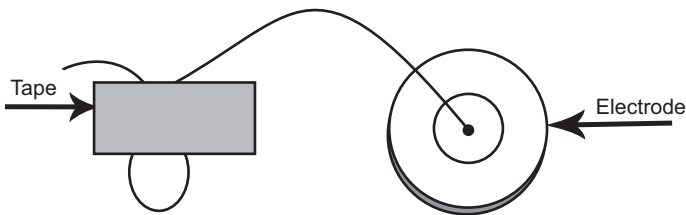


*have independent leads, and so, does not correspond to either Code 1 or 2, but is widely used in the United States and Canada.*

2. Prepare the patient's skin. If the patient has hair in any of the electrode areas, 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.
3. Attach the patient cable to the recorder. Next, snap a lead wire from the patient cable to each of the electrodes.
4. Attach an electrode at each of the patient's prepared sites. As you attach electrodes, be careful to not let any unattached electrode come in contact with other conductive objects, including ground. Be sure to refer to the diagrams on the previous page for correct placement of each colored lead. The electrodes should be placed over bone at each of the sites. Press the center of each electrode against the patient's skin, then rub the outer circle of each electrode to secure it.
5. If you use lead lock or clip lock electrodes, be sure to use the lock or clip to relieve stress on each lead wire; refer



*Using a clip lock electrode*



*Stress Loop*

to the diagram at right for proper use. Otherwise, tape each lead wire into a stress loop (see the diagram below) to help prevent movement of the electrode.

## Step 2: Prepare DR200/HE

After connecting the patient to the recorder, follow these steps to prepare the recorder:

1. Remove the battery cover from the back of the recorder. The battery compartment and the SD Card slot are now exposed.
2. With the recorder front facing up and away from you, insert an SD Card into the slot. The SD Card should have the connector contacts down and toward the recorder as you gently push it in. Be sure to use the SD Card you formatted for this patient.

If the card pops out slightly when you push it in, try again. **Pushing gently on the card both inserts it and allows you to remove it. Never pull the card out as it will damage the recorder.**

**Note:** *The SD Card should slide in easily. Make sure you do not force the card in; if you force the card in upside-down or force the card out by pulling, it can damage the connector inside the recorder.*

3. Insert a fresh 1.5 volt AA battery into the battery compartment, being sure to orient it as indicated in the diagram inside the compartment. See Appendix B for details about battery choices.
4. Replace the battery cover by sliding it into the slot until it clicks.
5. "DR200/HE" will first appear on the screen and then the NorthEast Monitoring information will appear. Press ENTER to continue.
6. If you did not erase the previous patient's data from the SD Card, you will now be

prompted to Erase memory. Use the green arrows to select “\*Yes” and press ENTER.

7. You will see ERASE DONE when erasing is complete.

**Note:** *If at any time you need to restart the set up process, just remove the battery to begin again.*

**Note:** *If your recorder is in Event mode, the 15-second countdown will begin when you put in a new battery. To interrupt the 15-second countdown, quickly press ENTER, down arrow, up arrow and then EVENT, in that order. You should now see the NorthEast Monitoring screen. Press ENTER to continue to the main menu.*

### Step 3: Set-up Patient ID

You will now see a screen with two choices: “New Patient” and “Settings”. Since the DR200/HE recorder will store settings between patients, you may only need to adjust settings when there is a time change or if you want to change between Holter and Event. For more information on adjusting settings, refer to Appendix C - To Adjust Settings on the DR200/HE Digital Recorder.

1. If you would like to input the Patient ID at this time, press ENTER and use the green up arrow to select the first character of the ID. Use the ENTER button when you have entered the first character and continue until all of the ID is entered. Once the patient ID is entered, press the EVENT button.

**Note:** *If you make an error while entering a character into the Patient ID, you can backspace one or more times by holding down the Enter key for several seconds until the cursor moves to the left.*

2. Now, the LCD will display the ECG signals, the battery level, and lead quality based on the level of impedance detected

between the two electrodes for each channel. Lead quality for each channel is a number between 0 and 5. The best possible signal quality reading is 5; that indicates a good electrode-skin connection. A “0” indicates no signal is being received by on the recorder.

3. Once a satisfactory lead quality signal of 3 or more is displayed for all channels, continue with the final step - Start Recording.

**Note:** *If you do not push the EVENT button, the recorder will display lead quality for 10 minutes, then start recording. To delay the start of recording, simply press the EVENT button briefly and the 10-minute countdown will start again.*

#### Step 4: Start Recording

1. Once the LCD displays satisfactory lead quality signals for all channels, you can start the recording by pressing the EVENT button for a 3 seconds till you see “Recording Started”. If you do not do this, recording will begin automatically after 10 minutes. During recording, time-of-day appears on the LCD. Once recording begins, it will continue until the battery is removed or the SD Card is full.
2. The patient can choose between a belt clip or pouch with strap for wearing the recorder. All equipment, except the electrodes and a portion of the lead wires, should be over at least one layer of clothing so that it is not in direct contact with the patient’s skin. Orient the recorder on the patient so that the EVENT button is accessible and the LCD is visible.
3. Advise the patient to not expose the recorder or electrodes to any wet environment; in addition, they should not shower, bathe, or swim while wearing the recorder.
4. 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. The patient may also be given the opportunity to enter a diary at the time of the event. They should use the up/down arrows to choose the most appropriate entry.
5. When the patient returns, remove the electrodes, leads and recorder from the patient. Open the recorder and remove the battery and SD Card from the recorder. **Pushing gently on the card both inserts it and allows you to remove it. Never pull the card out as it will damage the recorder.** The Holter signal is now ready to be analyzed.

#### Event Marker

The EVENT button on the recorder marks the recording so that when the Holter signal is analyzed, the ECG at the time-of-day the button was pushed is kept as a Saved strip and labeled as an Event and with the selected diary entry.

#### Power Loss Protection Feature

In Holter recording mode, if the battery is removed and replaced within 60 minutes, the recording will continue. If that happens, the LCD returns to the time-of-day and continues to record the patient’s Holter signal. When the patient’s recording is analyzed, the signal recorded while the batteries were not in place appears as continuous high-frequency artifact in all channels.

If the battery is left out for more than 60 minutes, recording cannot be restarted. Instead, you will have to use the recording as is, or you will have to re-initiate the recording after erasing the memory on the SD Card. (As of firmware version 1.09, restart time is up to 60 minutes, but for firmware versions 1.08 and earlier, it is only up to 10 minutes.)

If the SD Card has been removed and you wish to restart the recorder without a card in order to update settings, you will need to press the following buttons in this exact order during the 15 second countdown: ENTER, down arrow, up arrow, EVENT.

## Using the DR200/HE in Event Mode.

The DR200/HE can be used as a looping Event recorder to capture events automatically or when activated by the patient. Based upon your settings, the recorder can capture up to 90 minutes of event recordings. When one or more events are captured, the patient may transmit his/her recordings transtelephonically.

**Note:** No SD Card is used during event recording.

To use the DR200/HE in an Event mode, follow these steps:

**Step 1** - Hook up the patient;

**Step 2** - Prepare the recorder;

**Step 3** - Start recording.

### Step 1: Hook up Patient

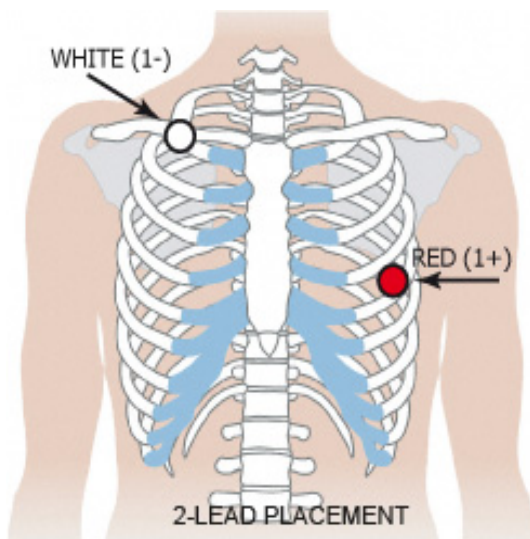
The DR200/HE uses a 2-electrode lead for 1-channel or an optional 3-electrode lead for 2-channel event recording.

Refer to Step 1: Hook up Patient in the Holter Recording section of this manual for hook-up instructions, but refer to the 2- or 3-electrode diagram on this page for electrode placement instructions.

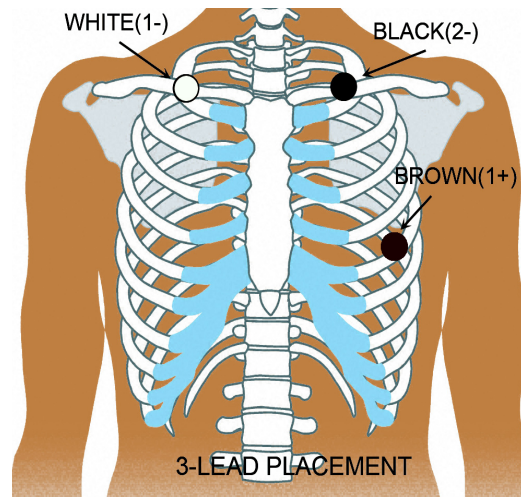
### Step 2: Prepare the DR200/HE

After connecting the patient to the recorder, follow these steps to prepare the recorder:

1. Remove the battery cover from the back of the recorder. Now the battery compartment and the SD Card slot are exposed.
2. If there is an SD Card in the recorder, it should be removed for event recording as it will drain the battery unnecessarily. To



**Channel 1:**  
+ Red: 5th rib, left anterior axillary line  
- White: Right manubrium



**Channel 1 (Lead 1):**  
+ Black: Left-mid-clavicular  
- White: Right mid-clavicular

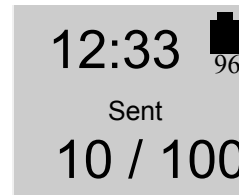
**Channel 2 (Mod V5):**  
+ Brown: 5th rib, left anterior axillary line  
- White

remove the SD Card, gently press on it and it should pop out slightly. You should be able to pull it out easily. If it doesn't work the first time, try again.

3. Insert a fresh 1.5 volt AA battery into the battery compartment, being sure to orient it as indicated in the diagram inside the compartment. The battery sits loosely in the compartment. See Appendix B for details about battery choices.
4. Replace the battery cover by sliding it into the slot until it clicks.
5. DR200/HE will first appear on the screen and then after 10 seconds, the recorder device should begin counting down from 15 seconds and will automatically begin recording. The time-of-day and battery level will appear on the display once recording has begun. If LCD also shows events stored on the recorder, regardless of whether they are sent, you need to erase them now.
6. If the recorder is in Holter mode, you will get an error asking for an SD Card which will then alternate with a 15-second countdown. Interrupt the countdown with the button sequence, ENTER, down arrow, up arrow and EVENT and the go to the General Settings menu to change the Recording Type from Holter to Event. After doing that, go back to "Return" on the menus until DR200/HE and the 15-second countdown begins again. Event recording will start after 15 seconds.

**To Erase**

**Events:** If the previous patient's events still exist on the DR200/HE and they have been transmitted or



stored, you will see the word "Sent" on the LCD screen and you must erase the events before hooking up the new patient. To erase the events, hold down either green arrow button for 3 seconds. You will see "ERASING MEMORY" and once memory has been erased, the event counter at the bottom of the LCD screen will be reset and the word "Sent" will be replaced with the word "Recordings".

If the previous patient's recordings were not "Sent" then you will need to transmit or store event data before erasing. For more information on saving event data, refer to "To Transmit or Store Events" on page 12.

**To Adjust Settings:** In order to adjust settings, you will need to press the following buttons in this exact order during the 15 second countdown: ENTER, down arrow, up arrow, EVENT. While in Event mode, to restart the countdown, simply remove and reinsert the battery.

For more information on settings and how to adjust them, refer to Appendix C.

**Note:** *If at any time you need to start the set up process over, just remove the battery to begin again.*

**Step 3: Start Recording:**

1. The recording will begin automatically after 15 seconds. At first you may see the ECG signal and quality on the screen. The quality can range anywhere between 0 (no signal) to 5 (best signal). A rating of 3 or above should suffice, although you may want to get a signal of 5 before continuing. To view the ECG again, just remove the cable and re-insert. There will be a 10-second delay.
2. During recording, time-of-day appears on the screen. Once recording begins, it will continue to record until the battery is removed or the memory is full.
3. The patient can choose between a belt clip or pouch with strap for wearing the DR200/HE. All equipment, except the electrodes and a portion of the lead wires, should be over at least one layer of clothing so that it is not in direct contact with the patient's skin. Orient the recorder on the patient so that the EVENT button is accessible and the LCD is visible.
4. Advise the patient to not expose the recorder or electrodes to any wet environment; in addition, they should not shower, bathe, or swim while wearing the recorder.
5. Instruct the patient how to use the EVENT button to record symptomatic events. Advise them to push the EVENT button briefly; when they use it depends on your institution's procedures.

**Note:** *Although the DR200's false negative rate is low, there is always the potential that an arrhythmic event being experienced by a patient is not captured automatically by the recorder. Therefore, we strongly recommend that even when automatic detection is turned on, that patients be informed that they should always press the EVENT button when they feel they are having an arrhythmic event.*

6. Instruct the patient when and how to send the recordings via the telephone.
7. When the patient returns, review the screen first to ensure that all events have been sent.
8. If the screen states that there are "Events Recorded" and does not state that any were "sent", you will now need to transmit and save the events for the patient.
9. After transmitting and erasing any unsent events, remove the electrodes, leads and recorder from the patient. You should now open the recorder and remove the battery.

**To Transmit or Store Events**

**Transmit.** Start the software application or recording device that will be recording the events. Once recording has begun, press the ENTER button on the DR200/HE for a second and the events will begin transmitting. Transmission will continue until all events are sent. Once the events are sent, you can now erase them from the recorder by pressing either one of the green arrows for 3 seconds.

At the beginning of the transmission a cal signal will be present. Additionally, at the beginning of each event there will be a marker. The marker is a digital signal that will include the serial number of the recorder and the time, date and type of each event. The digital signal can only be read by NorthEast's LX Event software. If you are using a different event recorder software, you will not be able to read the digital signal, but the signal will allow you to tell where each event begins.

The recorder's ECG transmission uses the standard FM transmission. The header uses a proprietary FSK format.

**SD Card store.** instead of transmitting events acoustically, users of the LX Event software can choose to store events on an SD Card. Before an SD Card is used for the first time, it must be formatted using the LX Event software. Also, only one set of data can exist on a card at any one time, so be sure that you save the previously stored data on the computer before beginning. (For more information on formatting the SD Card, please refer to your LX Event Software manual.)

To record the events onto a pre-formatted card, refer to the following steps:

1. Remove the battery cover from the back of the recorder. The battery compartment and the SD Card slot are now exposed.
2. With the recorder front facing up and away from you, insert an SD Card into the slot. The SD Card should have the connector contacts down and toward the recorder as you gently push it in. If the card pops out slightly when you push it in, try again.  
**Pushing gently on the card both inserts it and allows you to remove it. Never pull the card out as it will damage the recorder.**

*Note: The SD Card should slide in easily. Make sure you do not force the card in; if you force the card in upside-down or pull it out, it can damage the connector inside the recorder.*

3. Re-insert the battery into the battery recorder, being sure to orient it as indicated in the diagram inside the compartment.
4. A message on the LCD screen will now appear - "COPYING EVENTS." When the events are finished being copied to the SD Card, you will see the message "FINISHED REMOVE CARD." Do as you are told by gently pressing down onto the SD Card. It should pop out.
5. You should now insert the SD Card into your reader and save the data on your computer using the LX Event software. **If you**

***use the card again before saving on your computer, the data will be lost.***

6. Once the events are saved on the desktop, re-insert the battery into the DR200/HE and see the word "Sent" on the screen above the Event tally. You should now erase the events from the recorder by pressing either green arrow for 3 seconds.

## Event Recording: Patient Operating Instructions

The DR200/HE recorder is ready to use when you receive it from the technician.

### To Hookup:

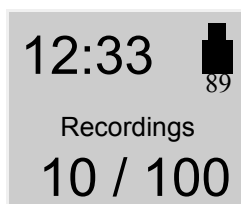
You will want to reapply fresh electrodes daily. To do this, simply snap lead wires into new electrodes first and then apply according to the technician's instructions. We recommend that you do this after bathing or showering as the recorder or electrodes should not get wet.

### To Record an event:

If your DR200/HE recorder has an automatic mode, the recorder may record events without your knowledge. This is normal operation and you may hear a beep when the DR200/HE is recording an event.

If you feel that it is time to record an event manually, simply press the RECORD button and hold for a second. If your recorder is set up to accept a diary entry, you will see the word "Manual Event" on the recorder. No further action from you is required.

After recording is complete, the screen will show the time, the word "Recordings" and a tally showing the number of event that were recorded and the total number of events that can be stored on the recorder. In this example, the patient has 10 events recorded out of a possible 100:



### To Send events:

You have been instructed by your technician to call the receiving center after time has passed or a certain number of events have been recorded. Your recorder may even beep and/or display a phone number when it is time to call. When it is time to call, please do the following:

**Step 1:** If the recorder is in a pouch, remove the cable from the recorder and remove the recorder from the pouch. If the recorder is not in a pouch, it is not necessary to remove the cables from the recorder at this time, but you can do so if it makes it easier for you. Now, set the recorder on a flat surface with the screen side up and within reach of your telephone.

**Note:** *Cell phones DO NOT work for sending transmissions.*

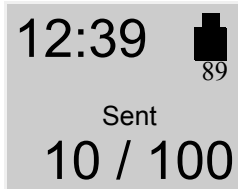
**Step 2:** Call the receiving center phone number provided by the technician.

**Step 3:** When the phone is answered, follow the instructions given to you by the technician on the other end of the line.

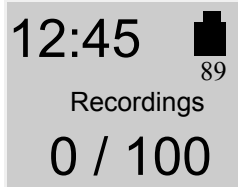
**Step 4:** When instructed to "send your events", do the following:

1. Press the ENTER button that is located on the bottom left corner of the recorder.
2. Gently rest the telephone on the table with the mouthpiece over the speaker that is located between the ENTER button and the down green arrow on the recorder.
3. The screen will display a message "Sending Event" with the number of the event that the device is currently sending and the total number of events it needs to send. (You may also be able to hear the events being sent over the phone line.) This process may take just a few or many minutes depending upon the number of events recorded and the amount of time of each event.
4. Once all the events are sent, you will now see that the word "Sent" has replaced the word "Recordings". This means that all of

the events in the recorder have been sent, but are still saved.



**Step 5:** At this time the technician may ask you to erase your events by pressing either of the green arrow buttons down for 3 seconds, but you SHOULD ONLY ERASE EVENTS WHEN INSTRUCTED TO DO SO. Once events are erased, you will see that the first number is changed to 0 as there are no longer any events stored on the recorder.



You are now ready to record new events.

### Cleaning

You can clean the outside of the recorder with a soft cloth.

### LCD Screen Messaging

Error messages may occur during recording. If you see an error message that is not listed on this page call your receiving center for further instructions.

- **If the time and event tally appears on the screen**, this is normal and means that the DR200/HE is functioning appropriately.
- **If the screen is blank**, this means that the DR200/HE is not working. It is possible that the battery no longer has enough power. Try putting in a fresh battery, but if this does not solve the problem, call your receiving center for further instructions.

- **Battery LOW:** Battery power is running low. When this message first appears, you will have about 5 days of recording time left on your battery. In order to ensure that your next transmission is successful, *be sure to replace the battery before you send any transmissions to the receiving center.*
- **Battery FAILURE:** Recording has stopped. Replace the battery as soon as possible.
- **LEAD LOOSE:** This error will occur when there is a problem with the patient hook up. The problem may be with an electrode, a lead, or the cable that connects the leads to the DR200/HE. Please check all of the connectors to be sure that they are still in place. If you continue to see this error after 10 seconds, call the receiving center for further assistance.

### Batteries

Your battery should last for the duration of your test, but if you need to change the battery, you can do so at any time and not lose any event data stored on the recorder.

To replace the battery, insert a blunt object (for example, pen, coin or non-pointy tool) in the space between the battery and the top edge of the recorder. Press gently to easily remove the battery.

To insert a fresh battery into the battery compartment, be sure to orient it as indicated in the diagram inside the compartment. The battery sits loosely in the compartment.

**Note:** *Do not leave batteries in the recorder for extended periods (more than two weeks) when the recorder is not in use.*

## **Appendix A: Maintenance and Care of the DR200/HE Digital Recorder**

Please follow these instructions to care for the DR200/HE:

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.

**Note:** *Always remove the battery before cleaning 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 wrap the lead wires tightly around the recorder after each use. This can damage them.

Do not pull on or stretch the lead wires when cleaning or untangling them. This can damage them.

Do not clean the cable with harsh chemicals, such as acetone.

Do not submerge the recorder or its cables in water.

Replace the cable on a regular basis or at the first sign of damage.

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

### **To Remove Belt Clip**

If you need to remove the belt clip, you will need a long flat tool like a screw driver. In order to remove the clip, one has to slightly pry up the end of the clip near the battery cover while pulling the clip out.

### **Warranty Repairs**

Please contact your dealer prior to returning a recorder for repair to determine the warranty period, conditions and exclusions. If your dealer is unavailable, contact:

NorthEast Monitoring, Inc.

Two Clock Tower Place, Suite 555

Maynard, MA 01754

866-346-5837 extension 3

service@nemon.com

Prior to returning a recorder, you must obtain a return authorization (RMA) number. This RMA number must be visible on the outside of the packing carton, otherwise, NorthEast will refuse delivery.

The DR200/HE contains no user-serviceable parts.

Removing the label or opening the recorder voids the warranty.

## **Appendix B: Batteries for the DR200/HE Digital Recorder**

The DR200/HE recorder uses one AA-size batteries. This requirement may be fulfilled in a number of ways. Battery types available on the market are:

- Alkaline (example: Eveready Energizer E91, Duracell NM1500)
- Heavy Duty
- Nickel Metal Hydride (example: MAHA AA 1800 mAh, Rayovac 1600 mAh NiMH)
- Nickel Cadmium (NiCd)

### **Alkaline**

The alkaline is the most common type of battery. When a new, properly stored battery is used, a recording time of 30 days can be expected in event mode and 7 days in Holter.

While a recording that runs for 24 hours will in theory use less than half the capacity of the battery, using a battery for two different patients' 24-hour recordings is not recommended. The risk is that the "second" recording will not reach 24 hours.

The primary limitation of this battery type is that there is only a limited ability to test the battery before it is used. Unfortunately, at times a defective battery will appear to initially have full capacity, but will fail well before the expected time. The probability of this type of failure is very small when the batteries are obtained from the primary suppliers.

The best prevention available against defective batteries is to obtain them from suppliers who do not store them for a long time and do store them properly. There are few requirements for storage of alkaline batteries. They should be stored at "room" temperatures (50-90 F) and in

a dry location. There is no advantage to storing them in a refrigerator. There is actually a significant problem with low-temperature storage. Normal refrigerators have a very high humidity inside and this can cause a much greater reduction of life that is gained by the lower temperatures. In addition, storage at a temperature below freezing will reduce battery life.

### **Heavy Duty**

Batteries that are labeled "Heavy Duty" vary widely in capacity. The use of "Heavy Duty" batteries is not recommended.

### **Nickel Metal Hydride (NiMH)**

This class of batteries is rechargeable and thus can be used in situations where a disposable battery is not desirable. Batteries of this type come in a range of capacities with the labeled capacity ranging from 1100 to 1800 mAh (milliamp hours). It is recommended that only batteries with a rating of at least 1500 mAh be used. Lower capacity batteries will operate the recorder for 7 days when they are new but after only a few uses may not be able to operate for the full 7 days.

Charging these batteries is the most difficult part of their use. Only standard chargers that are specifically rated for use with NiMH batteries should be used such as the MAHA MH-204F or Rayovac 1-Hour charger; although medically-approved chargers can be used, they are not necessary. Older chargers designed only for NiCd (Nickel Cadmium) will overcharge this type of battery and can significantly shorten battery life. A charger that applies an excessive continuous charge can also shorten the battery life. If in doubt it is best not to leave the batteries on charge for long periods of time after the charger indicates a full charge.

Unlike the older rechargeable battery types, NiMH batteries have no real "memory." Thus

they do not need to be completely discharged or "conditioned" to insure that they will fully charge. Doing a complete discharge will reduce the total life of the battery as every time the battery is discharged below about 25% capacity, the life of the battery is shortened more than for a normal discharge cycle.

Most chargers for NiMH batteries depend on a property of these batteries that causes them to heat up when they have reached full charge. This has two consequences. First, if the batteries are being charged in pairs, the first battery to be fully charged will heat up and shut down the charge cycle. This can leave one of the batteries partially charged. Thus it is best to keep pairs of batteries together so they are both discharged and charged together. Secondly, if the battery is too warm for any reason, it may shut down the charge early. For that reason the batteries should be charged at normal room temperatures and it is often best not to cover the batteries in any way during the charge. Even the charger's own cover may reduce the charge. Leave the cover open during charging.

When the battery is not being charged, it will slowly discharge by itself. This type of battery will lose about one percent of its charge for each day. Most chargers will bring a partially charged battery up to full capacity in under an hour. Batteries that have not been used for over two weeks should be charged before use.

If used properly, these batteries will last for 300 to 1000 recordings of 7 days each. They will still not last forever. To control battery life, writing the date on the battery that the batteries are first put in service can be helpful.

## **Nickel Cadmium**

This type of battery has less capacity than the NiMH and is not recommended. Also, disposal of this battery can pose problems.

## **Appendix C: To Adjust Settings on the DR200/HE Digital Recorder**

You should only adjust settings on the DR200/HE between patients. To begin, insert a battery to start the recorder.

**If your recorder is in Event mode, the 15-second countdown will begin when you put in a new battery. To interrupt the 15-second countdown, quickly press ENTER, down arrow, up arrow and then EVENT, in that order. You should now see the NorthEast Monitoring screen. Press ENTER to continue to move to the main menu.**

### **If recorder is locked**

If the recorder is locked, you will not be able to review or update settings. See **Menu Lock** details on this page.

### **To Adjust Settings**

To adjust the settings, use the green arrows to move up and down between the menu items and ENTER to accept. The cursor “>” will appear next to the item that you are able to update. Press ENTER to begin updating that item, and then use the green arrows to adjust the value. When finished adjusting a value press ENTER to save the value. To return to the previous menu, use the green arrows to move the arrow to “Return” at the top of the menu and press ENTER.

### **To Review Settings**

At any time, you can remove the battery from the recorder and re-insert. Then interrupt the 15-second countdown as instructed above. You can now review settings without losing any event data.

### **To Update Time and Date**

The recorder should save the correct time and date between uses, but if you ever need to update the time or the date, move the cursor to “Time and Date” and press ENTER. You can now update Hour, Minutes, Day, Month or Year by moving the cursor with the green arrows and pressing ENTER.

### **General Settings**

**Contrast.** Use arrows to increase or decrease contrast. You will see the update once you return to the main menu.

#### **Lead Loose.**

- On - Lead Loose message is enabled.
- Off - Lead Loose message is disabled.

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

#### **Key mode.**

- Normal - Sound enabled and no delay;
- Delayed - Patient will need to press Event and Enter buttons for several seconds in order to prevent false entries, and sounds enabled; or
- Quiet - Sound disabled. No delay.

**Rec Type.** Switch between Holter and Event only recording.

**Menu Lock.** Menu Lock will prevent anyone from reviewing or updating any other settings.

- **To lock the menu, enter 217.**
- **To unlock the menu, enter 151.**

**Language.** Select from U.S. English, International English, Danish, Finnish, German,

French, Italian, Polish, Portuguese, and Spanish.

**Diary Reset** - Pressing this button will reset the diary list back to the default. This will only have an effect if the user has loaded an alternative diary list onto the recorder. (The diary list feature only works in Holter mode and will be operational with version 5.4 of the Holter LX Analysis software.)

**More about the Diary -** If you do not want your patient to be able to enter a diary at the time of the event, you will be able to disable this feature by loading a blank diary list. The blank diary list, called DIARYUP.TXT, can be found on our web-site. You will need to copy this file to a blank SD card and then load it onto your recorder by putting in the card and a battery. When and if you choose to go back to the default diary list, you can do this easily by pressing "Diary Reset" from the General menu.

**Hi Res.** When turned On, the recorder will record in high resolution. High resolution mode provides enhanced R-wave reproduction for pediatric recordings.

## Event Settings

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

**Post Event Sec.** 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.

**Max 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 DR200/HE based on the num-

ber of seconds saved for each event as well as the number of channels.

If a Max Events is set to 0 (zero) and all previously recorded events have been erased, the recorder will function in real-time transmissions mode. No events will be saved on the recorder.

**Channels.** The recorder can record either one or two channels. If two channel recording is selected, the recorder will transmit both channels sequentially during the transmit process. A 3-lead cable is required for 2 channel recording.

### Send Settings.

- **Volume** - Choose between "Normal" and "Quiet". Quiet mode will lessen the discomfort for the patient while transmitting and will slightly improve battery life, however, Quiet mode will not work in all settings, such as distant rural locations.
- **Speed** - Transmit at either 1, 3 or 4X speeds.

**Call message.** Once events are recorded, you can inform the patient with either a sound or a phone number on the LCD screen:

- **Phone Num** - Will show the entered phone number on the LCD screen after events are recorded. "Any" will show number if there is one or more events, "Full" will show number only if maximum number of events have been recorded.
- **Enter Phone Num** - Enter the phone number that the patient should call when events are recorded. Use green arrows to update digits. Hold down ENTER button to back-space.
- **Reminder** - Will cause the recorder to beep repeatedly after events are recorded. "Any" will beep if there is one or more

events, “Full” will beep only if maximum number of events have been recorder.

SD card is greater than what is saved to the desktop, and this is appropriate.

### **Auto Detect Settings**

Additional event settings for the auto detect mode are:

**Auto Detect.** Turns all auto detect functions Off or On. Smart mode, which records on the “best” events for a given time period, can also be turned on here. See explanation of “Separation” below for more information on Smart mode.

**AF Detect.** Turns Atrial Fibrillation detection Off or On.

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

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

**Pause Limit.** If no heart beat is detected for at least the pause length in seconds, an event will be recorded. A range of 1.0 to 10.0 seconds is allowed.

**Separation.** Limits the number of events stored for the separation time period to one for each type. A range of 2 - 20 minutes is allowed.

**In smart mode,** the DR200 will save the best event for each event type for the entered time period. For example, if more than one tachy event is sensed during the time period, the event with the highest heart rate will be saved. If smart mode is turned off and auto detect is on, only the first event for each type will be saved within the separation time period. When the recording is running in Smart mode, you may see that the number of events saved on the

### **About**

To view the Serial No, the customer code (cc), the Version number of the software on the recorder, the build number for that software, and the number of times the recorder has been used in Holter mode.

## Appendix D: Error Messages and troubleshooting

If you see the time-of-day on the DR200/HE screen, the recorder is recording.

**Note:** *If the LCD screen is completely blank, this means that the DR200/HE is not recording.*

An error message will appear when there is a problem with the recorder. The DR200/HE may display the following error messages:

**Battery LOW:** Battery is running low. When this message first appears, you will have about 5 days of recording time left on your battery.

**Battery FAILURE:** Recording has stopped.

**Card Erase ERROR:** An error was found while attempting to erase the SD Card. This usually means a defective card.

**LEAD LOOSE:** This error will occur when there is a problem with the patient hook up. The problem may be with an electrode, a lead or the cable that connects the leads to the Tel-a-heart. The LEAD LOOSE message will remain on the screen for about 10 seconds after the problem has been corrected. This error message can be turned off in General Settings.

**Missing SD Card -** There is no SD Card in the device. A card is required for Holter recording.

**SD Access:** Unable to read the SD Card. This usually means a defective card.

**SD Card is write locked:** Write Lock tab is set on the SD Card. Unlock Write Lock tab and try again.

**SD Setup Failure:** Failure during write of patient ID to SD Card. You will need to re-initialize your card using the LX software.

**SD Card Incorrectly erased:** There may be disallowed files on the SD Card. Remove SD Card from recorder and use card reader and Explorer to identify and delete these files. The only file allowed is flash.dat.

**Short recording:** There are some SD Card types that may draw excessive power, and will therefore drain the battery prematurely, resulting in a short recording. If you purchase cards from a supplier other than NorthEast, it is recommended that you first test the SD card for a greater amount of time than the expected use.

**Unable to write SD:** An error was found while attempting to write to the SD Card. This message occurs when the card is full. Sometimes this message will appear when a card is defective.

**Write Timeout error:** This usually means a defective card.

## **Appendix E: Pacemaker Detection with the DR200/HE Digital Recorder**

The DR200/HE recorders have a built-in pacemaker detection capability. This was designed to overcome some of the problem 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 DR200/HE 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 microseconds 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.

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## ***Appendix F: DR200/HE Accessories***

NEMCA145 - 3-Lead Patient Cable, Adult

NEMCA150 - 3-Lead Patient Cable, AdultXL

NEMCA134 - 5-Lead Patient Cable, Adult

NEMCA144 - 5-Lead Patient Cable, Pediatric

NEMCA149 - 5-Lead Patient Cable, AdultXL

NEMCA133 - 7-Lead Patient Cable

NEMCA135 - 2-Lead Patient Cable (Event only)

NEMH112 - Battery Door

NEMH116 - Belt Clip

NEMH125 - Recorder Pouch and Straps

NEMP00387 - Memory - SD Card

NEMH81 - Replacement Shoulder Strap

NEMH106 - Replacement Waist Strap

NEMH137 - Recorder Pouch (no straps)



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**Approved By: SLS**  
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