

NorthEast Monitoring, Inc. Tel-a-heart (DR200/E) Digital Event Recorder

Operator's Manual



NorthEast Monitoring, Inc.

2 Clock Tower Place, Suite 555
Maynard, MA 01754 U.S.A.
www.nemon.com

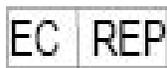
phone: [+1] 978-461-3992
fax: [+1] 978-461-5991
toll free U.S.A.: 866-346-5837

August 2012

NorthEast Monitoring, Inc.

Part number NEMM015_Rev_L

Copyright 2006 - 2012 NorthEast Monitoring, Inc. All rights reserved.



MediMark® Europe. BP 2332
F-38033 Grenoble Cedex 2. France



Tel-a-heart (DR200/E) Digital Event Recorder Operator's Manual

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

The NorthEast Monitoring, Inc. Tel-a-heart digital event recorder 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 transmitted to a NorthEast Monitoring, Inc. Event analysis or compatible system.

Note: The Tel-a-heart is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias and is not for In Vitro diagnostic use.

NorthEast Monitoring, Inc. is an FDA Registered Facility (1224919) that follows all FDA CGMP Manufacturing Practices. The DR200/E 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.

Physical Specifications

The Tel-a-heart 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 at 180 samples/second.
- 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 Tel-a-heart 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 reused 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 Tel-a-heart recorder is rated IPX0 and is not for use in wet environments.

Online help

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

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

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

Warning Symbols

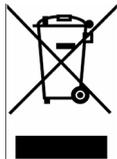
Please note that the recorder is labeled with the following warning symbols:



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



Type BF device.



This device uses batteries that should be recycled.

This product does not contain lead.



Repairing the Recorder

Should the DR200 fail to work properly during its useful life, contact NorthEast Monitoring at [+1] 978-461-3992, toll-free in the U.S.A. at 866-346-5837, or email technical support at support@nemon.com, to arrange for repair and/or replacement. There are no user-serviceable parts.

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

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.

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 Monitoring will refuse delivery.

The DR200 contains no user-serviceable parts.

Removing the label or opening the recorder voids the warranty.

LCD Screen

The Tel-a-heart 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 event recorder hookup procedure). For details about the information displayed on the LCD screen, refer to the hookup directions that follow.

Patient Leads

The Tel-a-heart is compatible with standard single-use silver/silver-chloride ECG electrodes. The Tel-a-heart uses NorthEast Monitoring, Inc. 2- or 3- lead shielded patient cable. 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 Tel-a-heart 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.

- 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.

Storage Capacity

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:

Using the Tel-a-heart to record events

The Tel-a-heart is a looping digital event recorder that captures events activated by the patient. If your Tel-a-heart has auto detect capabilities, it will also automatically record events according to the settings entered by the technician.

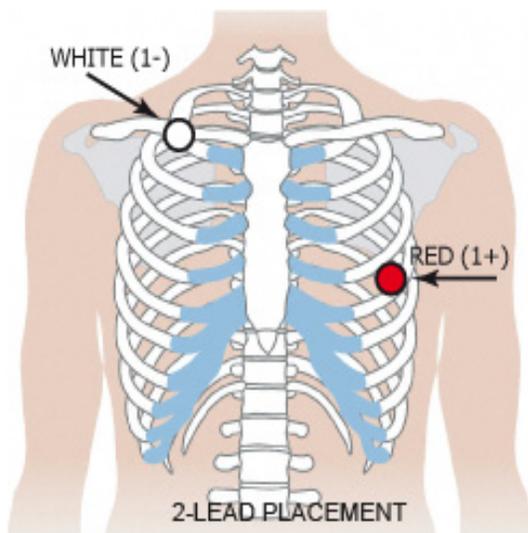
The Tel-a-heart can capture up to 90 minutes of event recordings. After one or more events are captured, the patient may transmit his/her recordings transtelephonically. Additionally, events can be saved in-house on an SD Card for quick and easy saving via Northeast's LX Event software.

To use the Tel-a-heart for event recording, follow these steps:

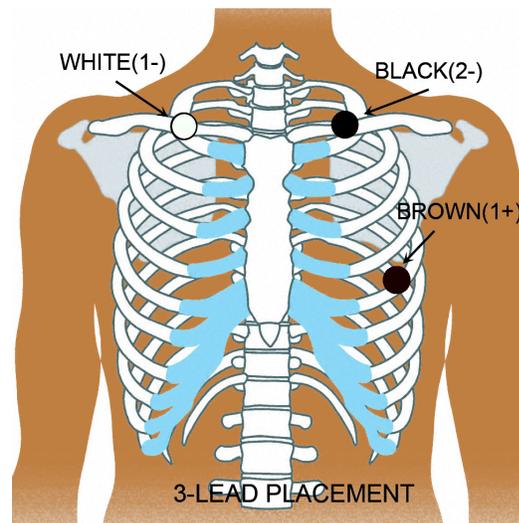
Step 1 - Hook up the patient;

Step 2 - Prepare the Tel-a-heart;

Step 3 - Start recording.



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



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

CHANNEL 2 (Mod V5):
- Brown: 5th rib, left anterior axillary line
- White: Right manubrium

Step 1: Hook up Patient

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

The Tel-a-heart uses a 2-electrode cable for 1-channel event monitoring. A 3-electrode cable is also available for 2-channel recording. To ensure proper hookup, follow these steps:

1. Using either the 2 or 3-Lead Placement diagram below, identify sites for the electrodes.
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 indicated in the picture below. 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.

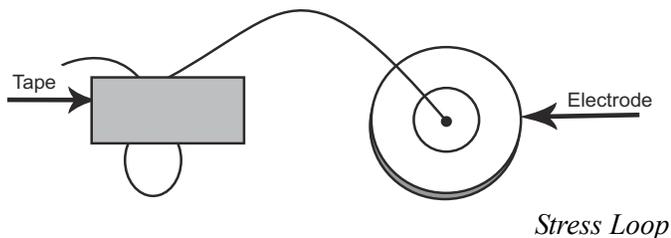
5. If you use lead lock or clip lock electrodes, be sure to use the lock or clip to relieve stress on each lead wire; refer to the diagram at right for proper use. Otherwise, tape each lead wire into a stress loop (see the diagram below) to help prevent movement of the electrode.



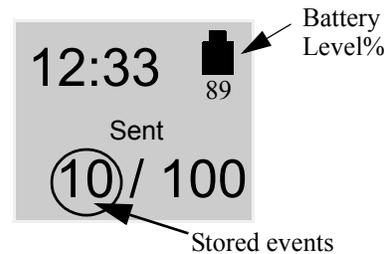
Using a clip lock electrode

Step 2: Prepare the Tel-a-heart

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 a used battery in the recorder, you should now remove it by inserting a blunt object (for example, pen, coin or non-pointy tool) in the space between the battery and the top edge of the recorder and pressing gently. The battery should pop out. If there is an SD Card in the recorder, you should remove it now by gently pressing down on it. It should pop out.
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. An SD Card is not used for event recording.
4. Replace the battery cover by sliding it into the slot until it clicks.
5. "Tel-a-heart" will first appear on the screen and then after 10 seconds, the LCD screen will 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 screen also shows events stored on the recorder, regardless of whether they are sent, you need to erase them now.



To Erase Events: If the previous patient's events still exist on the Tel-a-heart 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 8.

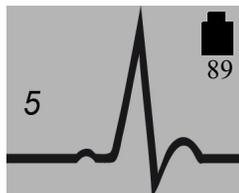
To Adjust Settings: In order to adjust settings, you will need to press the following buttons in this exact order during the 15 second countdown: SEND, down arrow, up arrow, RECORD. Your Tel-a-heart may or may not have Auto detect. If you see the Auto Detect option on the menu, you have it, but you will need to check the Auto Detect menu to ensure that it is turned on.

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 and reinsert the battery to begin again.*

Step 3: Start Recording:

1. The recorder 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 briefly 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. The numbers below the word “Recordings” stand for the number of events recorded and the maximum number that can be stored.



3. The patient can choose between a belt clip or pouch with strap for wearing the Tel-a-heart. 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 RECORD 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 RECORD button to record symptomatic events. When they use it depends on your institution’s procedures.

Note: *Although the Tel-a-heart'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 RECORD 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 to ensure that all events have been sent.
8. If the screen states that there are “Recordings” and does not state that any were “Sent”, you will need to transmit and save the events for the patient.
9. After transmitting and erasing any events, remove the electrodes, leads and recorder from the patient and open the recorder to 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 “SEND” button on the Tel-a-heart and the events will begin transmitting. Transmission will continue until all events are sent. Once the events are sent, you can 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 also 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 force the card out by pulling, 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. 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 again into the Tel-a-heart and see the word “Sent” on the screen above the Event tally. You should now erase the events from the Tel-a-heart by pressing either green arrow for 3 seconds.

Patient Operating Instructions

The Tel-a-heart recorder is ready to use when you receive it from your physician or nurse.

To Hookup:

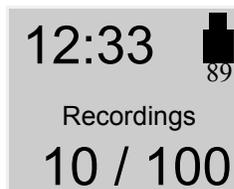
You will want to reapply fresh electrodes daily. To do this, simply snap lead wires into new electrodes first and then apply according to the technician's instructions. We recommend that you do this after bathing or showering as the recorder or electrodes should not get wet.

To Record an event:

If your Tel-a-heart 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 Tel-a-heart 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 10 events out of a possible 100 have been recorded. The battery level appears in the upper right-hand corner of the screen.:



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 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.*

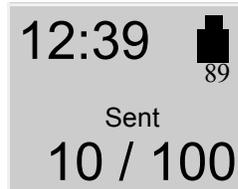
Step 2: Call the receiving center phone number provided by the technician.

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

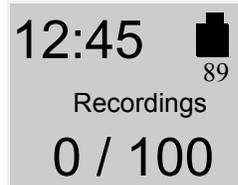
Step 4: When instructed to "send your events", do the following:

1. Press the SEND 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 SEND 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 event 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 Tel-a-heart is functioning appropriately.
- **If the screen is blank**, this means that the Tel-a-heart 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 Tel-a-heart. 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 Tel-a-heart Digital Recorder

Please follow these instructions to care for the Tel-a-heart:

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 products should be disposed of following local ordinances.

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

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.

Appendix B: Batteries for the Tel-a-heart Digital Recorder

The Tel-a-heart 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.

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 batter-

ies 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.

Battery Replacing

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.

Appendix C: To Adjust Settings on the Tel-a-heart Digital Recorder

You should only adjust settings on the Tel-a-heart between patients. To begin, insert a battery to start the recorder.

Once you insert a new battery, the 15-second countdown will begin. To interrupt the 15-second countdown, quickly press SEND, down arrow, up arrow and then RECORD, in that order. You should now see the North-East Monitoring screen. Press SEND 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 SEND to enter. The cursor “>” will appear next to the item that you are able to update. Press SEND to begin updating that item, and then use the green arrows to adjust the value. When finished adjusting a value press SEND 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 SEND.

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 SEND. You can now update Hour, Minutes, Day, Month or Year by moving the cursor with the green arrows and pressing SEND.

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 Record and Send buttons for several seconds in order to prevent false entries, and sounds enabled; or
- Quiet - Sound disabled. No delay.

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, Norwegian, Polish, Portuguese, Russian, Spanish and Turkish.

Diary. When the Diary is turned On and Post Event Seconds is set to 30 or greater, the patient will be able to select a symptom during a manual event,

Event Settings

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

Post Event Sec. The number of seconds saved after the RECORD 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 events may be automatically adjusted by the Tel-a-heart based on the number of seconds saved for each event as well as the number of channels.

When Max Events is set to 0, the recorder can be used for **real-time transmissions** only. No events will be saved on the recorder. Before doing a real-time transmission, you must erase any events that are currently saved north recorder.

Channels. The recorder can record one or two channels. If two channel 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 reminder 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 the maximum number of events have been recorder.
- **Enter Phone Num** - Enter the phone number that the patient should call when events recorded. Use green arrows to update digits. Hold down SEND button to backspace.
- **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 the maximum number of events have been recorder.

Auto Detect Settings

If your event recorder is equipped with auto-detect, it will have the following settings:

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 On. 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 Telaheart 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 an SD Card is greater than what is saved on the desktop, and this is appropriate.

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 on LCD Screen

If you see the time-of -day on the Tel-a-heart screen, the recorder is recording.

Note: *If the LCD screen is completely blank, this means that the Tel-a-heart is not recording.*

An error message will appear when there is a problem with the recorder. The Tel-a-heart 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.

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.

Appendix E: Tel-a-heart Accessories

NEMCA135 - 2-Lead Patient Cable

NEMCA145 - 3-Lead Patient Cable, Adult

NEMCA150 - 3-Lead Patient Cable, AdultXL

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)

Appendix F: Pacemaker Detection with the Tel-a-heart Digital Recorder

The Tel-a-heart recorders have a built-in pacemaker detection capability. This was designed to overcome some of the problem inherent with the analysis of ECG 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 Tel-a-heart 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 ECG recording, the pulse is detected by the recorder. The time of the pulse is then digitally stored along with the 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

Appendix G: EMC Information

Attention should be paid to the following EMC information prior to installing or using the Northeast Monitoring DR200/E Digital Recorder device.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the Northeast Monitoring DR200/E Digital Recorder device.
- The Northeast Monitoring DR200/E Digital Recorder 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 Northeast Monitoring DR200/E Digital Recorder device.

Verify normal operation if utilizing the Northeast Monitoring DR200/E Digital Recorder device adjacent to or stacked with other electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Northeast Monitoring DR200/E Digital Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Northeast Monitoring DR200/E 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 DR200/E 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 DR200/E 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 DR200/E Digital Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Northeast Monitoring DR200/E Digital 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
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 DR200/E Digital 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 DR200/E Digital 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 DR200/E Digital Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Northeast Monitoring DR200/E Digital Recorder should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile communications equipment should be used no closer to any part of the Northeast Monitoring DR200/E Digital Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
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 Northeast Monitoring DR200/E Digital Recorder is used exceeds the applicable RF compliance level above, the Northeast Monitoring DR200/E Digital Recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the Northeast Monitoring DR200/E Digital 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 DR200/E Digital Recorder

The Northeast Monitoring DR200/E Digital Recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the Northeast Monitoring DR200/E Digital Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Northeast Monitoring DR200/E Digital 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.

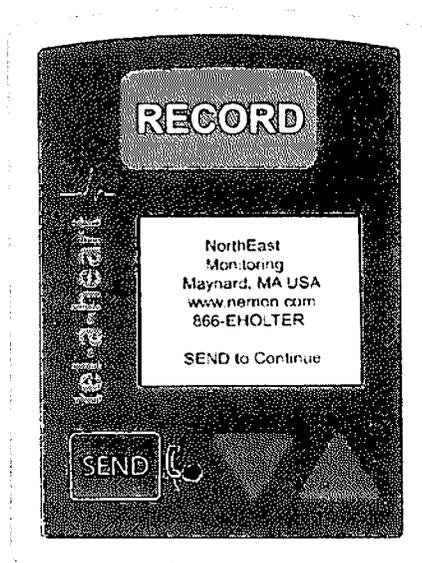
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NorthEast Monitoring, Inc. Tel-a-heart (DR200/E) Digital Event Recorder

Operator's Manual

Approved By: **SLS**

ECO Number: 623



NorthEast Monitoring, Inc.

2 Clock Tower Place, Suite 555
Maynard, MA 01754 U.S.A.
www.nemon.com

phone: [+1] 978-461-3992
fax: [+1] 978-461-5991
toll free U.S.A.: 866-346-5837

August 2012

NorthEast Monitoring, Inc.

Part number NEMM015_Rev_L