DR181 Digital Holter Recorder Operator's Manual

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Part number: NEMM031-Rev-F
Last updated: January 2016
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Chapter 1: Introduction

The NorthEast Monitoring, Inc. DR181 Holter recorder is a Holter monitor designed to facilitate the ambulatory cardiac monitoring, on order of a physician, of those patients 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. Only a trained Holter technician should do patient hookups.

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 DR181 3-channel recording mode is compatible with v5.2 or newer version of Holter LX Analysis. The DR181 in either OxyHolter (this includes analysis for OSA, i.e., Sleep) or the 12-lead mode requires v5.4b or newer version of Holter LX Analysis. SAECG requires additional Predictor® software.

The DR181 Holter recorder is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias and is not for In Vitro diagnostic use.

Physical Specifications

The DR181 Holter Recorder will meet the following physical specifications:

- Size: 12.3 cm (length) x 7.0 cm (width) x 2.4 cm (depth)
- Size: 4-7/8 inches (length) x 2-3/4 inches (width) x 1 inch (depth)
- Weight: 136 g (4.8 oz) without batteries; 184 g (6.5 oz) with batteries

Electrical Specifications

The DR181 Holter Recorder electrical specifications are:

- Recording bandwidth: 0.05 to 70 hertz in 3-channel mode; 0.05 to 150 hertz in 12-lead mode.
- Resolution: 12-bit, 12.50 microvolts/LSB in 3-channel mode12-bit, 6.25 microvolts/LSB in 12-lead mode
- Prefilter sampling rate: 1440 samples/second in 3-channel mode
- Data stored: 180 samples/second. In high resolution mode, signal processing ensures capture of peaks of narrow QRS complexes.
- Pacemaker sensitivity: 2 millivolts
- Pacemaker pulse duration: 100 to 2,000 microseconds

- The degree of protection against electric shock is Type BF

- The recorder has not been tested for use in the presence of a Flammable Anesthetic mixture and, therefore, is not suitable for use in the presence of a Flammable Anesthetic mixture with air or with oxygen or nitrous oxide

- Overall system amplitude accuracy is +/- 5% under all operating conditions

- Timing accuracy is within 5 seconds per 24 hours

This device is not known to be affected by or cause electromagnetic compatibility conflicts with other medical devices. As is always the case, the use of this device in magnetic imaging systems is to be done only with the imaging system manufacturer's instructions due to the ferric components in the device.

Power Supply

The DR181 is powered by two 1.5 volt AA alkaline batteries (MN1500 or the equivalent), or two AA rechargeable NiMH (nickel metal hydride) batteries.

Do not leave the batteries 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.

Environmental Specifications

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

The operating range of the device is between 10 and 45 degrees C, between 10 and 95% humidity, and between 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 recorder has an Ingress Protection Marking of IP22. The solid particle protection is level 2 as the device is protected against objects > 12.5mm, such as fingers or similar objects. The liquid ingression protection is level 2, which meant that vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.

Intended Use

The DR181 Holter recorder is intended to be used for long term ECG and oximetry recordings in formats from 3-CH Holter to continuous 12L formats with the option of replacing 1-CH of the 3-CH recordings with the continuous oximetry recordings.

Indications For Use

1. Detection of Arrhythmias: The DR181 Holter recorder is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.

2. Efficacy of Treatment: The DR181 Holter recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.

3. Pacemaker Evaluation: The DR181 Holter recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.

4. Oxygen: The DR181 Holter recorder is indicated for use for trending of Oxygen Saturation (SpO2) in the blood for periods up to 24 hours. If the device is to be used for home monitoring, periods of activity or excessive movement are to be omitted due to the artifact that would be generated.

5. The DR181 Holter recorder is to be used only on the order of a physician.

Warning Symbols

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

Refer to instruction manual/ booklet. Follow instructions for use.

Type BF device.

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

This product does not contain lead.

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

LCD Display and Keypad

The DR181 has a 13-key keypad on the face of the recorder around a liquid crystal display (LCD). Use the keypad to interact with and program the recorder. The function of each key on the keypad changes depending on the display.

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. Operation with non-approved equipment or cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Patient Leads

The DR181 is compatible with standard silver/ silver-chloride ECG electrodes.The DR181 uses patient cables with either seven leads or five leads for a 3-channel Holter recording, or ten leads for a 3-channel Holter plus 12-lead data. The cable connects to the recorder via a 15-pin female connector on the recorder.

An oximetry lead set with an oximetry sensor replacing the channel 3 leads is also available. The oximetry lead set consists of five leads for a 2-channel Holter recording and a detachable Nonin Medical lead with a pulse oximetry sensor. The cable connects to the recorder via a 15-pin female connector on the recorder.

Patient electrodes should not be applied to anything except the patient. Patient electrodes should be left sterile in their original packaging until use. Follow manufacturer's instruction for use, and discard after use. Dispose of elec-

trodes 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 isopropyl 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.

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 manufacturer's instructions.

Warranty Repairs

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

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

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

Operating the Recorder

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

The DR181 Holter Recorder contains no user-serviceable parts. Removing the label or opening the recorder voids the warranty.

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

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

Online help

In addition to the information in this manual, more information and help 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, the warranty and our software can always be found on our web-site on the "Downloads & Documents" page.

Chapter 2: Recording Holter

Overview

To use the DR181 to record a patient's long-term ECG (Holter), follow the appropriate steps listed below:

Step 1 - Hook up patient;

Step 2 - Prepare the DR181 for recording;

Step 3 - Enter patient ID on recorder;

Step 4 - Review Lead Quality

Step 5 - Start recording.

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

If you have a new flashcard 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. Refer to Initializing a Flashcard later in this chapter.

Step 1: Hook up Patient

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:
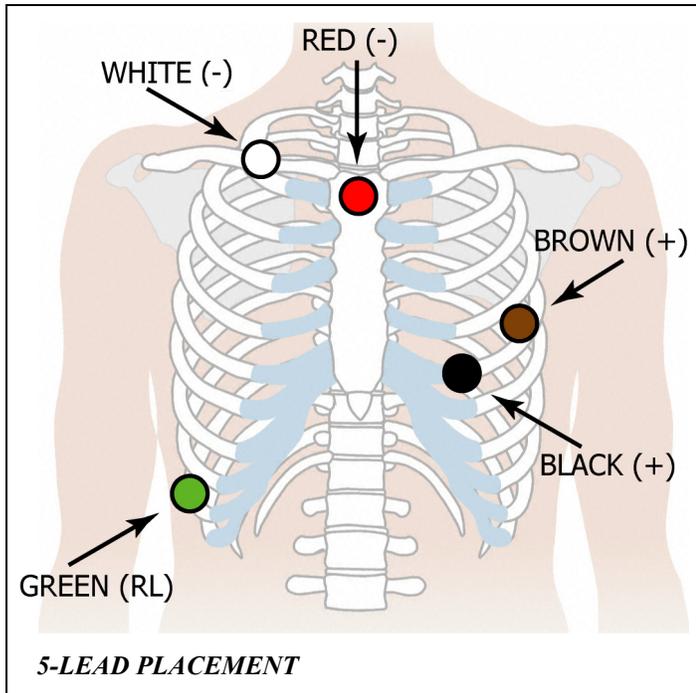
1. Using either the 5-lead (3-channel) or the 7-lead (3-channel) diagram shown below or the 10-electrode (3-channel Holter, 12-lead) diagram on the following page, identify sites for the electrodes. For oximetry patients, use only channels 1 and 2 on the 7-electrode hookup; two channels of Holter data will be recorded, and the oximetry lead will use channel 3.

5-LEAD PLACEMENT

5-LEAD PLACEMENT

Channel 1:
+ Brown   5th rib, left anterior axillary line
- Red   centered on manubrium
Channel 2:
+ Black   5th rib, left of mid-clavicular line
- Red
Channel 3:
+ Black
- White   right manubrium
Ground:
Green   centered over rib

7-LEAD PLACEMENT

Channel 1:
+ Red   5th rib, left anterior axillary line
- White   right manubrium
Channel 2:
+ Brown   2 cm. right of xiphoid process
- Black   left manubrium
Channel 3:
+ Orange   5th rib, left of mid-clavicular line
- Blue   centered on manubrium
Ground:
Green   centered over rib

7-LEAD PLACEMENT
**For Oximetry**, use channels 1 and 2 only
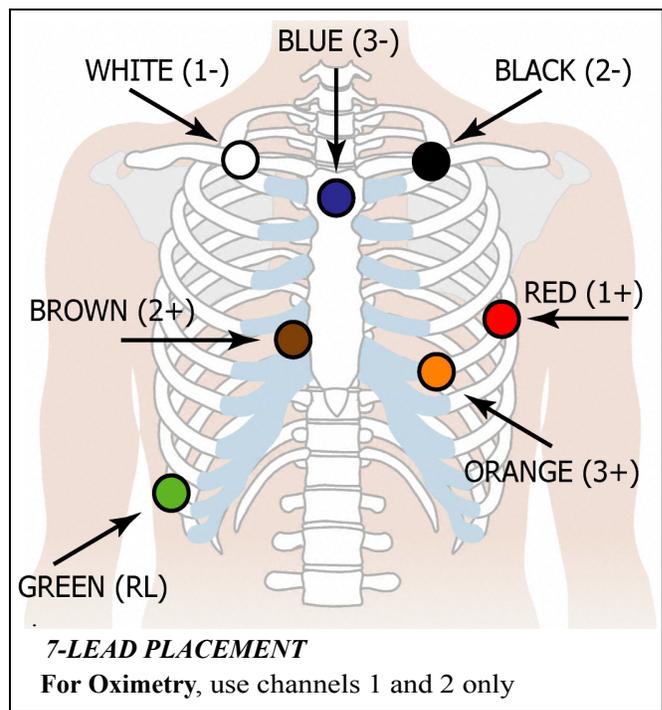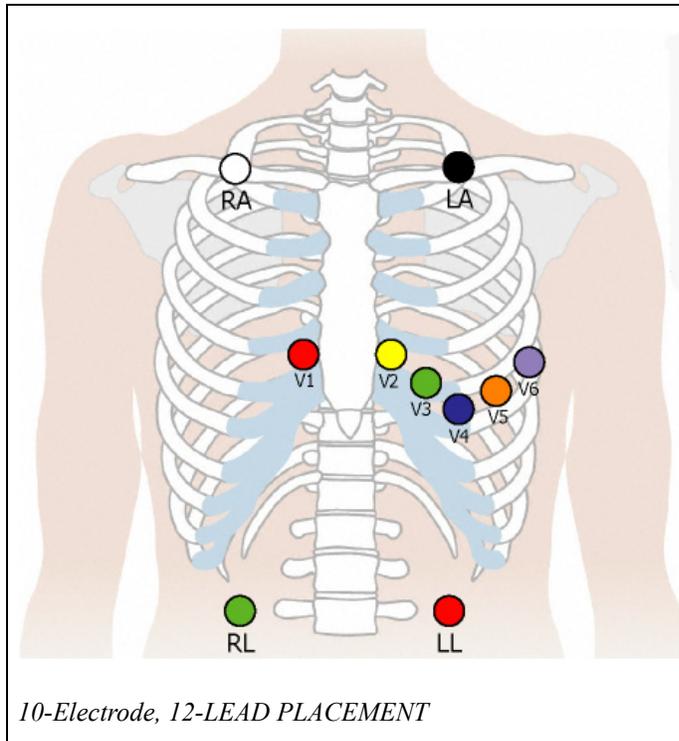
12-LEAD PLACEMENT

RA   right mid-clavicular
LA   left mid-clavicular
RL   right iliac crest
LL   left iliac crest
V1   4th intercostal space, right of sternum
V2   4th intercostal space, left of sternum
V3   between V2 and V4
V4   5th intercostal space, mid-clavicular line
V5   5th intercostal space, mid-clavicular line
V6   5th intercostal space, mid-clavicular line

10-Electrode, 12-LEAD PLACEMENT

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.

    For oximetry patients, determine the site for the sensor. Recommended application sites include the index fingers and toes, with a tissue thickness of 5 to 21 mm.

3. Attach the patient cable to the recorder, then snap a lead wire from the patient cable to each of the electrodes.

4. Attach the electrodes to the patient by securing an electrode at each of the prepared sites. Be sure to refer to the diagrams for correct placement of each colored lead. Where possible, 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.
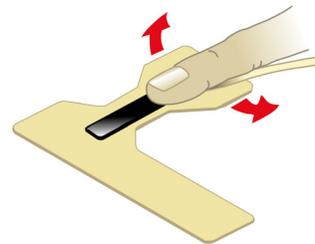
Positioning oximetry sensor on index finger

For oximetry patients, attach the oximetry sensor to the patient. If you use the Nonin Medical sensor wraps, follow the directions on the sensor wrap insert. If you do not use the Nonin Medical sensor wraps, follow the directions on the oximetry sensor insert.

Please note that for paced patients, when oximetry is being recorded, no pacemaker spikes will appear on the Holter recording and no pacemaker analysis will be done.

For oximetry, use 7-lead placement for channels 1 and 2 only.

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.
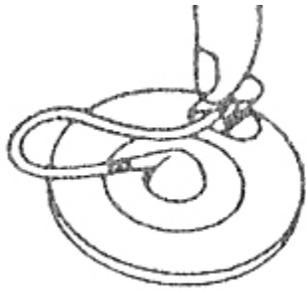
Using a clip lock electrode

Tape   **Electrode**

Stress loop

Step 2: Prepare the Recorder

After connecting the patient to the recorder, follow these steps to start the recording:

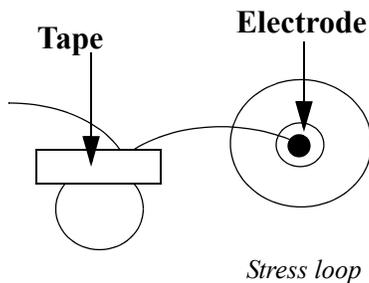**1.** Remove the door from the battery compartment of the DR181, then insert a flashcard into the slot inside the compartment. Hold the flashcard by the edge with the ridge and orient it so that the opposite edge (with the connector) slides in first. The metal connectors should be away from you, and the flashcard label facing you, but upside-down as you slide it into the recorder. It should snap into place.

Note: In order to remove the flashcard, just press down on it and it should pop up.

Note: The flashcard should slide in easily. Make sure you do not force the flashcard in; if you force the flashcard in the wrong way, it can damage the connector inside the recorder.

2. Insert two fresh AA batteries into the battery compartment, being sure to orient them as indicated in the diagram inside the compartment. Replace the door to the battery compartment. After 10 seconds, the following screen will appear on your recorder:
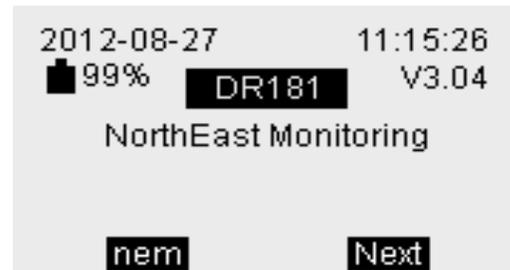
Start-up display

The start-up display includes the current date and time-of-day. Verify they are correct. It also displays the DR181 firmware version.

If, instead of the Start-up display, you see the message, "Erase SD card? Yes/No", the flashcard still has a previous patient's recording on it, and you must erase it first. Press Yes to erase the previous patient's recording. The Start-up display will then appear.

If you get the message NO SD CARD OR FLASH.DAT FILE IN RECORDER, refer to that section later in this chapter.

3. Press Next to display the main menu with these choices:
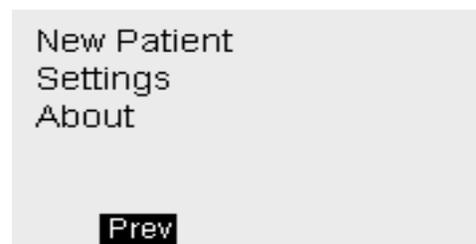
Main menu

Note: For information on Settings, Refer to Appendices A and B.

Step 3: Enter Patient ID

If no settings need to be updated, the next step is to enter the Patient ID. When the recording is complete, this number will help keep track of the identity of the patient whose ECG is recorded on the flashcard.   Press the New Patient button to go to the Patient ID screen:

Patient ID screen with ID number entered

The "x" appears as the cursor. Enter a Patient ID by pressing the keys next to the appropriate digits. Press Delete to backspace and erase the previous digit.   You must enter an ID number for the patient. If you press Next without entering one, an error message appears; press "Prev" and then enter the patient ID number.

Step 4: Lead Quality

After entering the patient ID number, press Next and you will see the lead quality for each cable:.)

Recording mode menu for 3-channel

This screen shows the lead quality and ECG for each channel. A range from 0 - 5 will displayed for each lead. An entry of 4 or 5 is acceptable.

For 12-Lead recording, press the Next button 3 times to review all 12 channels.

For Oximetry recording, you will see channels 1 and 2 and channel 3 will be replaced with the

SPO2 level. If the SPO2 is not attached properly, you will get the error message "No cable" if the entire cable is not connected, or the message "No sensor" if the cable is connected but without a sensor (finger-wrap, clip, etc.). Correct the problem and the SPO2

Step 5: Start Recording

Once you are satisfied with the Lead quality, press the Diary button and recording will begin. You will then see the following screen display for the duration of the recording. The colon will blink to let you know it is recording:


Recording Screen

Instruct the patient on how to indicate symptomatic events during the recording by pressing the Diary button. Details appear in the following section.

Power Loss Protection Feature

During 3-channel and non-continuous 12-lead recording, if the batteries are removed and then reinserted within 60 minutes, the recording will continue. When the batteries are re-inserted, the screen shows a countdown display starting at 5. Once the countdown is complete, the DR181 continues to record the patient's Holter signal on the same file.

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 you want to record a new patient and less than an hour has gone by since you finished your last, the recorder may try to continue recording. If you get the 5-second countdown, but you want to erase the flashcard and begin recording a new patient, you can do this by interrupting the countdown. Do this by pressing the 5-left hand buttons starting at the top. This will allow you to erase the SD card and start a new patient.
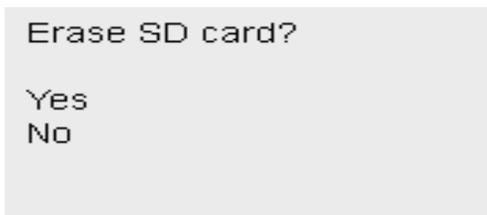
Erase Screen

How Patients use the Diary Button

If you choose, the patient can use the Diary button on the recorder to mark the Holter signal at times the patient feels symptoms or is performing particular activities.

When the patient pushes the Diary button during the recording, the signal is marked with an Event marker and, when the recording is analyzed, the strip with the Event marker is saved during Holter analysis. After pressing the Diary button, the patient can indicate the symptom or activity at that time; when analyzed,

that symptom or activity is saved as the strip label.

To use the Diary button:

Press the Diary button. A list of symptoms and activities appears:
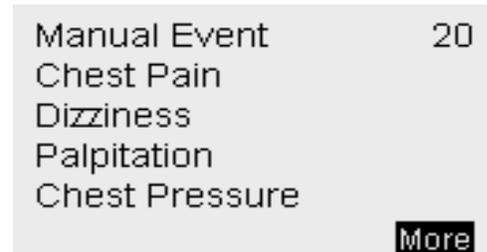
Example List of Diary choices

From the list, the patient should select an option to save the entry. The patient can either select "Manual Event" or select the one that best describes the symptom or activity. To display additional symptoms/activities, press the More button.

A 20-second countdown appears in the upper right-hand section of the screen. For each display, the patient has 20 seconds to select an appropriate option. After 20 seconds, the recorder automatically chooses "Event" as the label.

Once the symptom/activity is selected, the recorder confirms the entry with the message "Diary Saved" the display then returns to the time-of-day.

No Card or Flash.dat File in Recorder

If you see "NO SD CARD OR FLASH.DAT FILE IN RECORDER when you try to start a new Holter recording, one of the following is true: (1) the flashcard is not in the recorder or (2) the flashcard is not formatted properly or (3) the flashcard in the recorder does not have a flash.dat file or (4) or the card may be corrupted.

If a card is properly inserted in the recorder, to use the card, you must make sure that it is formatted properly (as FAT file system, not FAT32) and then erased using NorthEast Monitoring, Inc. Holter LX Software (using Patient > Flashcard > Erase).

Initializing a Flashcard

If you choose to purchase flashcards from a source other than NorthEast Monitoring, the cards must be formatted prior to being used in the recorder. To initialize a flashcard for the first time or to erase the card contents at any time, do the following using your Holter LX Analysis or Remote software opened:

1. Insert the flashcard into the flashcard reader and, from the Holter menu, select File > Flashcard Initialize.

2. When the Flashcard Initialize window appears, the drive where your card appears should be visible. A check will appear if a flash.dat file already exists on the card. If it is not highlighted, click on the drive for the card.

3. Select the appropriate format option for the DR181 Holter recorder and click Erase. (If you have an older version of Holter LX Analysis software, you should choose either of the DR200 / SD360 options and then click the Erase button.) When the erase is complete, the card is ready for use in the DR181.

4. Once the card is initialized, you will see a message "Initialization complete" and 100%. You can remove the card at this time.

Note: If for some reason there is another file on your flashcard, you will get a message "This card contains unknown files..." Click "Yes" to proceed and delete the files. However, you may want to view the flashcard using Explorer before erasing the files in question

Storage Capacity

The patient's Holter data is stored on a removable flashcard. To store 24 hours at either normal or high resolution, the minimum capacity of the flashcard should be 52 megabytes. Although 48 hours of 3-channel Holter signal might fit in 32 megabytes, we recommend that you use 64-megabyte flashcards instead. Flashcards of up to 2 GB can be used.

Battery Life

A single pair of AA alkaline batteries, MN1500 or the equivalent, can be expected to last 7 days for 3-channel and 12-lead Holter recording, and 48 hours for OxyHolter recording. We recommend that new batteries be used for each new recording.

Memory Requirements

The following table lists the memory requirements for recording in different modes and criteria for a 24 hour period.

Recording mode	12-lead strips saved and sampling rate	Memory required Normal Resolution	Memory required High Resolution
3 channel or oximetry	n/a	26 MB	52 MB
12-lead	3 sec every 180 at 720 s/s.	35 MB	61 MB
12-lead	3 sec every 18 at 720s/s	119 MB	145 MB
12-lead	10 sec every 60 at 720s/s	119 MB	145 MB
12-lead	continuous at 720s/s	585 MB	611 MB
12-lead	3 sec every 180 at 1440s/s	45 MB	71 MB
12-lead	3 sec every 18 at 1440s/s	212 MB	238 MB
12-lead	10 sec every 60 at 1440s/s	212 MB	238 MB
12-lead	continuous at 1440s/s	1145 MB	1171MB

Memory Requirements for 24 hours of recording

Appendix A: Adjust Settings

Change the Time and Date

Change the Time. To change the time or the date on the recorder, select Time and Date from the Settings menu. You will be taken to the Time menu. Here you can update either the hours or minutes by pressing the button to the left.
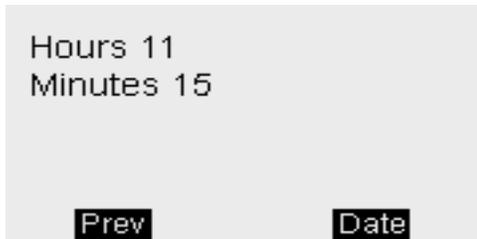
Time entry display

For hours, entries from 00-23 are acceptable. To update, you can simply press the Delete button twice to zero out and then enter the two-digit entry of your choice. Once complete, press the Enter button to save and return to the previous menu.
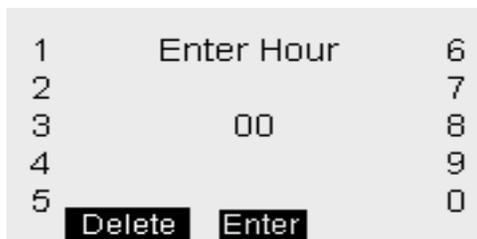
Hour update display

The minutes screen works similarly to the hours, except that 00-59 are the acceptable range.

Change the Date. To change the date, press the Date button that is available from the Time entry display. You will see the current Day, Month and Year displayed, and can choose which you want to update by pressing the button next to the entry.

Date entry display

A screen similar the Hour Update pictured to the right will become available for updating the date values.   To return to the Settings menu, press Prev, to update the Time, press the Time button.

Change the Language

To change the language used on the recorder, select Language from the Settings menu. The following languages are displayed first:

Language selection menu

The language that is currently in use is marked by the arrow ">" next to it. Select a new language from the list by pressing the key next to it. or press More to see more options. To continue, press the Prev button to return to the settings menu.

Invert the Display

The DR181 displays the date and time-of-day oriented so that the figures are right-side up when the patient cable connector is at the right-hand end. If, when you hook up the patient, you would prefer to have the display oriented so that right-side up is with the connector to the left, you can do so. This makes the figures right-side up when the patient looks down at the recorder.

To invert the display, select Display from the Settings menu. The LCD confirms the change. Once the recording starts, the screen displays the opposite way.

```
>Normal display
 Invert display




    Prev
```
Display menu

Lock or Unlock Settings

If you always select the same Recording mode and Settings when hooking up patients, you can lock the settings so that there is no possibility that the wrong selection will be made during hookup. Do this by selecting Lock Settings and see that the arrow is next to the current choice. In order to lock or unlock the settings, press the button next to your choice and it will be identified with the arrow ">".".
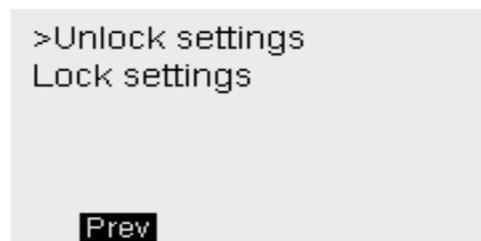
```
>Unlock settings
 Lock settings




    Prev
```
Lock settings menu

Now press the Prev key to display the settings menu and Prev again to return to the main menu.

Press More at the bottom of the first Settings screen to see more options. From the Settings menu, select More and you will see the Contrast and General Settings and,

if your recorder is configured, the optional 12-Lead and SAECG Settings.
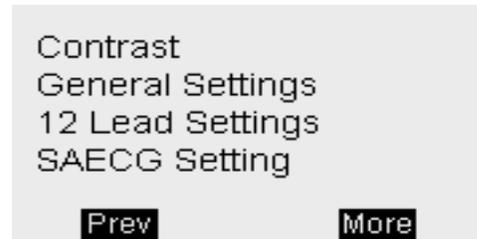
```
Contrast
General Settings
12 Lead Settings
SAECG Setting

  Prev            More
```
More Settings

Contrast

Adjust the LCD screen contrast to your liking by entering a number between 35 and 63. On some recorders the screen is not adjustable.

General Settings

From General Settings, you can select from Resolution, Mark Diaries or select a different Record Type.
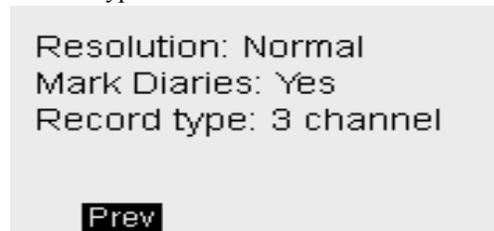
```
Resolution: Normal
Mark Diaries: Yes
Record type: 3 channel


  Prev
```
General Settings

Resolution

Choose from High and Normal resolution.

A 3-channel Holter recording in Normal resolution will be stored at 180 samples/second

A 3-channel Holter recording in High resolution will record higher slew rate, allowing for more accurate rendition of narrow QRS complexes.

Mark Diaries

If Mark Diaries is set to "Yes", the ECG will be labeled with one second of 6-cycle square wave where the event took place.

If Mark events is set to "No", the events will still be saved and visible, but there will be no identifier directly on the ECG.

Record Type

The DR181 has up to 4 Recording types to choose from. Your menu may look as follows, but not all recording types are available on all recorders:

Recording Type menu

- 3 channel - Standard with all recorders.
- 12-Lead - optional.
- SAECG - optional.
- Oximetry - An oximetry cable is required to record oximetry data.

SAECG Setting

Enter the number of minutes for SAECG recording. When this time is complete, the recorder will continue to record in 3-lead only.

About

The About item in the menu displays the serial number of your DR181 Holter recorder, the customer code, use count and the build and version numbers of the software on the recorder.

Appendix B: Maintenance and Care of Recorder

Please follow these instructions to care for the DR181:

Clean the outside of the recorder with a damp soft cloth. DO NOT use any abrasive cleaners, such as acetone, on the outside of the recorder.

Do not remove the cable from the recorder after each use.

Do not wrap the lead wires tightly around the recorder after each use.

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

Do not pull on or stretch the cables when cleaning them or when hooking up a patient.

Do not submerge the recorder or its cables in water.

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

In cases of infection control, refer to your infection control department. Sani-Cloth germicidal surface wipes are recommended.

Do not store the recorder at temperatures below 45 degrees F or above 100 degrees F (between 5 and 45 degrees C).

Appendix C: 12-Lead Settings

If your Holter includes 12-lead, there is an option on your menu labeled "12-Lead Settings. If you have the 12-lead option and choose the 10-electrode hookup, standard 3-channel Holter signal is recorded, along with 12-lead data. For the Holter signal, channel 1 uses the V5 (+) and RA (-) electrodes; channel 2 uses V1 (+) and LA (-); channel 3 uses LL (+) and LA (-). There are three 12-Lead Settings that you can change: Interval, Length and Sample rate.

```
12 lead recording
Interval  60
Length  3
Sample rate 720

      Prev
```

12-Lead settings menu

Interval

The Interval setting indicates how often 12-lead data is saved. One sample is saved after the number of seconds set here; the setting indicates the number of seconds between the beginnings of sequential recordings.

```
1   Interval between   6
2      recordings      7
3          60          8
4                      9
5   Delete     Enter   0
```

12-lead Interval

A default setting of 60 seconds is recommended. Any entry between 15 and 300 is accepted. To update, just Delete the current entry and press the number buttons of your new choice.

Length

The Length setting shows the length (in seconds) of each 12-lead stripA default of 3 seconds has been selected. Any entry between 3 and 60 seconds is accepted. To update, just Delete the current entry and press the buttons of your new choice. .

```
1   Interval length    6
2                      7
3          3           8
4                      9
5   Delete     Enter   0
```
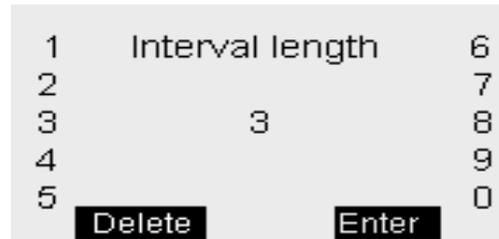
12-lead Length

Continuous 12-lead

Continuous 12-lead recording is for research purposes only. To record continuously, set either the 12-lead Length or 12-lead Interval to zero "0".

Sample Rate

This refers to the sampling rate for the 12-lead strips. Sampling rates (samples/second) of 720 and 1440 are the choices. Each choice directly affects the highest frequency recorded and the amount of memory used.

Appendix D: Batteries

The recorder uses two 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 Medal Hydride (example: MAHA AA 1800 mAh, Rayovac 1600 mAh NiMH)

Alkaline

The alkaline is the most common type of battery. When a new properly stored battery is used, a recording time of at least 90 hours can be expected. With this type of battery a recording time of 24 or 48 hours can be reliably obtained. While a recording that runs for 24 hours will in theory use slightly less than half the capacity of the battery, using a battery for two 24-hour recordings is not recommended. The risk of the first recording being slightly in excess of 24 hours will lead to frequent "second" recordings that do 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. When it is inserted into the recorder, the recorder does an evaluation of the capacity of the battery and indicates that on the display. 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 (50-90F) 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; 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 24 hours when they are new but after only a few uses may not be able to operate for the full 24 hours.

Charging these batteries is the most difficult part of their use. Only chargers that are specifically rated for use with NiMH batteries should be used such as the MAHA MH-204F or Rayovac 1-Hour charger. 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 24 hours 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

Nickel cadmium batteries do not have enough capacity to reliably run the recorder for 24 hours and are not recommended.

Appendix E: Pacemaker Detection

The recorder has 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 2000 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 DR181 Holter 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. The two channels of pacemaker detection in 3-channel recording are Lead 1+ and Lead 1- and Lead 2+ and Lead 1-. In 12-lead recording, the two channels of pacemaker detection are V5 and RA; and V1 an RA.

As pacemakers are normally programed to a pulse width greater than 150 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. There are however occasional cases where the size of the pulse is marginal. To insure that the pacemaker is being detected, the detection is shown as a vertical line on the display of the ECG during the recorder setup. If the patient is frequently paced, the recorder's detection can be verified. In the infrequent cases that pace pulses are being missed, moving one of the listed electrodes will usually solve the problem.

Please note that when Oximetry is being recorded, no pacemaker spikes will appear on the Holter recording and no pacemaker analysis will be done.

Appendix F: Processing Continuous 12-lead Data

Recordings made using any 12-lead continuous mode require additional processing of the data to use it in the Holter LX system. It is also possible to convert the data into a form that can be used for analysis by another application. Doing the conversion uses a number of command-line utilities, so a knowledge of the operating system directory structures and command-line operations is required.

The options for processing are: (1) to have the Holter LX program convert the data into separate 3-second strips or (2) to use separate utilities to convert the data into files for analysis by other methods.

To convert the continuous data into separate 3-second strips, a setting in the "Research settings" window must be accessed. For instructions about accessing the Research settings window, contact NorthEast Monitoring's Technical Support for assistance.

In the Research settings window, the Continuous Interval field should be set to the time desired between the start of the 3-second strips. The value entered must be 3 seconds or greater. When analysis is then started, the system will generate a 3-second strip of a 12-lead presentation at the interval selected.

If the Length and Interval settings in 12L continuous are not set to zero during the recording, then the time at the start of each strip saved will be measured from the beginning of each recording period. That means that if the recording was originally made with a length of 10 seconds every minute, and for analysis you set Continuous Interval to 4, a strip will be saved (1) at the beginning of each 10-second interval, (2) at 4 seconds into the interval.

Conversion Options for all Modes

All recordings made using the 12-lead continuous mode can be converted to binary files for use by other applications. All converted files are in the form of 16-bit binary samples or 2 bytes per sample with the least significant byte first. The data are right-justified in the data

word, and scaling is such that a count of one least significant bit corresponds to an input value of 6.25 microvolts.

The utilities available for data format conversion are "procfl.exe" and "conhires.exe", and are in the bin directory of the Holter LX installation, which is usually c:\nm\bin. The procfl.exe program converts the data on the compact flashcard to a set of files that can then be used by conhires.exe to generate the final binary files. Both programs display their instructions from the command line in the bin directory. From the command line, type either: **"procfl -?"** or "**conhires**" and then press the Enter key.

Using \nm\bin\procfl

The call uses the format:

> **procfl [-ooptions] [-bbase_path]**
> **[-fflash_path] [-mmax_hours]**
> **[-eEGM_sample_offset]**
> **[-l12_lead_interval_period]**

Options is the sum of:

- 4 - output debug information
- 8 - convert all ECG data directly to a data-card.dat file (in place of flashcx.dat file); **this must always be used**
- 16 - output EMG files in 8-bit format; this should not be used with option 1
- 32 - output add_datacard debug
- 64 - output recorder debug file

Base_path is the path to be used for all files unless the flash_path is specified.

Flash_path is to be used as the path only for the flash.dat input file. Flash.dat will be copied to base_path if base_path !=flash_path.

Max_hours is the maximum number of hours to be converted (50 is used if this is not specified). Use 0 for cleric file only.

EGM_sample_offset is the number of samples added to the time of the EGM data for time alignment.

12_lead_interval_period is the time in seconds between simulated 12-lead records made from continuous 12-lead data (using 12-lead modes only).

Using \nm\bin\conhires

Use call uses the format:

> **conhires mode outfiles-path infile-path**

Mode choices include:

- 0 - to generate 9 files of 16-bit binary data corresponding to the 9 patient leads
- 1 - to generate 12 files of standard 12-lead format in 16-bit binary format (only valid for modes 13, 16, 19)
- 2 - to generate 1 file of standard 12-lead format in 16-bit binary records of 12 words per sample
- +8 - all modes to output in ASCII format

Conhires converts the hires.dat file from procfl to separate files for further processing. The input is hires.dat and the output is n files each of 16-bit samples reconstructed from the sequential channel in hires.dat. Paced markers are indicated by a data value replaced by 0x8000. Time values are inserted in the data as 32-bit times, starting as 0 at the beginning of the dataset. The time resolution is 1/320 seconds. The time value is preceded by the value 0x8001.

Processing Procedure

Normal use of the programs procfl and conhires would consist of running them in sequence, like this:

- procfl -ff: -btmp - 08
- conhires mode tmp

In those commands:

> **F:** is the drive that the compact flashcard is in or is the full path (including "flash.dat") to the flash.dat file if that file has been copied from the compact flashcard to another location.
>
> **Tmp** is the path of a temporary directory for the scratch files and the final files. Note

that if processing is being done as a part of the Holter LX system, it is possible to leave these files in the normal patient directories (normally in the form \nm\pat\xx, where xx is the number of the patient directory).

Mode In mode 0, files of the form of hireschX.dat where X is 0 through (channels recorded - 1) for the recording channels 1 through channels recorded. Each file is in the form of 16-bit values with one sample per value. Each file is a separate channel.

Each channel represents the signal at the respective lead relative to the right arm lead (RA). To output these files in a 12-lead format instead, set Mode to 1; this generates a sequence of files of the form hiresch0.dat to hiresch11.dat. There will be a separate file for each of the 12 leads in the same format described for mode 0.

The file correspondence appears in this table:

Hires file correspondence to leads

File	Lead mode 0	Lead mode 1
hiresch0.dat	V5	1
hiresch1.dat	RA	2
hiresch2.dat	V1	3
hiresch3.dat	LA	aVR
hiresch4.dat	LL	aVL
hiresch5.dat	V2	aVF
hiresch6.dat	V6	V1
hiresch7.dat	V4	V2
hiresch8.dat	V3	V3
hiresch9.dat		V4
hiresch10.dat		V5
hiresch11.dat		V6

Appendix G: Extraction of ECG data on 3-channel

It is possible to retrieve the raw ECG files from the DR181 files. For all 3-channel data the process results in three files, one for each channel. Each file is then in the form of a binary file consisting of 16-bit words (little endian) with each word representing one sample. The sampling is at 180 samples per second. The data is scaled so that the least significant bit has a value of 12.5 uv. If a pacemaker pulse was detected, the sample at the time of detection will be replaced by the value 0x8000.

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

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

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

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

unpackdc d1 f1 f2 f3 0

- where d1 is the path to the source datacard file, for example,

  d1= c:\nm\pat\xx\datacard.dat

- f1, f2 and f3 are the resultant binary destination files, for example:

  f1 = c:\nm\pat\xx\flashc0.dat

  f2 = c:\nm\pat\xx\flashc1.dat

  f3 = c:\nm\pat\xx\flashc2.dat

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

Appendix H: EMC Information

Attention should be paid to the following EMC information prior to installing or using the Northeast Monitoring DR200/HE or DR300 Digital Recorder device.

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Northeast Monitoring DR181 Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Northeast Monitoring DR181 Holter 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 DR181 Holter 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 DR181 Holter 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 DR181 Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable. No cables exceed 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable. Northeast Monitoring DR181 Holter 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 DR181 Holter 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 DR181 Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the recorder should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile communications equipment should be used no closer to any part of the Northeast Monitoring DR181 Holter Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$ **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 recorder is used exceeds the applicable RF compliance level above, the recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or recorder			
b Over frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Northeast Monitoring DR181 Holter Recorder

The Northeast Monitoring DR181 Holter Recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the recorder as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

Appendix I: Test Issues

The DR181 has passed all tests, however, two issues that do not affect device performance were discovered while testing. These issues will be corrected in a subsequent release:

1. For 12-lead recording with a 1440 sampling rate, the user must press the Record button to ensure that recording begins appropriately. The user should not allow for the 10-minute delay start-up to occur in this mode.

2. When the battery capacity falls below 2.0 volts, or 0%, the recorder will read "Low Battery" for about an hour. However, this is not the case as once the "Low Battery" message is on the screen, the recorder has stopped recording.

Appendix J: DR181 Accessories

NEMCA130 - 5-Lead Shielded Patient Cable

NEMCA132 - 5-Lead Shielded Patient Cable, Pediatric

NEMCA131 - 7-Lead Shielded Patient Cable

NEMCA124 - 12-Lead Patient Cable

NEMCA152 - Dual Piece Oxy Cable

NEMCA120 - Single Piece Oxy Cable

NEMH141 - Battery Door Cover

NEMH77 - Recorder Pouch and Straps

NEMH85 - OxyHolter Pouch and Straps

NEMH81 - Recorder Shoulder Strap

NEMH106 - Recorder Waist Strap

NEMK138- DR181 5-Lead Hook-up Kit

NEMK139 - DR181 7-Lead Hook-up Kit

NEMK140 - DR181 12-Lead Hook-up Kit

NEMP00411 - Memory - SD Flashcard

NEMP00267 - Nonin Sensor Finger-Clip Probe (includes Flex-wrap pkg - 25)

NEMP00269 - Nonin Flex-wrap pkg - 25

NEMP00368 - Nonin Flex-wrap (infant) pkg - 25

NEMP00344 - Nonin Sensor Finger-Clip Probe

NEMP00345 - Nonin Ear-Clip Probe

NEMP00384 - Nonin Forehead Sensor