

NorthEast Monitoring, Inc. DR181 Digital Holter Recorder

Operator's Manual



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The DR181 Digital Recorder Operator's Manual

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

Note: For In Vitro Diagnostic Use

The NorthEast Monitoring, Inc. DR181 digital 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.

Note: The DR181 is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

NorthEast Monitoring, Inc. is an FDA Registered Facility (1224919) that follows all FDA CGMP Manufacturing Practices. The DR181 Digital Recorder has FDA 510K Product Classification (K001288 and K004007) and meets the AAMI EC-11/EC-38 standard for frequency response, amplitude accuracy and timing accuracy.

Physical Specifications

The DR181 Digital Recorder meets the following physical specifications:

- 12.3 cm (length) x 7.0 cm (width) x 2.4 cm (depth)
- 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

- 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 mode; 12-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 Anaesthetic mixture and, therefore, is not suitable for use in the presence of a Flammable Anaesthetic 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.

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 DR181 recorder is rated IPX0 and is not for use in wet environments.

Warning Symbols

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



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

Type BF Equipment



Repairing the Recorder

Should the DR181 fail to work properly during its useful life, contact NorthEast Monitoring, Inc. at 866-346-5837 (866-EHOLTER) to arrange for repair and/or replacement. There are no user-serviceable parts.

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

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

Operator Interface

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.

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.

Note: *Please be sure to not pull on or stretch the patient cables when you clean them or attach them to the recorder or the patient. This can cause premature failure of the cable.*

Record with the DR181

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 - Start recording.

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

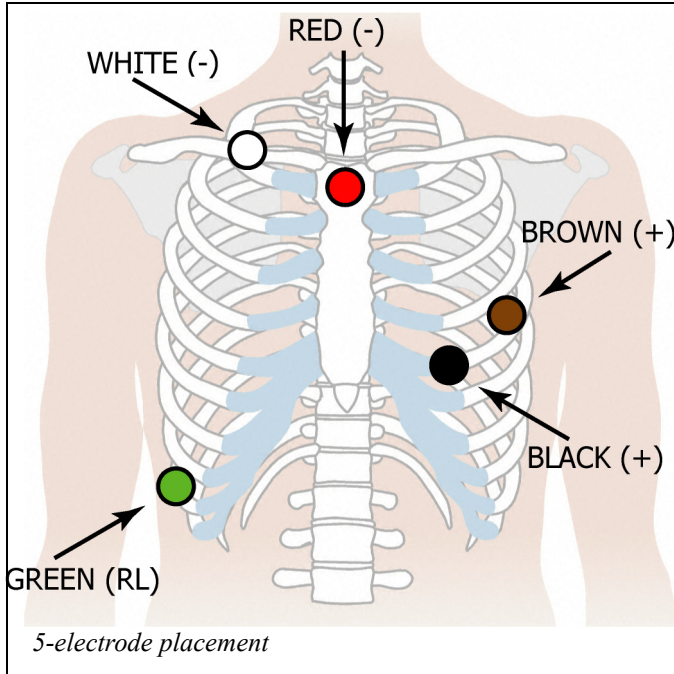
If you have a new SD Flashcard that has not been formatted with a flash.dat file, you will need to use your NorthEast Monitoring, Inc. Holter LX Analysis software to initialize the card for the first time. Refer to Formatting a New Flashcard later in this chapter.

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

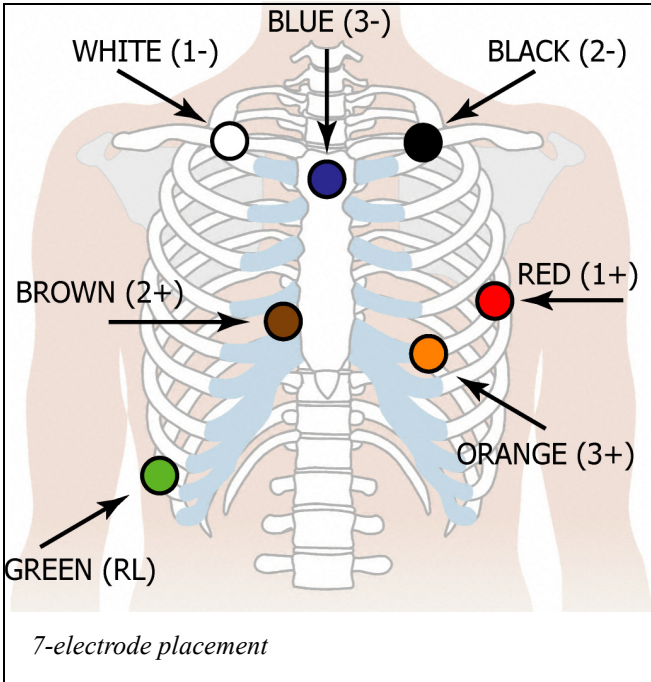
To ensure proper hookup, follow these steps:

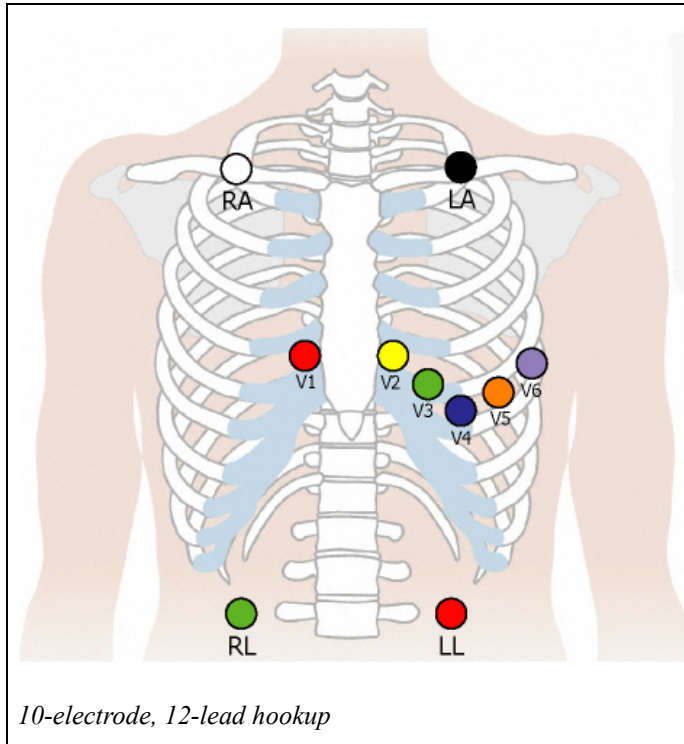
- Using either the 5-electrode (3-channel) or the 7-electrode (3-channel) diagram shown below or the 10-electrode (3-channel Holter, 12-lead) diagram on the following page, identify sites for the electrodes. For oximetry patients, use only channels 1 and 2 on the 7-electrode hookup; two channels of Holter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



5-electrode 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-electrode 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



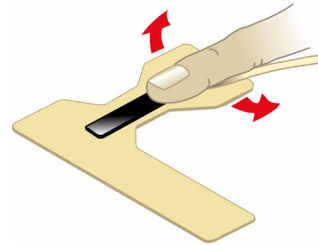


RAright mid-clavicular
LAleft mid-clavicular
RLright iliac crest
LLleft iliac crest
V14th intercostal space, right of sternum
V24th intercostal space, left of sternum
V3between V2 and V4
V45th intercostal space, mid-clavicular line
V55th intercostal space, mid-clavicular line
V65th intercostal space, mid-clavicular line

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. 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.

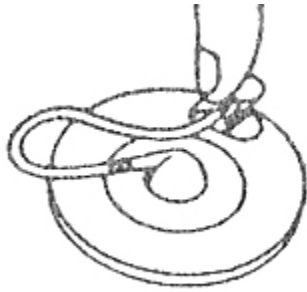


Positioning oximetry sensor on index finger

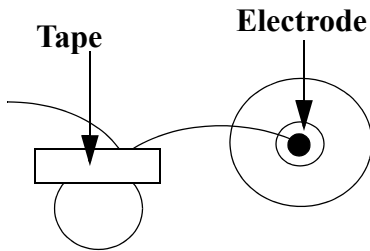
For oximetry patients, attach the oximetry sensor to the patient. If you use the Nonin Medical sensor wraps, follow the directions on the sensor wrap insert. If you do not use the Nonin Medical sensor wraps, follow the directions on the oximetry sensor insert.

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.

- 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



Stress loop

Step 2: Prepare the Recorder

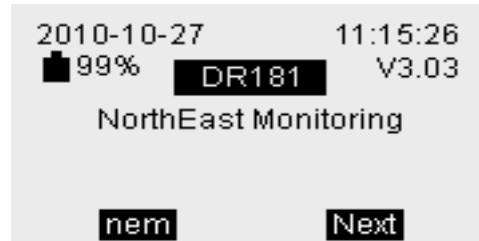
After connecting the patient to the recorder, follow these steps to start the recording:

- 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.

- 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:



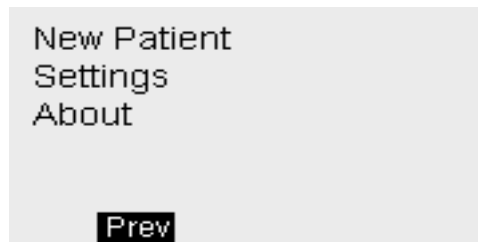
Start-up display

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.

- Press Next to display the main menu with these choices:



Main menu

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 without 12-lead

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 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 Record 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

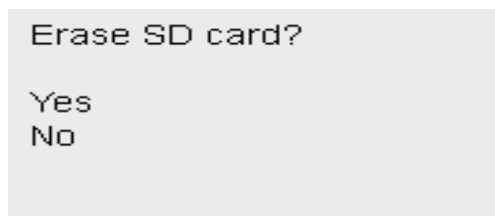
Instruct the patient on how to indicate symptomatic events during the recording by pressing the Diary button. Details appear in the following section.

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

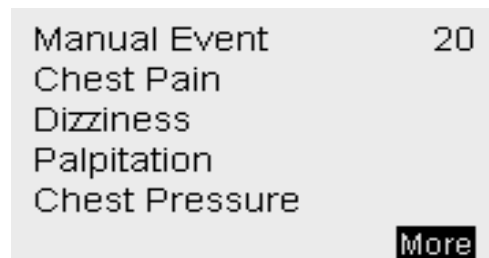
How Patients use the Diary Button

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 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).

Erasing a Flashcard

To erase a flashcard using the Holter LX Software:

1. Insert the flashcard into the flashcard reader and, from the Holter menu, select File > Flashcard > Erase.
2. When the Flashcard Erase window appears, highlight the Standard selection and then click the Erase button.
3. Respond Yes to the query that appears in the Confirmation window. When the procedure is complete, the message “PC card may be removed” appears. Do not remove the flashcard until you see that message.

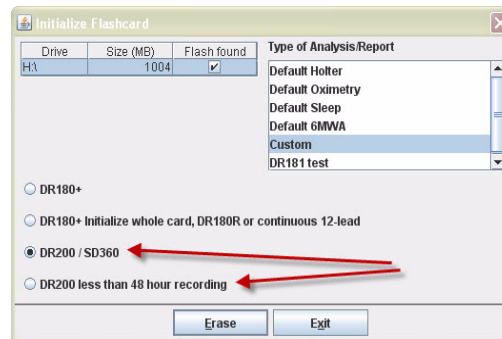
Note: If other files are present on the flashcard, they must be removed (either deleted or moved using Explorer) before you can erase the card for use in the DR181 Digital Recorder. This may include a bootex.log file of 0 length that is installed by Windows XP if the flashcard is in your computer’s flashcard reader when the computer boots up. We recommend that you not leave flashcards inserted in the reader when you turn your computer on.

Formatting a New Flashcard

If you choose to purchase flashcards from a source other than NorthEast Monitoring, Inc., the cards must be formatted for use in the DR181 Digital Recorders. This is a two-step process that includes (1) formatting and (2) establishing the flash.dat file.

To format the flashcard, insert it in the card reader attached to your computer system, and then select My Computer. In the My Computer window, click on the icon designating your flashcard reader, then select File > Format. When the window opens, set the File system to FAT (not FAT32), then click Start. Click Close when formatting is complete.

To establish a blank flash.dat file on the flashcard, insert the flashcard in the card reader attached to your computer system, then launch the Holter LX Software. Then select Patient > Flashcard > Erase. In the Flashcard erase window, highlight either of the DR200 / SD360 choices and then click the Erase button. When the erase is complete, the card is ready for use in the DR181.



Initialize Flashcard

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
microvolt	n/a	445 MB	471 MB

Memory Requirements for 24 hours of recording

Maintenance and Care of the DR181 Digital 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).

Warranty Repairs

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

NorthEast Monitoring, Inc.

Two Clock Tower Place, Suite 555

Maynard, MA 01754

866-346-5837 extension 3

service@nemon.com

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

The DR181 contains no user-serviceable parts.

Removing the label or opening the recorder voids the warranty.

Warranty Repairs

Appendix A: Batteries for the DR181 Digital Recorder

The DR181 recorders use 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 Metal 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 B: Pacemaker Detection with the DR181 Digital Recorder

The DR181 recorders have a built-in pacemaker detection capability. This was designed to overcome some of the problem inherent with the analysis of Holter recordings from patients with pacemakers.

A pacemaker is designed to initiate cardiac conduction by stimulating a spot on the myocardium with a pulse of 1-4 volts and a duration of typically 250 to 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 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 and RA.

As pacemakers are normally programmed 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 C: Adjust Settings

Change the Time and Date

Changing 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.

Changing 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 Inverted from the Settings menu. The LCD confirms the change. Once the recording starts, the screen displays the opposite way.



Invert 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 “>”.



Mode lock menu

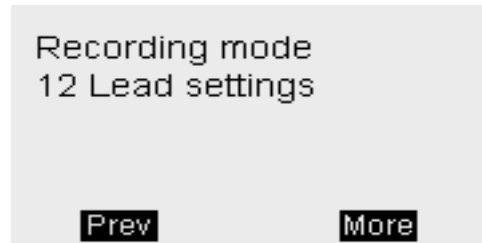
Now press the Prev key to display the settings menu and Prev again to return to the main menu.

Press More at the bottom of the first Settings screen to see more options.

General Settings

From the Settings menu, select More and you will see the General Settings and the optional 12-Lead Settings.

From General Settings, you can select Resolution, Mark Diaries or select a new Recording Type:



Recording Mode 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.

Recording 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. 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 (-).
- Microvolt - optional.
- Oxymetry - Oximetry cable is required to record oxymetry data.

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 D: 12-Lead Settings

If your Holter includes 12-lead, there is an option on your menu labeled “12-Lead Settings”. There are three 12-Lead Settings that you can change: Interval, Length and Sample rate.



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.



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 strip. A default of 3 seconds



12-lead Length

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.

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 E: Processing Data Collected in Continuous 12-lead

Recording 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 the toll-free NorthEast Monitoring, Inc. support line at 866-346-5837 option 1.

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,” usually in the \nm\bin directory of the Holter LX installation. 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 nm\bin directory. From the command line, type either: **procfl ?** or **conhires** and then press the Enter key.

Using \nm\bin\procf1

The call uses the format:

```
procf1 [-ooptions] [-bbase_path]
[-fflash_path] [-mmax_hours]
[-eEGM_sample_offset]
[-I12_lead_interval_period]
```

Options is the sum of:

- 4 - output debug information
- 8 - convert all ECG data directly to a datacard.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 outfile-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 procf1 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 files' correspondence to leads

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

Appendix F: 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

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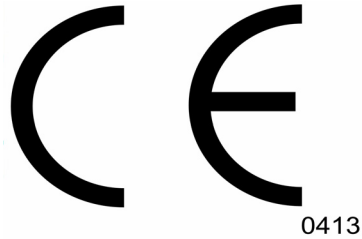
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