

OPERATOR'S

MANUAL

FOR

DMS 300-4A

HOLTER ECG RECORDER

WARNING

**Only a physician can order
a Holter ECG test.**

WARNING

**Only the ordering physician
can decide on the application
technique used for affixing
electrodes to the patient's body.**

WARNING

**Only the ordering physician
can determine the length of
time for a Holter ECG recording.**

WARNING

**Do not modify or alter electrode
Lead Wires for any reasons.**

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DMS 300-4A Holter ECG Recorder



Description of Device

The DMS 300-4A recorders can record a continuous Holter ECG for a period of time of up to six (6) days.

The read-in sample rate is 1,024 samples per second. The memory is 512 MB. The memory is built onto the recorder's circuit board.

The recorder is both a 12-Lead and 3-Lead ECG recording device. It is a miniature device with a weight of two (2) ounces. The miniature dimensions are 3.1 x 2.2 x .75 inches.

The recorder is powered by a single AAA battery.

The recorder permits a selection of one of two ECG Cables. One ECG Cable is a 4-electrode cable with Lead Wires of 60 cm in length. The second ECG Cable is a 10-electrode cable with Lead Wires of 110 cm in length.

There are two (2) other cables that are used with the recorder. There is a Download Cable that transfers the Holter ECG file from the 300-4A to the hard disk of the Holter Software PC. There is a Patient Isolation Cable that allows the real-time ECG from the recorder to be displayed on a PC.

The first 10-minutes of the recording is a high resolution ECG recording at 1,024 samples per second for each of the ECG channels.

Indications for Use

Per USA FDA 510(k) Number: K062959

Dated 16 October 2006

DMS 300-4 Holter ECG Recorders

Regulation Number: 21 CFR 870.2800

Regulatory Class: Class II

Product Code: 74 MWJ

Indications for Use:

The “Indications for Use” of the modified DMS 300-4 recorder is indicated for use in a clinical setting, by qualified medical professionals only, for recording multi-lead ECG data of patients during a minimum ambulatory time period of 24-hours.

It is not a life-supporting system, and is not connected to an AC power source.

The “intended uses” of the modified DMS 300-4 is exactly the same as the predicate devices (DMS 300-7 and 300 ECG recorders). Ambulatory multi-day electrocardiography is used for the below indications:

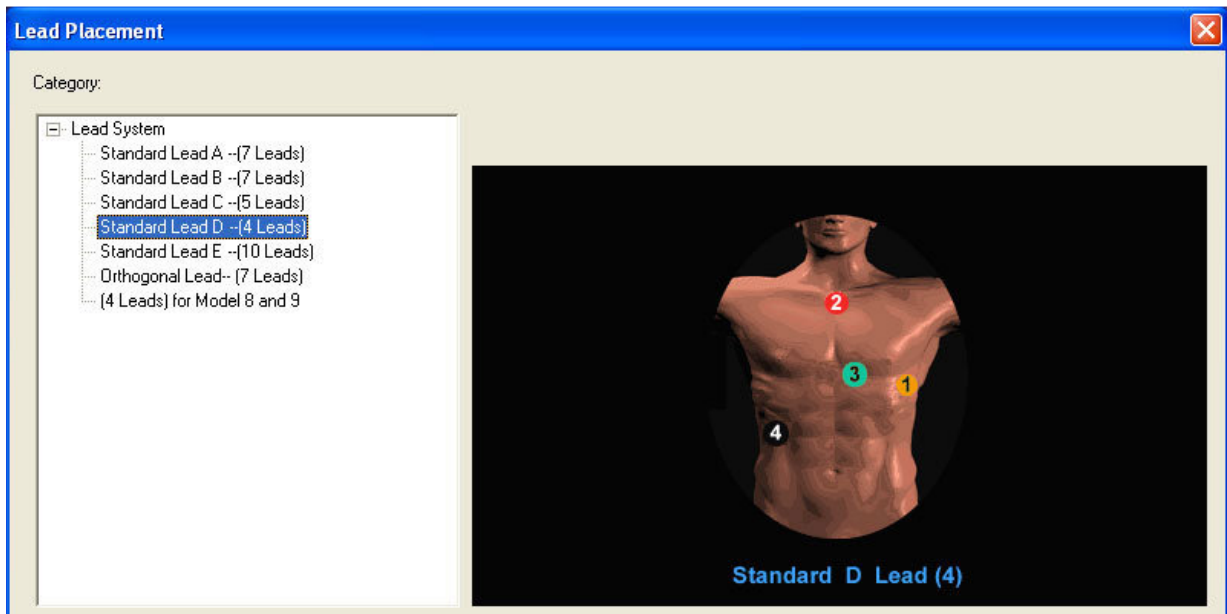
- Evaluation of patients with symptoms suggesting arrhythmias.
- Evaluation of patients with pacemakers.
- Evaluation of patient heart rate changes and QRS interval changes.
- Evaluation of patient responses to drug therapy treatment.

Patient Electrode Hook-Up Preparation

Digital Holter recorders operate at a high frequency and at very high sample rates. This provides better ECG resolution. As a result, patient skin preparation at the electrode sites is an important process.

Only the ordering physician can determine the actual skin preparation for each individual patient. General application techniques are as follows:

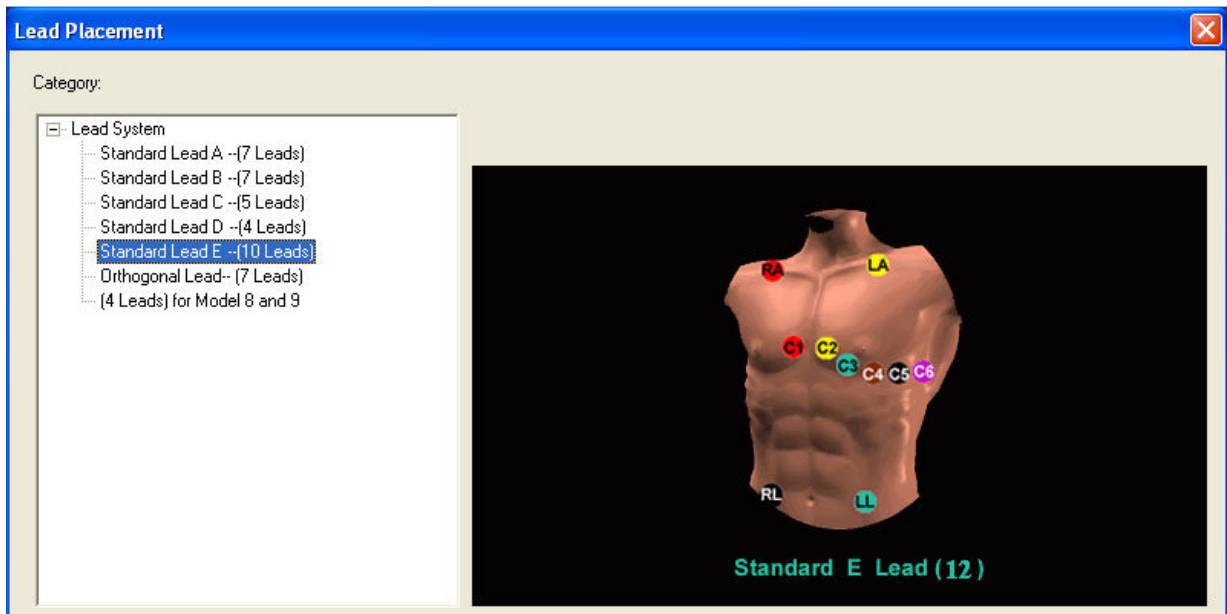
1. Scrub each electrode site per the ordering physician instructions to remove the dead skin, as well as the skin oil and dirt.
2. Clean the scrubbed site with physician approved alcohol.
3. Use disposable electrodes that are recommended by the ordering physician.
4. Snap the electrode onto the Lead Wire before placing the electrode on the patient's skin.
5. Place the electrode on the desired physician recommended location.
6. Electrodes should be placed on bony-type surfaces. Avoid muscle or fat locations for placing the electrodes.
7. The patient should be standing, or sitting in an upright position when applying electrodes.
8. The ordering physician will determine if a 4-electrode or a 10-electrode ECG Cable will be used.
9. With the Lead Wire, make a circular stress loop about 1.5 inches from the electrode site. Place a tape over the x in the stress loop. If done properly, a tug on the Lead Wire will only make the diameter of the circular stress loop smaller, and not tug on the Lead Wire at the electrode site.
10. Prepare a circular stress loop for each Lead Wire connected to an electrode.
11. Typical electrode sites are shown in next pages. However, only the ordering physician is responsible for the placement of electrodes.



Standard 4-Electrode 3-Lead Hookup

The above photo shows a standard 4-Electrode 3-Lead ECG Hookup. The leads are as follows:

| | | | |
|-----------|----|---------------|----------------|
| Channel 1 | V5 | 2 - Red (-) | 1 - Yellow (+) |
| Channel 2 | V2 | 2 - Red (-) | 3 - Green (+) |
| Channel 3 | V6 | 3 - Green (-) | 1 - Yellow (+) |
| Ground | | 4 - Black | |



Standard 10-Electrode 12-Lead Hookup

The above photo shows a standard 10-Electrode 12-Lead ECG hookup.

Optional ENROLL of Patient Data into the Recorder

Prior to placing the battery into the DMS 300-3A recorder, you may want to ENROLL the patient's demographic data into the storage memory of the recorder. This is a back-up security measure for writing the patient data into the recorder, which will then be automatically correlated with the Holter ECG report for this particular patient.

The ENROLL process is as follows:

1. Make certain that Download Cable is connected to both the DMS 300-4A recorder and the Holter Software PC. There is no need to load a driver for this cable. The Holter Software PC will automatically recognize the Download Cable.
2. Before you connect the Download Cable to both the recorder and the Holter PC, make certain that there is no battery in the recorder.
3. You now need to enter into the Holter ECG program that is installed in the Holter Software PC.
4. On the Windows Desktop display, double-click on the Holter icon.
5. You have now entered into the Holter ECG program
6. At the top of this display, you will see an ENROLL icon. Click on the ENROLL icon.
7. The Patient Info menu will appear. Enter all of the desired patient and physician data.
8. When you have entered all of the desired data, click on NEXT at the top right to end this process.
9. The entered data has now been entered into the memory of the Holter recorder.
10. Disconnect the Download Cable from the Holter recorder.
11. When you process this Holter recording at a later time, the patient demographic data that has been stored in the Holter recorder will be transferred into the Holter ECG report file when you later process this Holter ECG with the Holter Software PC.

Reviewing the ECG Quality of the Electrode Application

Before sending the patient out of the office for the Holter recording, you may want to check the quality of the electrode site cleaning and application.

After you have completed the electrode application and completed the ENROLL process, then place the battery into the recorder.

1. Note the exact clock-time when the battery is placed into the recorder.
2. The insertion of the battery into the recorder is the ON power switch for beginning the Holter ECG recording.
3. There is a Patient Isolation Cable that connects from the recorder to the Holter PC, or any Windows PC or Notebook.
4. A separate Holter Recorder software program needs to be loaded into the desired PCs or Notebooks or PDAs.
5. Inside the Cable line is a special circuitry that isolates the Patient Isolation Cable from all un-wanted power surges.
6. Connect the Patient Isolation from the recorder into the computer.
7. After the Patient Isolation Cable has been connected from the recorder to the computer, press the F5 key, and you will see the three (3) channel ECG display.
8. Then use your finger to tap several times on the top of the yellow and red electrodes. This is the ECG on channel 1. If you see an artifact displayed on the ECG on channel 1 while you are tapping on the electrode, then you know that the electrode site has not been cleaned enough. The green electrode is the ECG for channel 2. When you tap on an electrode, and the ECG remains clean, then that electrode should give you a good ECG trace for the entire recording. When you tap on an electrode, and the ECG shows artifact, you should re-clean the skin and re-apply a new electrode.
9. Note that only the ordering physician can determine the methodology for cleaning the skin and applying the electrodes.
10. After completing the "electrode tap test" remove the Patient Isolation Cable from the Holter recorder.

Patient Instructions

1. The patient should never play with the battery. If the patient was to remove and re-insert the battery, all of the patient recorded ECG in the DMS 300-4A recorder will be automatically erased.
2. The patient name and recorder start time should be written onto the Patient Diary.
3. Instruct the patient on how to use the Patient Diary.
4. The recorder has an Event button.
5. The purpose of the Event button is to match symptomatic patient events with the specific ECG at the time of the symptom.
6. When the patient feels a symptom that you have asked him/her to recognize, show the patient how to press the off-white colored Event button.
7. The pressing of the Event button will insert a special “flag” signal onto the Holter recording. When the Holter ECG is processed with the Holter Software PC, the Holter program will automatically recognize each “Event flag” and generate an ECG strip and/or an ECG display at the time that each Event flag was activated by the patient.
8. This will allow the physician to see the actual ECG that was associated with the patient’s symptomatic event.
9. It is recommended that the patient do a test Event button press while receiving these instructions in the office or laboratory.
10. The patient should not go swimming with the recorder, nor should the patient take a shower or bath with the recorder.
11. The recorders can be worn in a leather-type carrying case or with a cloth-type necklace for wearing inside the patient clothing.
12. The recorder will display a flashing light every few seconds. This indicates that the battery is still providing the appropriate power to the Holter recorder.
13. Never use a used battery on a new patient.

Downloading the Holter ECG File into the Holter Software PC

When the patient returns to your office after the Holter recording has been completed, transfer the ECG data from the recorder to the Holter Software PC as soon as possible. This will allow the Holter recorder to be immediately available for the next patient.

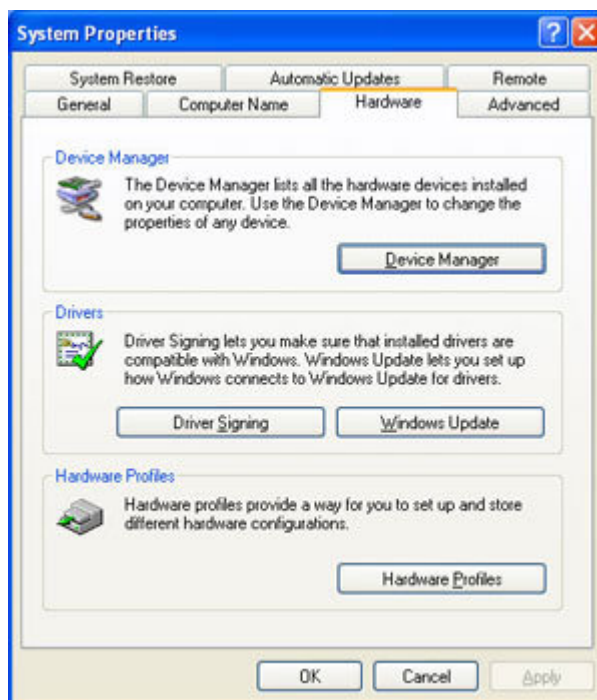
1. The Download Cable will transfer the Holter ECG file from the memory in the recorder to the hard disk in the Holter Software PC.
2. Remove the battery from the DMS 300-4A.
3. Remove the Lead Wires, tape, and electrodes from the patient.
4. Disconnect the ECG Cable from the Holter recorder.
5. Insert the Download Cable into the Holter recorder.
6. The Download Cable cannot be inserted into the recorder while the ECG Cable is connected. This is a patient safety feature.
7. When the Download Cable is connected to both the Holter recorder and the Holter Software PC, you are ready to transfer the ECG data.
8. Go into the first screen display of the Holter program.
9. At the top of the screen display you will see a "New Patient" icon.
10. Click on New Patient.
11. If you used the ENROLL function, all of the patient's information will be displayed on the screen display.
12. If you did not use the ENROLL function, enter all of the patient's data into the information fields.
13. Some information fields are mandatory for receiving data. They are Start Time and Date, Physician Name, and Patient Name.
14. When you have completed entering the data into the various fields of this screen display, press the NEXT icon at the top right. This will begin the Holter ECG processing and analysis.

Viewing Real-Time ECG

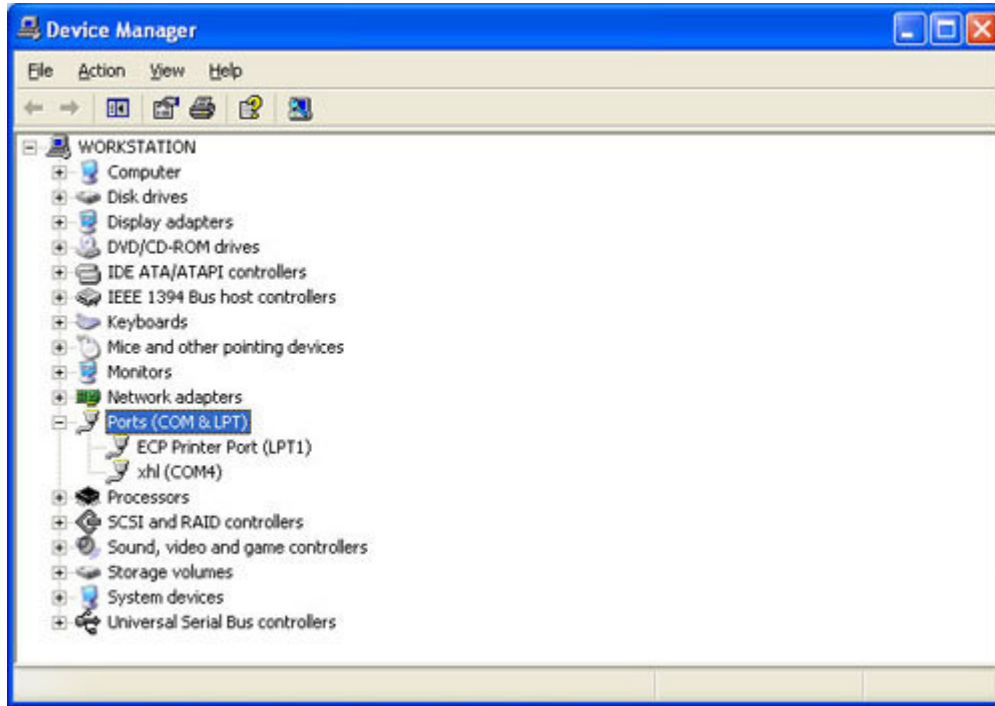
1. Make sure the Holter recorder is hooked up to the patient properly. After inserting the battery, the LED will flash for a few seconds and then you will hear 3 beeps.
2. Connect the round plug of the patient isolation cable to the Holter recorder, and the USB plug into the computer.
3. Run CardioScan Premier. From the main screen, press F5 on your keyboard. A black screen will appear with the real-time ECG display.

If the real-time ECG does not appear:

1. Click on Start > Settings > Control Panel > System > Hardware tab > Device Manager.



2. Double-click on "Ports (COM & LPT)". Next to "xhl" you will see a COM#. In the example below, we have COM4. Make a note of this number.



3. Return to CardioScan Premier, click on System Setting > Other B tab.
4. Under "Monitor Port", select the Com # determined during step 2. Click OK, then press F5 on your keyboard. The real-time ECG should now be displayed.

