



PHN Marfan Trial

Holter Monitor Hookup Instructions for Parents

This brief set of instructions is to show non-medical personnel how to complete a hookup and removal of the Holter monitor for the PHN Marfan Trial.

You should have:

Holter monitor
Patient cable (already attached to monitor)
Compact Flash card (already inside monitor)
Pouch and strap for monitor

Hookup kit – which includes:

1 - AA Battery
1 - Patient Diary
5 – electrodes
2 - Alcohol prep pads
1 - Razor



Overview:

It is very important that the monitor that you have received be applied correctly. Please follow these instructions carefully. The monitor has 5 wires or “leads” with an electrode or “sticker” to be attached at the end of each wire. These color-coded wires must be applied to the skin as described. Proper skin preparation and the placement of the wires/electrodes are very important so that a good recording of heart rate can be obtained. As explained by your study advisor, this procedure records the electrical activity of the heart over an extended period (usually 24-hours). It monitors every heartbeat using the 5 electrodes placed on the skin, through the wires and the recorder and stores the information on the flash memory card inside the recorder. There is no danger of electrical shock from the recorder. The recording is safe and painless. All components are hypoallergenic and latex free.

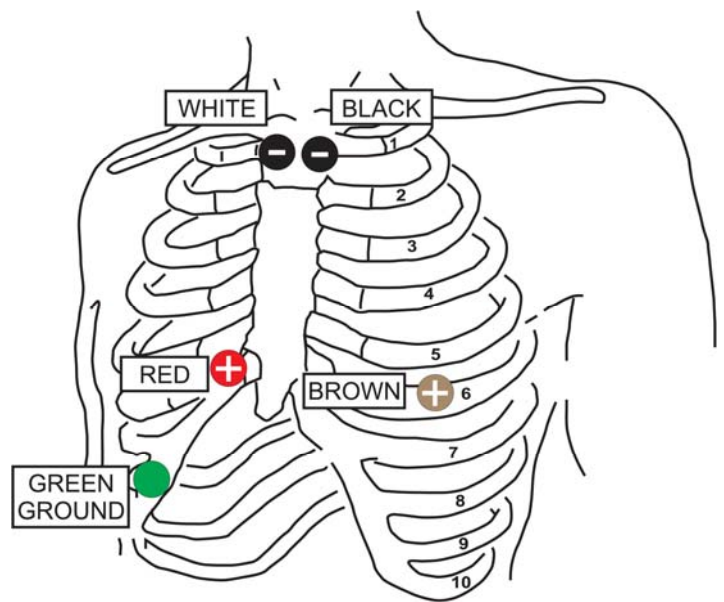
Preparing the Participant

Prepare electrode sites

Select flat areas over bone, avoiding thick muscle mass and breast tissue as much as possible.

Shave, clean and abrade electrode sites

- All components are hypoallergenic and latex free.
- Shave all locations where tape and electrodes contact the skin. (As required)
- Cleanse the areas well with soap, water and a washcloth using some pressure to remove any oil or cream that may be on the skin.
- Rub and clean electrode sites aggressively with the alcohol prep pads provided: Remove dead tissue cells, body oils, perspiration, dirt, creams, etc.
- Again rub electrode sites using 2 X 2 or 4 X 4 cotton gauze or a dry washcloth. Some redness may result.

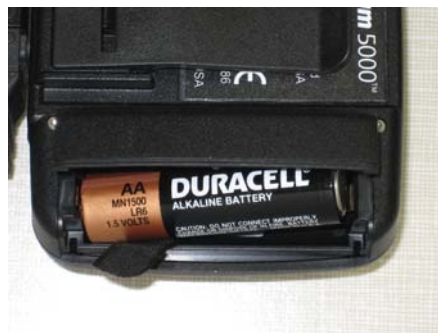


Apply electrodes:

- Allow the alcohol to dry completely.
- Attach electrodes to the snaps on each lead wire.
- Remove the protective backing from the electrode using the tab only.
- Do not touch the adhesive but hold the electrode by the colored snap wire cap.
- Carefully apply electrodes ensuring the center gel is in solid contact with the skin.
- Press electrodes' adhesive border firmly for consistent adhesion without wrinkling or creasing the tape.
- Replace any electrode not firmly adhering to the skin with a fresh electrode.
- Repeat for each of the 5-electrodes/lead wires.

Preparing the Recorder

Insert battery and close door



Insert battery + end first toward the left as shown above, then push firmly on the – end of the battery to ‘click’ it into place. Be sure to put the ribbon under the battery so it can be removed easily later. Close the battery door and press it in to latch it.

Press Enter Button

With battery door closed, press Enter button “↵”. The PHN logo will appear for a few seconds, then the “Tab” menu will be displayed across top of LCD screen as below.



Observe Tabs at top of screen

The Tabs are labeled:

ID	CH1	CH2	Settings
Date/Time	Start	About	

The Left and Right Arrow buttons will move between Tabs.

Applying the Monitor

Attach lead wires as shown in diagram

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Observe signal quality on each channel

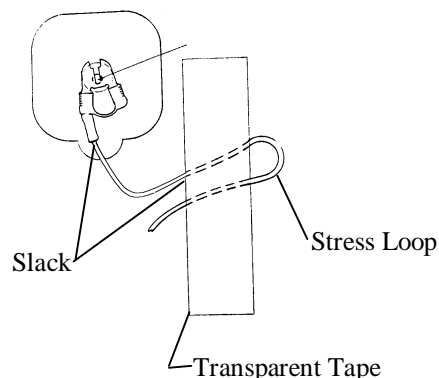
Press the right Arrow button once to display the Channel 1 signal display



The display should be similar to that above. Now press the right arrow button once again to display the Channel 2 signal display, which should also look like that above -

When good signal quality is achieved, create stress relief loops on lead wires as shown:

To minimize artifact (electrical noise) in the recording, tape a “stress loop” on each lead-wire. The slack will allow for normal movement without pulling on the electrode.



When stress loops are completed, press the right arrow button two times to Tab over to the Start Display:

Starting the Procedure

Tab over to “Start”



Press Enter Button:

The Current Time will appear in large numbers with Time Remaining (countdown timer) Below



Place recorder in pouch – Setup is complete!

The Monitoring Period

Partake in normal activities, but please remember - do not get the monitor, wires or electrodes wet - no swimming, bathing, showering, etc. for the duration of the monitoring period.

The monitor may be clipped to your waistband, placed in a pocket or worn in a pouch with the strap over your shoulder or neck as long as there is no ‘pulling’ on the wires. Please be careful not to drop the monitor.

Wear the monitor at all times, wear under loose, comfortable clothing so as to contain wires, etc, but not to restrict movement or pull on wires.

At the end of Recording

At the completion of the monitoring period (24 hours), the recorder will display “Shutting Down Please Wait” then the display will go blank.

The recorder and electrodes may now be removed from the participant.

Please discard the electrodes after carefully detaching them from the snaps on the wires.

Detach the lead wires from the electrodes (stickers) by prying the color-coded buttons at the end of the wires from the electrode “snap”. Do not cut or dispose of the lead wires! Do not pull on the wires. The tape and electrodes may be discarded. You may use rubbing alcohol, lanolin, or soap and water to loosen the tape by soaking a washcloth then soaking the tape, or slowly pull on the tape gently wiping the skin with the wet washcloth as the tape is being removed. After 30 seconds the tape will be easier to remove. Please DO NOT remove the battery or disconnect the wires from the monitor.

Returning the Device

The monitor must be sent back to the study site within 24-hours of the completion of the monitoring period.

No need to remove recorder from the pouch. No need to remove battery from the recorder.

Check to make sure diary sheet is filled in with participant’s name, ID, address, recording date, etc. before placing it in return envelope.

Place the recorder, with the cable connected, and the diary in the return envelope and seal it.

Drop in any mailbox to return it to PHN study site. (Envelope is pre-addressed and prepaid)

If you have any questions, please do not hesitate to call the study coordinator;

_____ at _____ or pager _____.
Name Phone Pager

Your continued thanks for participating in this important research project.