

Eclipse PRO **Ambulatory ECG and Patch Recorder**

Model 98700

For the Clinician





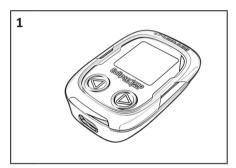




The following instructions are divided into two parts. The first part are instructions for the clinician when preparing an Eclipse PRO recorder for shipment to a patient who will be self applying the recorder patch. The second part is instructions for the patient as to how to apply the patch, and should accompany the recorder when sent to the patient.

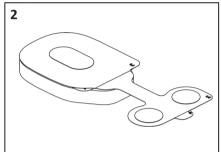
Items to supply to patient:

- 1. Eclipse PRO Recorder- configured and fitted into Sensor Patch
- 2. Patient Diary
- 3. Part 2 of these instructions.

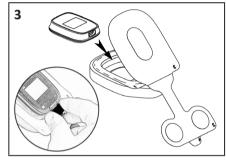


Configure the recorder for the patient. See the Eclipse PRO User's Manual for further information.

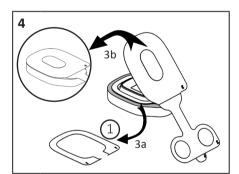
Also complete the patient information page in the Patient Diary being supplied to the patient.



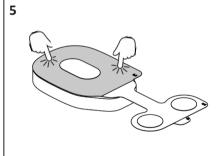
Remove patch electrode from outer packaging (do not discard packaging) and place face down on a flat surface.



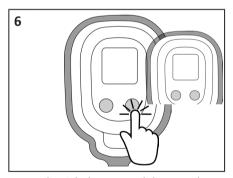
Open the patch pocket door, insert the Recorder (face down) into the patch, and connect the USB connector into the recorder socket.



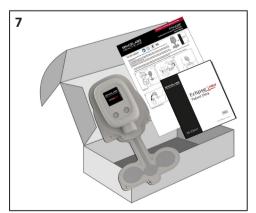
Remove the 1st release liner (3a) to expose the pocket adhesive seal and close the pocket door (3b).



Apply pressure over the back of the patch to ensure a good seal. Place the patch and recorder assembly back in the outer packaging ready for shipping.



Press the right button until the recorder displays the 'Recording' screen.



Package the assembled Sensor Patch along with Part 2 of these instructions, and a Patient Diary (enter patient and contact details on page 3), and ship to the patient.



- This Eclipse PRO ECG Sensor is for use in combination with the Eclipse PRO Ambulatory ECG Recorder only. The Eclipse PRO is intended to be used by either pediatric (>10Kg) or adult patients suspected of cardiac arrhythmias in either a clinical or home setting..
- For an extended recording multiple Eclipse PRO ECG Sensors might be required.
- This Eclipse PRO ECG Sensor consists of an adhesive, spunlace, nonwoven medical tape, supporting four multilayer, sensing ECG hydrogel electrodes. Optimizing the sensing capabilities, the Eclipse PRO ECG Sensor is available in one size (195.5 mm by 90 mm) only.
- The Eclipse PRO ECG Sensor is a single use, disposable device. Used Eclipse PRO ECG Sensor must be treated as biohazard waste. The Eclipse PRO ECG Sensor should be disposed of according to local waste disposal regulations.
- Prolonged Eclipse PRO ECG Sensor wear can cause excessive itchiness or irritation and redness to the skin but is unlikely to be permanent. This Eclipse PRO ECG Sensor is contra-indicated for patients with known allergic reactions or hypersensitivity to adhesives or hydrogels. The Eclipse PRO ECG Sensor might not be suitable for patients with sensitive or fragile skin. Use of appropriate medical adhesive removal wipes helps reduce the chance or skin irritation post Eclipse PRO ECG Sensor removal.
- The Eclipse PRO ECG Sensor or the Eclipse PRO should not get excessively wet through activities such as swimming or having a bath. Showering is permitted.
- Using a defibrillator with the Eclipse PRO ECG Sensor attached to the patient may reduce the effectiveness of the defibrillator. The Eclipse PRO ECG Sensor must be removed prior to de-fibrillating a patient.
- Never attempt to connect any other device or instrument to the internal connections or circuitry of the Eclipse PRO
 recorder while it is connected to a patient. The electrodes of the Eclipse PRO ECG Sensor must not be allowed to
 contact other conductive parts even if they are at ground potential.
- This Eclipse PRO ECG Sensor is not designed for use in proximity to high frequency surgical equipment or near an MRI machine. Remove the Eclipse PRO ECG Sensor before treatment involving such equipment.
- No modification of this equipment is allowed.





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Eclipse[™] PRO

Ambulatory ECG and Patch Recorder Model 98700

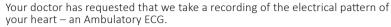
For the Patient











You have been provided with an Eclipse PRO Recorder which has been preconfigured and fitted in a Sensor Patch ready for you to apply, and a Patient Diary for you to record any symptoms you have during the recording period.

The following are instructions for applying the supplied Sensor Patch. The Recording will start automatically when the patch picks up your heart rhythm once the patch is applied to your chest.

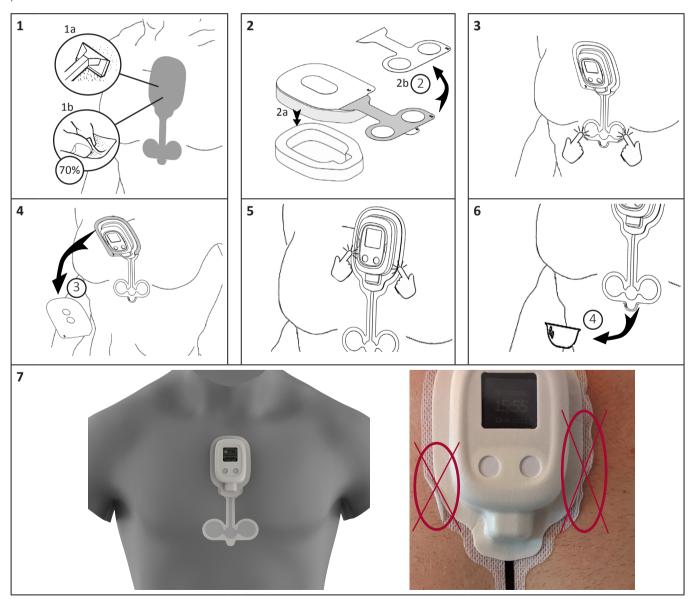


- The Sensor Patch Electrode is water resistant and can be worn during showering but NOT when bathing. However try to minimize the amount of water touching the patch and gently pad dry with a towel after showering.
- Patients should avoid activities that cause excessive sweating as this may cause the patch or electrodes to become detached.

Write any symptoms that you feel as you go about your normal daily activities in the provided Patient Diary.

For each event, please note any activity you were doing at that time (examples are shown in the diary). You may also press either button on the recorder, and make an entry in the diary of any symptom(s).

If you have any questions or problems, please contact the hospital or caregiver via the details shown in your Patient Diary or otherwise provided.





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