

3-Lead ECG Monitoring Electrode Array

The HFVI Sensor PLUS is a disposable, pre-gelled 3-lead array. Place the large and the small electrodes on the patient in order to detect a cardiac signal of good amplitude. For example, the large electrode can be put on the right shoulder and the small electrode at the apex of the heart as shown in the diagram on the pouch label.

The sensor is self-adhesive and contains bio-compatible materials where the array comes into contact with the skin.

The sensor is designed for use in the Adult population and for the population above the age of 2 years although supervision is required.

The HFVI Sensor PLUS is to be used with the HFVI Monitoring System and may be worn for a continuous period of 24 hours in a hospital environment.

Cautions:

Rx only – US Federal law restricts this device to sale by or on the order of a physician.

HFVI Sensor PLUS may damage the skin if removed carelessly.

The HFVI Sensor PLUS should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas).

The HFVI Sensor PLUS should only be used by or in consultation with a healthcare provider familiar with their proper placement and use.

Ensure the skin area is clean, dry and hair free before sensor application. Use alcohol wipes for cleaning the application area.

Apply the HFVI Sensor PLUS within 1 hr of removal from the inner packaging.

Replace the HFVI Sensor PLUS if it no longer sticks firmly to the skin.

Reddening of the skin and slight irritation may occur. This is normal.

Dispose of the HFVI Sensor PLUS properly after use under hospital guidelines.

The sensor is not waterproof.

Store in a cool dry place.

The HFVI Sensor PLUS is not made with natural rubber latex.

Precautions:

During surgical procedures, the HFVI Sensor PLUS should be placed as far as possible from any electro-surgical area to minimise unwanted RF current flow.

Do not wear the HFVI Sensor PLUS during an MRI or X-Ray

Do not bend the sensor.