

URGENT Field Safety Notification

Summary

01-JULY-2024

To: Users of HeartStart Intrepid Monitor/Defibrillators

WHAT IS THE PROBLEM?

When monitoring ECG using either a 5-Lead or 10-Lead ECG cable, the HeartStart Intrepid Monitor/Defibrillator may display intermittent ECG waveforms when the fourth limb lead is placed on the patient. The ECG tracing is normal when only three limb leads are connected (right arm, left arm, and left leg). However, when there are one or more poor ECG lead connections to the patient, the ECG tracing either displays a dashed line or is intermittent between waveform and dashed line (see Figures 1-3 below). This failure may occur any time the HeartStart Intrepid Monitor/Defibrillator is being used to monitor 5-Lead or 12-Lead ECG.

Figure 1 – 12-Lead ECG

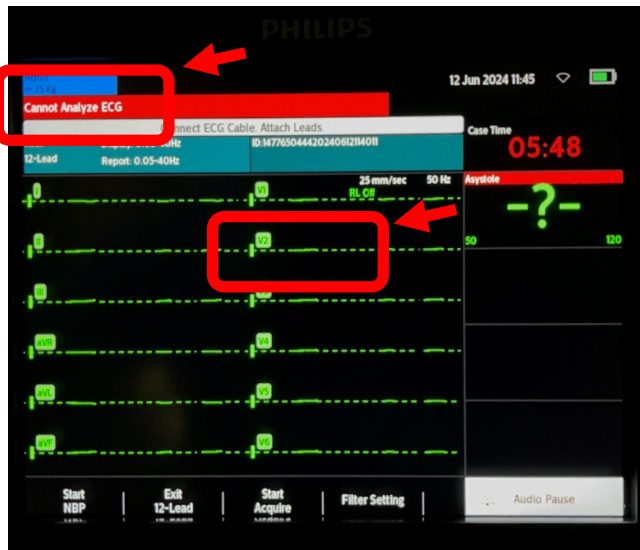
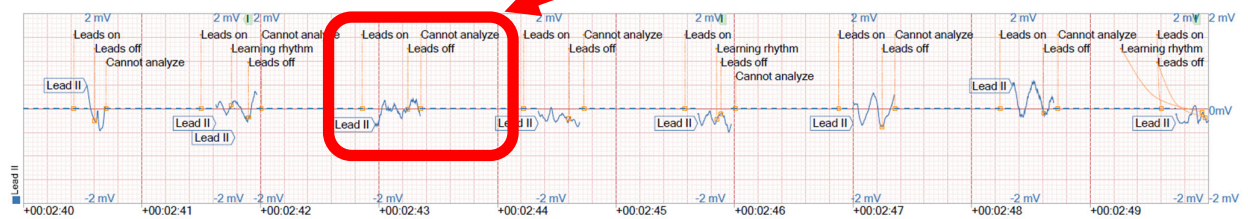


Figure 2 – Monitor mode



Figure 3 – ECG printout



WHAT SHOULD I DO?

- Should you experience gaps in the ECG waveform, removal of the Right Leg and Chest connections will force the device to default to 3-Lead measurement and ensure a continuous ECG during monitoring, pacing, or cardioversion.
- Continue to follow the Instructions for Use (IFU) for proper use of ECG electrodes and their application to patients, including skin preparation. Use only Philips approved lead sets listed in the IFU with the HeartStart Intrepid. Failure to do so may introduce noise and result in intermittent 'Cannot Analyze' or 'Leads on/Leads off' ECG messages.
- Use only Philips monitoring electrodes, multifunction electrode pads, battery, and accessories listed in the IFU. Substitutions may cause the HeartStart Intrepid to function improperly and cause patient injury.