Safety Notice 024/22

Issue date
5 December 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Critical Care
- Emergency Departments
- Surgical Departments
- Medical Departments
- Outpatient Areas

Clinicians who use PageWriter ECG's

Expert Reference Group Content reviewed by:
ACI Cardiac Network
HealthShare NSW
Representatives from:
State Preparedness & Response Unit

Clinical Excellence Commission
Tel: 02 9269 5500
Email: CEC-Recalls@health.nsw.gov.au
Internet Website: https://www.health.nsw.gov.au/sabs/Pages/default.aspx
Intranet Website: http://internal.health.nsw.gov.au/quality/sabs/

Review date
December 2023

Philips 12-Lead Chest Lead-set Defect

Situation

The Therapeutic Goods Administration (TGA) has issued a Product Defect Correction for Philips 12-Lead Chest Lead-set (RC-2022-RN-01345-1). The manufacturer has identified V1 and V3 leads were incorrectly assembled. The internal wiring of V1 and V3 leads being incorrectly positioned (swapped) in the lead-set hub generates the wrong electrocardiogram (ECG) report and potentially the wrong interpretation of results.

Background

Philips 12-Lead Chest Lead-set is used to transmit electrical signals from electrodes placed on the patient's body to the ECG machine. Upon setting up the ECG, there is no indication that the V1 and V3 leads have been swapped. Therefore, the user will not know the lead wires are incorrectly assembled until an inaccurate ECG result is recognised. This occurrence has the potential to result in misdiagnosis of and / or harm to the patient.

The swapped lead-set issue is for some 12-lead chest lead set (long (PC 989803151691) / standard (PC 989803151671)) manufactured between 2018 to 2021, and only applicable for the **PageWriter TC70, TC50, and TC30 ECG machines.** To identify affected lead sets, please follow instructions on page 2.

Replacement lead-sets are not anticipated to be available till February 2023.

Assessment

Philips state no adverse events associated to the issue have been reported to date. A review of NSW Health incident data has also not identified any clinical incidents.

There is a potential risk of misdiagnosis of the patient. Please note there is no impact on ST segments or T waves as ECG interpretation does not rely on single leads for diagnosis.

Clinical Recommendations

- Conduct a test on all **PageWriter TC70, TC50, and TC30 ECG machines** to identify if lead sets have V1 and V3 incorrectly wired (see further details on page 2).
- If possible, replace affected lead sets with unaffected lead sets and return affected lead sets to Philips as per customer letter.
- If no alternative stock available and decision is made to use affected stock, attach this notice to the ECG machine until the affected leads have been replaced.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where affected ECG machines are located
2. Include this Safety Notice in relevant handovers and safety huddles
3. Undertake a stocktake to identify locations of affected Philips ECG 12 lead-sets and work with Philips to replace affected stock when available
4. Escalate any concerns to the CEC-Recalls@health.nsw.gov.au
5. Report any incidents associated with these [devices] into ims+ and TGA.

How to identify if V1 and V3 leads have been incorrectly wired

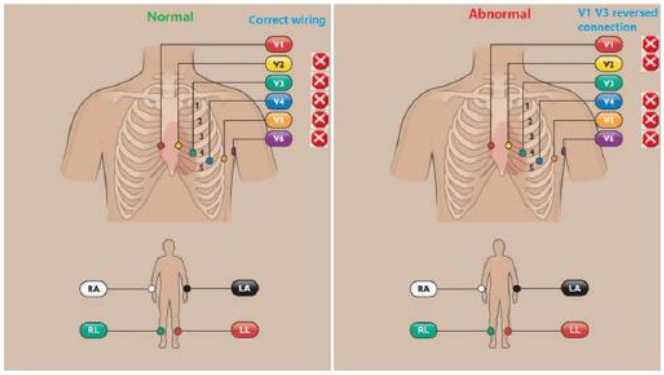
Determining if Your Lead-set is Affected

To determine if your leads set is affected, connect the limb leads and **only** V1 to a person.

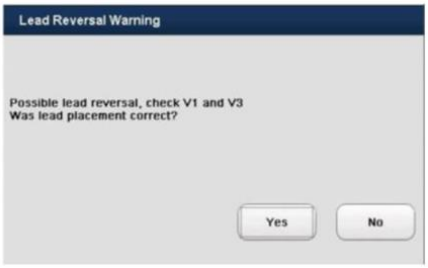
If the lead-set is working normally, **V1** will be **on** and V3 will show which means this lead is not connected.

If the leads are reversed (Abnormal) **V3** will show **on** and V1 will show off

All other connections should show off as they are not connected to the person.

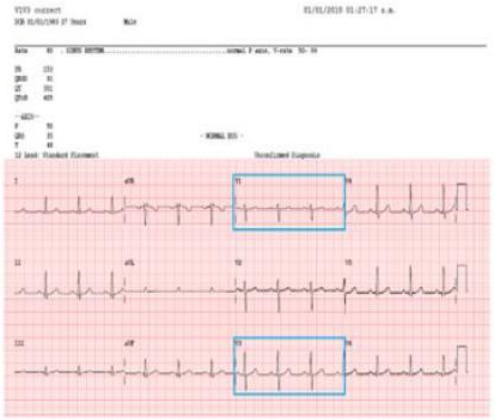


When all the leads are placed, if V1 and V3 are swapped, the system could display a warning message notifying the user of the swapped leads.

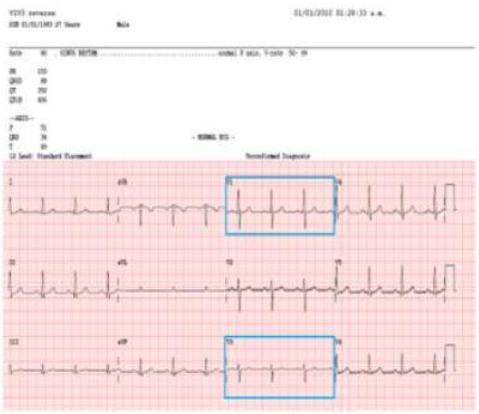


Determining Electrocardiogram (ECG) Results

When comparing results generated by normal working ECG leads, the swapped V1 and V3 leads are noticeable on V1 and V3 waveform amplitude.



Correct Waveform



Reversed V1/V3 Waveform