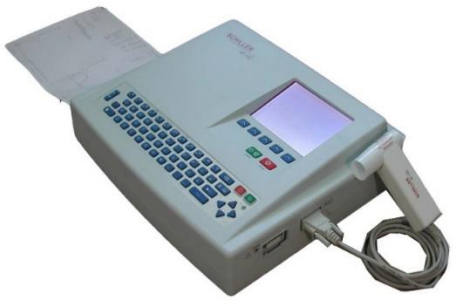
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Safety Notice

## Medical Devices

# SCHILLER CARDIOVIT AT-102 ECG



### Priority 2 – Warning

**HPRA Safety Notice: SN2023(01)** **Issue Date: 13th September 2023**

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|---|---|
| SCHILLER AG | V53993 |

**ISSUE**

The HPRA is informing health care providers of an issue identified with ECG readouts on the Schiller Cardiovit AT-102 ECG devices.

**In some situations, ECG readouts may become distorted, which could lead to misinterpretation or misdiagnosis.** This distortion can lead to changes to the baseline and QRS complexes, which may lead to erroneous clinical decisions.

This distortion may occur if all three of the following conditions are met:

1. An ECG is performed on a patient who has a pacemaker *in situ*,
2. The device's 'pacemaker detection function' is not activated, and
3. The ECG reading is electronically transferred to a data management system, such as an electronic patient record.

The manufacturer has advised that, while the ECG in the data management system can be distorted, the original ECG produced by the Cardiovit machine (prior to transfer to the data management system) will not show this distortion.

The manufacturer has confirmed that this distortion will not occur if the 'Pacemaker' detection function is selected prior to carrying out the ECG on the patient. They have also confirmed that this distortion cannot occur for patients who do not have a pacemaker *in situ*.

The manufacturer has issued the accompanying field safety notice (FSN) highlighting this issue and has provided an addendum to the device's Instructions For Use (IFU) document.

Although the HPRA is not aware of any serious incidents associated with this issue in Ireland, the AT-102 was discontinued in Europe in February 2019 and no further corrective action or software update is planned by the manufacturer at this time and therefore this notice aims to:

- remind healthcare professionals of this ongoing potential issue and associated risks,
- re-emphasise the continued importance of ensuring that the 'Pacemaker' field is ticked / selected 'YES' prior to performing the ECG for patients with pacemakers *in situ* (see background section for further information).

## ACTION OR RECOMMENDATIONS

The HPRA advises users the following:

1. Review the list of potentially affected devices in the accompanying FSN and identify whether your device is one of the impacted models listed. Please note, all AT-102 models of Cardiovit ECG devices are affected.

2. Read the FSN and follow the instructions as described. The FSN must be kept together with the IFU and acts as addendum to the existing IFU for the device. Refer to the background section of this HPRA Safety Notice below for further information.

3. Complete and return the reply form included with the FSN to the distributor of your device.

4. If you have experienced the issue described above or any other adverse incidents associated with this device, please report them to the manufacturer and to the HPRA.

5. Forward a copy of this Safety Notice and the accompanying FSN to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred.

## TARGET GROUPS

| | |
|---|---|
| General Practitioners and Practice Nurses<br>Cardiologists<br>Cardiac Technicians and Catheterisation Lab staff<br>Cardiac Care Unit medical and nursing staff<br>Intensive Care Staff<br>Anaesthesiologists<br>General medical consultants<br>Emergency Medicine medical and nursing staff | Risk Managers<br>Healthcare IT Department<br>Bioengineering Department |

## BACKGROUND

Schiller was notified of an incident where an ECG printout differed from the ECG that was seen in the database on the data management system. This behaviour was only found to occur under the conditions described the 'Issue' section of this HPRA Safety Notice.

To reduce this risk of ECG distortion **the manufacturer has advised that, for patients with a pacemaker in situ, when entering new patient's details ensure that the 'Pacemaker' field is correctly ticked / selected 'YES', prior to performing the ECG** (see figure 1). This will avoid distortion of the transmitted ECG.

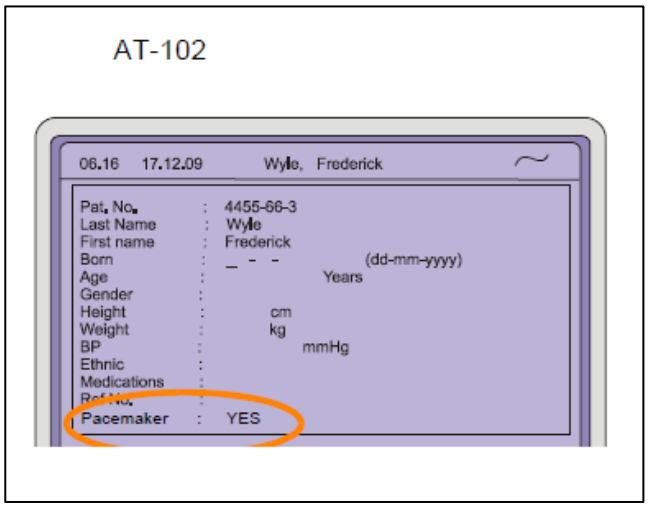



*Figure 1 - Ensure that the 'Pacemaker' field is correctly selected prior to performing the ECG (image copied from the IFU addendum for the Cardiovit AT-102 / AT-102 Plus / AT-10 plus /AT-104 PC / CS-200 / MS-2010 / MS-2015)*

The HPRA has been informed by the manufacturer that the Cardiovit AT-102 is in use on the Irish market and is affected by this issue. A list of all affected models and further information on the issue is available in the accompanying FSN issued by Schiller.

## MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION (amend as required)

Enquiries to the **manufacturer** should be addressed to:

SCHILLER AG, Altgasse 68, Baar, Switzerland, 6341

Telephone: +41 41 766 42 42
E-mail: vigilance@schiller.ch
Website: www.schiller.ch

Enquiries to the **authorised representative** should be addressed to:

SCHILLER Medizintechnik GmbH, Otto-Lilienthal-Ring 4, Feldkirchen, Germany, 85622

Telephone: +49 89 629 98 10
E-mail: EU-Rep@schillermed.de
Website: www.schillermed.de

Enquiries to the **distributor** should be addressed to:

Fleming Medical
Corcanree Business Park
Dock Road
Limerick

Telephone: +353 61 304600
E-mail: quality@flemingmedical.ie
Website: www.flemingmedical.ie

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:


Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie