

Safety Notice

Medical Devices

Philips PageWriter TC Cardiographs (TC20/30/50/70)

Priority 2 – Warning



HPRA Safety Notice: SN2019(17)

Issue Date: 27th May 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Healthcare	V38556

ISSUE
<p>Philips has received reports in which the lithium ion batteries in PageWriter TC Cardiographs have overheated and ignited when batteries had exceeded their life expectancy and should have been replaced. Battery replacement should have occurred when the number of charge-discharge cycles first exceeded 300 cycles or when the battery capacity fell below 80% of that of a new battery. Although the cardiograph can display the battery's status, the existing labelling for these cardiographs does not include full instructions on when to replace the batteries or the potential hazards if a user fails to do so. Therefore, Philips is issuing a PageWriter TC Cardiograph (TC20/30/50/70) Service Manual addendum with information to assist users with managing the battery and its replacement.</p> <p>The HPRA previously issued a safety notice relating to the same issue for Philips SureSigns VS VM & VSV patient monitors and viewing stations.</p>

ACTION OR RECOMMENDATIONS

The HPRAs advise that users:

- 1 Read the manufacturer's field safety notice (FSN) and accompanying PageWriter TC Cardiograph (TC20/30/50/70) Service Manual addendum carefully.
- 2 Promptly complete the Battery Maintenance instructions as described in the Addendum for each PageWriter TC Cardiograph (TC20/30/50/70) in service and replace batteries as needed.
- 3 Acknowledge receipt of the FSN if you have not already done so.
- 4 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
- 5 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRAs.

TARGET GROUPS

Hospitals	All departments
Clinics	All staff
A&E consultants	All wards
A&E nurses	A&E departments
Adult intensive care units	A&E directors
Cardiac consultants	Hospital IT managers
Patient Transport Managers	Clinical Engineers

BACKGROUND

Philips Healthcare issued a FSN to remind users about battery management and replacement for PageWriter TC Cardiograph devices.

Overheating of the battery may cause the device exterior case to become excessively hot, causing the case to melt and/or the device to ignite, which can cause injury to a patient, nearby users, or cause damage to property.

The affected products are all PageWriter TC Cardiographs (TC20/30/50/70) manufactured before November 20, 2018 that are capable of operating under battery power and have lithium-ion batteries presently installed.

Specifically, the following PageWriter TC Cardiographs with software revisions up to and including A.07.05.22.

Product	Description
860315	PageWriter TC70
860310	PageWriter TC50
860306	PageWriter TC30
860332	PageWriter TC20

860352	PageWriter TC70 w/trolley Government Bundle
860353	PageWriter TC70 w/o trolley Government Bundle
860354	PageWriter TC30 w/trolley Government Bundle
860355	PageWriter TC30 w/o trolley Government Bundle
860429	PageWriter TC50 Government Bundle

NOTE: The PageWriter TC10 (860392) is not affected by this safety notice.

Please refer to the FSN for further instructions on how to identify affected products.

The HPRA is issuing this safety notice to raise awareness of this issue. The HPRA may issue further communications should additional field actions be undertaken by the manufacturer.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Philips Healthcare UK
The Philips Centre
Guildford Business Park
GU2 8XG
UK.

Telephone: 0044 870 532 9741
E-mail: safetynoticeuki@philips.com
Website: www.philips.co.uk

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

Cardiac Services Ltd.
Unit 3
Northern Cross Business Park
Finglas
Dublin 11

Telephone: 01 830 7499
E-mail: recall@cardiac-services.com
Website: www.cardiac-services.com

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