IMPORTANT PRODUCT NOTICE

August 2021

RE: Update regarding PageWriter TC Cardiograph (TC20,30,50,70) battery management

Dear Customer,

This letter is a follow-up to the enclosed Medical Device Correction, FSN86000263-264, which was dated January 2019. That notice described the requirements for managing the lithium ion batteries to prevent overheating. The FSN included interim measures that could be taken until new battery monitoring software became available. That software is now available for installation in your Cardiograph(s) and Philips will contact affected customers to arrange a software upgrade on the devices. Upgrades will be performed by either a Philips field engineer, authorized service provider, or at a Philips bench repair facility.

To ensure that your Cardiograph(s) will be ready for use when the software upgrade is complete, it is important that you have a Philips-supported battery in good condition (see section 3 of this letter) available or installed in the device.

Please note this software upgrade also corrects a separate issue involving the Storage Encryption option on these devices which make it difficult to open ECG reports from the archive or transfer them.

1. **What the problem is and under what circumstances it can occur:**

   Battery Management:
   To ensure that your Cardiograph(s) will be ready for use when the software upgrade is complete, it is important that you have a Philips-supported battery in good condition (see section 3 of this letter) available or installed in the device.

   The battery should be replaced when the number of charge-discharge cycles reaches 300 cycles or when the remaining battery's State of Health (SOH) has decreased to 80% or less of the total battery capacity.

2. **We will contact customer to arrange upgrades on the following products:**
   All PageWriter TC Cardiographs Models TC20/30/50/70 manufactured before March 2021
   (see Table 1 on the next page).

Table 1:

Product Number	Device Identifier (DI)	Description
860315	00884838026582	PageWriter TC70
860310	00884838026568	PageWriter TC50
860306	00884838081123, 00884838026612	PageWriter TC30
860332	00884838028784	PageWriter TC20
860352	00884838032514	PageWriter TC70 w/trolley Government Bundle
860353	00884838081116, 00884838032521	PageWriter TC70 w/o trolley Government Bundle
860354	00884838082007, 00884838032538	PageWriter TC30 w/trolley Government Bundle
860355	00884838032545	PageWriter TC30 w/o trolley Government Bundle
860429	00884838091689	PageWriter TC50 Government Bundle

NOTE: The PageWriter TC10 (Product Number 860392) is not affected by this issue.

3. **To avoid issues after the upgrade, ensure that the cardiograph batteries meet the operational requirements below:**
   - Batteries are Philips-supported battery (see Table 2 below)
   - Battery cycle count is within the acceptable operating limits (less than 300 cycle counts)
   - Battery State of Health (SOH) is within the acceptable operating limits (greater than 80% battery capacity)

Table 2. Philips Supported Batteries:

Battery Part Number	Description
989803194541	11.1V **7800mAh**, ME202EK
989803199221	11.1V **7800mAh**, DR202i (U80221-4)
989803170371 (Sales discontinued)	11.1V **7200mAh**, ME202C

NOTE: If your Cardiograph uses two batteries, both batteries must be the same brand/model. It is recommended that both batteries be replaced at the same time when replacement is needed.

Important!
   - The battery monitoring software cannot monitor the performance of non-supported batteries.
   - If the battery's health is poor (too many cycles or state of health is 50% or lower), multiple issues may occur:
     o The battery management software will no longer allow the battery to charge.
     o The battery's temperature could become hot resulting in:
        1) An inability to charge the battery
        2) The cardiograph suddenly powering down.

For specific guidance on checking the status of your batteries to determine if they need to be replaced, and instructions for purchasing batteries, please refer to the enclosed document, Attachment 1, *Instructions for Checking the Status of the Battery in your Cardiograph*

For specific guidance on determining the battery management software version that best meets your workflow needs, please refer to the enclosed document, Attachment 2, ***Instructions for Determining the Correct Battery Management Software Version for your Cardiograph***

4. **The actions planned by Philips:**
Philips will contact affected customers to arrange software upgrades on the devices. Upgrades will be performed by either a Philips field engineer, authorized service provider, or at a Philips bench repair facility.

5. **Additional Information and Support:**

If you need any further information or support concerning this upgrade, please contact your local Philips representative:

0800 80 3000

If you need a copy of the *PageWriter TC Cardiograph Service Manual Addendum - Battery Maintenance* (453564844701 Rev A), referenced in Medical Device Correction FSN86000263A, 264A, please contact your local Philips representative or Philips Response Center.

Sincerely,

Christine Trefethen
Head of Quality and Regulatory Affairs
General & Specialty Care

Attachment 1:
Instructions for Checking the Status of the Battery in your Cardiograph

Before installing the battery management software, you must first determine if the cardiograph's batteries need to be replaced with approved batteries that are in good health.

This document provides instructions how to check if your cardiograph batteries:

- are approved/supported
- cycle count is within acceptable operating limits
- state of health (SOH) is within appropriate operating limits

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WARNING: You must first determine if the cardiograph's batteries needs to be replaced. If replacement batteries are required, please replace the batteries, with the supported/approved batteries in the table below, **before** installing the battery management software.

Table 1:

Battery Part Number	Description
989803194541	11.1V **7800mAh**, ME202EK
989803199221	11.1V **7800mAh**, DR202i (U80221-4)
989803170371 (Sales discontinued)	11.1V **7200mAh**, ME202C

If battery management software has been installed while the unit is utilizing unsupported batteries, and the cardiograph has been automatically shut down, then the unsupported batteries must be removed from the cardiograph and the cardiograph will need to run on AC power until the unsupported batteries are replaced with approved, replacement batteries.

If the cardiograph is running on AC power without any batteries in the cardiograph, after the cardiograph has been upgraded to the battery management software, the cardiograph will continue to function normally.

If a cardiograph with unsupported batteries is upgraded to one of the battery management software versions and running with the batteries inserted, upon power up, the cardiograph application software will detect that it has unsupported batteries installed, and force an automatic shutdown of the cardiograph, **rendering it unusable**.

If the batteries meet one or more of the following conditions, after upgrading to the battery management software, then you must remove both batteries and run the cardiograph on AC power ONLY:

- Unsupported batteries (see Step 1)
- Batteries with too many cycles, which will result in the cardiograph not charging the batteries (See Step 3)
- Batteries in which the State of Health (SOH) is too low (see Step 4)

Prior to installing one of the battery management software versions, the following activities MUST be completed to determine battery type and battery conditions, to support the software upgrade.

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers.

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Note: If a cardiograph with unsupported batteries is upgraded to one of the battery management software versions and running with the batteries inserted, upon power up, the cardiograph application software will detect that it has unsupported batteries installed, and force an automatic shutdown of the cardiograph, rendering it unusable.

Step 1. Determine Supported/Unsupported Battery Status:

To determine if your system is operating with a supported battery navigate to the main screen as shown below.

Battery status information is displayed on the "*About the Cardiograph*" screen in Diagram #1 below. To get to this display, navigate to the following:

> "*Setup*" button on the Main screen → "*Setup and Service Utilities*" button → "*About the Cardiograph" tab* → "*Battery Status"* section

Diagram 1:

IMPORTANT: An unsupported battery is indicated with one or more blank entries in the "*Battery Status*" section shown in the "*About the Cardiograph Tab*" (see Diagram 1 above).

If it is determined that your battery is **unsupported**, please refer to Step 5 (Ordering Replacement Batteries for your Cardiograph).

If it is determined that your battery is **supported**, proceed to Step 2, to determine if your battery is Approved/Unapproved.

Step 2: Determine whether the batteries are Approved/Unapproved

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers.

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Approved Batteries

An approved battery has been verified as meeting the requirements for use with a TC cardiograph and will allow the cardiograph to function normally after the cardiograph has been upgraded to the battery management software.

To consider a battery "*approved*," both statements below MUST be true:

a. "*Supported*" in which the battery communicates required battery status information to the cardiograph, such as cycle count, battery temperature, etc. so that it can monitor the health of the battery (see Step 1 - *Determine whether the batteries are Supported/Unsupported*).
b. Battery has one of the Approved battery IDs (listed below).

Unapproved Batteries

An unapproved battery communicates required battery status information to the cardiograph, such as cycle count, battery temperature, etc. (see section 2 - *Determine whether the batteries are Supported/Unsupported*) but has not been verified for use with a TC cardiograph. Unapproved batteries are supported, but are not approved for use, and should be replaced as soon as possible.

To consider a battery "*unapproved*," both statements below MUST be true:

a. "*Supported*" in which the battery communicates required battery status information to the cardiograph, such as cycle count, battery temperature, etc. so that it can monitor the health of the battery (see Step 1 - *Determine whether the batteries are Supported/Unsupported)*.
b. Battery does **not** have one of the Approved battery IDs (listed below).

> **IMPORTANT**: A cardiograph is still functional with unapproved batteries after the upgrade to the battery management software. However, the unapproved batteries will cause the cardiograph to prompt the user (under certain conditions) to see if the user wants to continue to use the cardiograph or shut it down and replace the unapproved batteries with approved (replacement) batteries.

To determine if your system is operating with an approved battery navigate to the main screen as described in Step 1 above.

Within the "*Battery Status*" section on the main screen, you will see the battery ID information as shown in Diagram 2:

Diagram 2:

Approved & Supported battery IDs include:

- P508;
- P510;
- 202CJC;
- E013RJ;
- T508;
- PH.

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Unapproved battery IDs include:

- Amazon
- P507

If the cardiograph's battery does not contain one of the Approved & Supported battery IDs listed above, it could damage the cardiograph and should be replaced with one of the tested replacement batteries listed below.

The PageWriter TC tested battery IDs are:

- P508 - Part # 989803194541 (Replacement battery)
- T508 - Part # 989803199221 (Totex battery – Replacement battery)
- 202CJC – Older supported battery version
- P510 - Part # 989803170371 (Supported battery for China only. **NOTE**: The previous listed replacement battery is no longer available for ordering. Please contact your Philips service engineer for the appropriate replacement battery.)

If it is determined that your battery is **unapproved**, please refer to Step 5 (Ordering Replacement Batteries for your Cardiograph).

If it is determined that your battery is **approved**, proceed to Step 3, to determine if your Cardiograph's Battery Cycle Count is Within Acceptable Operating Limits.

Step 3: Determine if the Cardiograph's Battery Cycle Count is Within Acceptable Operating Limits

a. If the batteries' cycle count is 300 cycles or greater, Philips **highly** recommends that the cardiograph batteries be replaced before upgrading the cardiograph to one of the battery management software versions.

b. If the batteries' cycle count is 600 cycles or greater, you **MUST** replace the cardiograph batteries **IMMEDIATELY** before upgrading the cardiograph to one of the battery management software versions.

> **WARNING**: The new battery management software will not charge a battery that has a cycle count of 600 cycles or greater.

To view the battery "*Cycle Count*" information within the "*Battery Status*" section on the "*About the Cardiograph*" tab, navigate to the following:

"*Setup*" button on the Main screen → " *Setup and Service Utilities*" button → "*About the Cardiograph*" tab → "*Battery Status*" section → "*Cycle Count*" list box

Diagram 3:

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers.

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Battery Status	Batt 1 (Frnt)	Batt 2 (Bck)
Current Status	Charging	Charging
Battery Voltage	11.8 V	11.8 V
Expected Max Error(%)	1%	1%
Full Cap.(mAH)	7772 mAh	7902 mAh
Remaining Cap. (mAH)	3802 mAh	3779 mAh
% Charged/SOH	49/99	48/101
Charge Current	1518 mA	1396 mA
Discharge Current	0 mA	0 mA
Cycle Count	14	9
Temperature (°C/°F)	22/72	22/72
B1 Unique ID	EONEMOLI-P508-20160119-0068	
B2 Unique ID	EONEMOLI-P508-20160121-1350	

If it is determined that your cardiograph's Battery Cycle Count is outside acceptable operating limits, please refer to Step 5 (Ordering Replacement Batteries for your Cardiograph).

If it is determined that your cardiograph's Battery Cycle Count is within acceptable operating limits, proceed to Step 4, to determine if your Cardiograph's Battery SOH (State of Health) is within acceptable operating Limits.

Step 4: Determine if the Cardiograph's Battery SOH (State of Health) is within acceptable operating Limits

Before upgrading the cardiograph to the battery management software, you must determine if each battery's SOH (State of Health) is within acceptable operating limits (greater than 80 %). The following SOH rules must be followed:

a. If a battery's SOH is 80 % or less, Philips **highly** recommends that the cardiograph battery be replaced before upgrading the cardiograph to one of the battery management software versions.

b. If a battery's SOH is 50 % or less, you **MUST** replace the cardiograph battery **IMMEDIATELY** before upgrading the cardiograph to one of the battery management software versions.

WARNING: The new battery management software will not charge a battery that has a SOH of 50 % or less.

It is the customer's responsibility to calculate the SOH, utilizing the following equation:

$$SOH = (Full\ Capacity/Design\ Capacity) * 100$$

Step 4.1 Determining Full Capacity:

The battery's "*Full Capacity*" can be found within the "*Battery Status*" section on the "*About the Cardiograph*" tab by navigating to the following screen, as shown in Diagram 4:

"*Setup*" button on the Main screen → " *Setup and Service Utilities*" button → "*About the Cardiograph*" tab → "*Battery Status*" section → "*Full Cap.(mAH)*" list box

Diagram 4

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers.

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Step 4.2 Determining Design Capacity:

The Design Capacity for approved replacement batteries can be found in Table 2 and indicated in **red**:

Table 2:

Replacement Battery Part Number	Description
989803194541	11.1V **7800mAh**, ME202EK
989803199221	11.1V **7800mAh**, DR202i (U80221-4)
989803170371 (Sales discontinued)	11.1V **7200mAh**, ME202C

If the cardiograph is released with A.07.07.04 or newer, the following steps should be taken to determine the battery's SOH.

Step 4.3 Determine SOH for Cardiographs installed with A.07.07.04 or Newer:

If the cardiograph is installed with software release A.07.07.04 (or newer), the battery's SOH (State Of Health) can be found within the "*Battery Status*" section on the "*About the Cardiograph*" tab by navigating to the following screen, as shown in Diagram 5:

"*Setup*" button on the Main screen → " *Setup and Service Utilities*" button → "*About the Cardiograph*" tab → "*Battery Status*" section → "*% Charged/SOH*" list box

Diagram 5:

Battery Status	Batt 1 (Frnt)	Batt 2 (Bck)
Current Status	No activity	No activity
Battery Voltage	12.2 V	12.0 V
Expected Max Error(%)	1%	1%
Full Cap.(mAH)	7787 mAh	7766 mAh
Remaining Cap. (mAH)	6843 mAh	6342 mAh
% Charged/SOH	88/99	82/99
Charge Current	0 mA	0 mA
Discharge Current	0 mA	0 mA
Cycle Count	16	16
Temperature °C/°F	25/77	25/77
B1 Unique ID	EONEMOLI-P508-20170808-1632	
B2 Unique ID	EONEMOLI-P508-20170809-1937	

Step 5: Replacement Batteries for PageWriter TC70, TC50, TC30, and TC20

The batteries listed in Table 2 above are the only replacement batteries for the PageWriter TC20/30/50/70 cardiographs.

> **NOTE**: If the cardiograph is running using dual batteries, both batteries must be the same brand/model. It is recommended that both batteries be replaced at the same time when replacement is needed.

Ordering Replacement Batteries for your Cardiograph

To order a replacement battery, contact your Philips Customer Care center.

To contact Philips Customer Care for your country, go to the Philips Customer Care website at https://www.healthcare.philips.com

From there, select your country and language, then navigate to the appropriate Philips Customer Care center.

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Attachment 2:
Instructions for Determining the Correct Battery Management Software Version for your Cardiograph

Before installing one of the battery management software, you should first determine if the cardiograph's batteries need to be replaced.

Please refer to Attachment 1, *Instructions for Checking Battery Status on your Cardiograph.*

The following instructions include:

Determining which battery management software best meets your workflow needs.

Step 1. Selecting the Correct Battery Management Software

The Battery Management correction, consists of three (3) different battery management software releases for your PageWriter TC cardiograph:

- A.07.07 (A.07.07.07)
- A.06.08
- A.05.05

All PageWriter TC70, TC50, TC30, and TC20 cardiographs worldwide are required to be upgraded to one of the three versions.

Table 1 below will help you decide which software best supports the customer's workflow needs.

Table 1

	Software Releases for the 2ⁿᵈ Battery Mgmt FCO	Cardiographs that are Candidates for this Software Release	Affected Software Releases
1	A.05.05	All PageWriter TC70 cardiographs in China and all PageWriter TC50 and TC30 (manufactured in the US) that resides in China must be upgraded to the A.05.05 FCO software. **IMPORTANT**: To easily identify cardiographs manufactured in the US,	A.01.01 A.02.00, A.02.01 A.03 (A.03.00), A.03.01 A.04.00, A.04.01, A.04.02, A.04.03, A.04.04 A.05.00, A.05.01, A.05.02, A.05.03, A.05.04

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		the cardiograph's serial number will start with "*US*".	
2	A.06.08	Any cardiograph that meets one or more of the following conditions: 1. Configured to use the "*PH090A*" algorithm. Customer wants to only use the "*PH090A*" algorithm. 2. Uses the modem/fax. 3. Uses the smart card reader.	A.01.01 A.02.00, A.02.01 A.03 (A.03.00), A.03.01 A.04.00, A.04.01, A.04.02, A.04.03, A.04.04 A.05.00, A.05.01, A.05.02, A.05.03, A.05.04 A.06.00, A.06.01, A.06.02, A.06.03, A.06.04 A.06.05, A.06.06, A.06.07

3	A.07.07 (A.07.07.07)	Any cardiograph that meets both of the following conditions:
		
		1. Not configured to use the "*PH090A*" algorithm.
		IMPORTANT: All cardiographs installed with SW release, A.07.00 or newer, supports algorithms, "*PH100B*" and "*PH110C*".
		2. Does not support:
		    a. modem/fax.
		    b. Smart card reader
			A.01.01
			
			A.02.00, A.02.01
			
			A.03 (A.03.00), A.03.01
			
			A.04.00, A.04.01, A.04.02, A.04.03, A.04.04
			
			A.05.00, A.05.01, A.05.02, A.05.03, A.05.04
			
			A.06.00, A.06.01, A.06.02, A.06.03, A.06.04
			
			A.06.05, A.06.06, A.06.07
			
			A.07.00, A.07.01, A.07.02.07, A.07.03.07, A.07.03.07M, A.07.04.03, A.07.05 (A.07.05.20), A.07.05.22, A.07.06, A.07.07.04, A.07.07.06

Step 1.1 Determining the Software Version installed on the Cardiograph

To determine the software version that is currently installed on your cardiograph, power up the cardiograph and navigate to the following screen:

"*Setup*" button on the Main screen → "*Service Utilities*" button → "*Main Application Revision*" list box on the "*About the Cardiograph*" tab on the "*Setup and Service Utilities*" screen.

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers

Step 1.2 Determining the DXL Algorithm that is configured on the Cardiograph

To determine the current DXL algorithm that is currently configured on your cardiograph, power up the cardiograph and navigate to the following screen:

"*Setup*" button on the Main screen → "*Configure Cardiograph Default Settings*" button → "*Algorithm/Pacing*" tab on the "*Default Cardiograph Settings*" screen.

a. Cardiographs installed with Software older than A.07.00

If the cardiograph has a software release older than A.07.00, the "*Algorithm/Pacing*" tab would look as follows:

NOTE: Only algorithm versions, "PH090A" and "PH100B", are present.

A customer may choose to stay with a software version that supports the older algorithm, PH090A, because the clinicians may prefer the results from the PH090A algorithm over the newer algorithms or the clinicians may have only approved the analysis of ECGs using the PH090A algorithm.

b. Cardiographs installed with Software, A.07.00, or Newer

If the cardiograph has a software release, A.07.00, or newer, the "*Algorithm/Pacing*" tab would look as follows:

NOTE: Only algorithm versions, "*PH100B*" and "*PH110C*", are present.

NOTE: PH100B and PH110C are the latest DXL algorithms, with multiple bug fixes and enhancements. Philips recommends that the customer use the latest PH110C algorithm.

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers

Step 2. Determining if the Cardiograph's Batteries need to be replaced before installing the Battery Management Software

Before installing one of the battery management software, you should first determine if the cardiograph's batteries need to be replaced. Please refer to Attachment 1, *Instructions for Checking Battery Status on your Cardiograph*.

WARNING: You should first determine if the cardiograph's batteries needs to be replaced before installing the new software.

After the upgrade, batteries that do not meet the performance requirements could render the cardiograph unusable.

However, the cardiograph will continue to function normally on AC power without batteries. After the cardiograph has been upgraded to the battery management software, the cardiograph will continue to function normally.

Step 2.1 Cardiograph's new Battery Charging Behavior

After the cardiograph is upgraded to one of the battery management software, the cardiograph will have the following new battery charging behavior:

   a.   It will no longer recharge its batteries when the power is off.
   b.   It will only charge its batteries during while it powered "*On*" and in "*Standby*" mode (A.K.A. Sleep Mode).

Automatic shutdown will be delayed until it has completed recharging to 90% power during "*Standby*" mode.

The information in this document is intended for customers/hospital biomedical engineers, Philips field engineers and field bench repair technicians, or authorized service providers

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URGENT - Medical Device Correction
Philips PageWriter TC Cardiographs (TC20/30/50/70)
User Maintenance of Lithium Ion Batteries

Dear Customer,

A problem has been detected with the Philips PageWriter TC Cardiographs (TC20/30/50/70), that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Philips has received a report in which the lithium ion battery in a PageWriter TC Cardiograph overheated and ignited. The battery had exceeded its 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 labeling 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. The Service Manual Addendum is included with this letter.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice. This notice has been reported to the appropriate Regulatory Agency.

Philips sincerely regrets the inconvenience that this may cause you. Your satisfaction with Philips' products and with our response to this issue is very important to us. Please contact Philips

0800 80 3000

with questions or concerns about this correction.

Sincerely,

Vivian Dai
Post Market Surveillance Manager

AFFECTED PRODUCTS	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.

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 Field Safety Notice.

PROBLEM DESCRIPTION	Philips has received a report in which the lithium ion battery in a Philips PageWriter TC cardiograph overheated and ignited. In this case, the battery had exceeded its life expectancy and should have been replaced when the number of charge-discharge cycles first exceeded 300 cycles or when the remaining battery capacity fell below 80% of that of a new battery.
	Although the Philips PageWriter TC Cardiographs can display actual information on the battery State of Health (SOH) and charge-discharge cycles, the existing labeling does not include full instructions on how to use this information to determine when to replace the battery.
HAZARD INVOLVED	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.

HOW TO IDENTIFY AFFECTED PRODUCTS	You can determine whether your device is affected by identifying the software revision. This can be performed by; <ol type="a"> - Locate and verify the Product Number of your PageWriter TC cardiograph found on the cover page of the *Instructions for Use* or on the back label of your cardiograph, and - Locate and verify the software revision on the PageWriter TC cardiograph's *System Utility* screen. To determine if your device is capable of battery operation, verify on the upper right hand corner of the cardiograph's display to see if the battery symbol is exhibited. TC20 TC30 TC50 TC70
ACTION TO BE TAKEN BY CUSTOMER / USER	Upon receipt of this notification, carefully read the enclosed PageWriter TC *Service Manual Addendum*. Promptly determine the number of cycles and the State of Health (SOH) on each of your affected Philips PageWriter TC cardiographs (TC20/30/50/70), as specified in the attached *Service Manual Addendum*. If the number of cycles is greater than 300 and/or if the SOH is less than 80%, this indicates that your battery has reached the end of its life and requires replacement. An approved replacement battery can be ordered using the standard Philips replacement processes. Details on how to replace the battery can be found in the PageWriter TC Cardiograph *Service Manual Addendum.* Once it is determined the battery is not in need of replacement, or once the battery is replaced, the PageWriter TC Cardiograph is safe to continuing using. In addition, review this information with all staff members who are responsible for device management of the Philips PageWriter TC cardiographs. Please store the below *Service Manual Addendum* with your Philips PageWriter TC cardiograph Service Manual documentation. Complete and return the response card provided.
ACTIONS PLANNED BY PHILIPS	Philips plans to release a customer installable, software update for PageWriter TC cardiograph (TC20/30/50/70) that will provide alerts to assist users in managing the battery replacement cycle. You will be notified when the customer installable software update is available.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**