

URGENT Field Safety Notice

**Philips BV Endura Release 2.3, BV Pulsera Release 2.3, Veradius Unity Release 2.1
Maximum System Component Surface Temperature**

November 2021

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.




Dear Customer,

A problem has been identified in the Philips BV Endura Release 2.3, BV Pulsera Release 2.3 and Veradius Unity Release 2.1 that could pose a potential risk for patients and users. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified that the Instructions for Use of these products do not specify the maximum surface temperature of the X-ray tank (assembly housing the X-ray tube, beam filter & cooling oil) and the image intensifier/detector of the system as required:

- X-ray Tank: Prolonged usage of the equipment may cause the surface temperature of the X-ray tank to reach up to 60° C which can cause burns if the X-ray tank comes into contact with the skin. While the X-Ray tank is not directly applied to patients, it may accidentally come in contact with patients as well as with users, when positioning the system. An anesthetized or unconscious patient will be unable to sense and react to the contact of the high temperature component. A Heat Indication Level Icon is shown on the information area of the C-arm stand or the status area of the C-arm stand touch screen. The table below shows how the Heat Indication Level Icons relate to the X-ray tank surface temperature:

Heat Icon Viewing Monitor		
		
Icon indicates that the X-ray tank is warm – this is a temperature of approximately 44° C	Icon indicates that the X-ray tank is very warm – this is a temperature of approximately 48° C	Icon indicates that the X-ray tank is hot – this is a temperature equal to or higher than 50° C

- Image detection subsystem: The temperature of the image intensifier/ detector surface may get up to 45 degrees (Celsius) after prolonged usage.

To date, Philips has not received any reports of adverse events associated with this issue.

2. Hazard/potential harm associated with the issue

If a patient/user gets in contact with the X-ray tank, the patient/user could sustain a burn. The degree of the burn will depend on the temperature of the X-ray tank and the time of contact:

Temperature	Degree of burn based on contact times		
	1 st degree burn	2 nd degree burn	3 rd degree burn
45°C	<2 hours	2 hours	3 hours
49°C	<8 minutes	8 minutes	10 minutes
51°C	<2 minutes	2 minutes	4.2 minutes
55°C	<17 seconds	17 seconds	30 seconds
60°C	<3 seconds	3 seconds	5 seconds

Table 1. Burn Exposure Chart (antiscald.com)

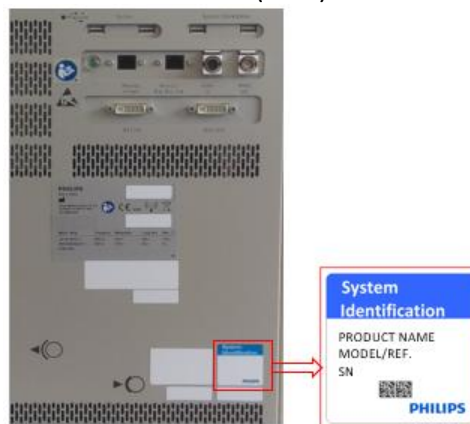
Degree of Burn	Effect
1st	Damage to outer layer of skin. Burn heals on its own.
2nd	First layer of skin burns through, and damage to the second layer of skin occurs. However, burn does not pass through to underlying tissues.
3rd	Involves damage to all layers of the skin.

Table 2. Skin Burn Degree definition

3. Affected products and how to identify them

Product Name	Release	Model Numbers
BV Endura	2.3	718075
BV Pulsera	2.3	718095
Veradius Unity	2.1	718132

The affected products can be identified by checking the model reference on the system identification label pasted on rear side of the Mobile View Station (MVS).



Picture 1 – Rear Side of Mobile View Station with label location

4. Actions that should be taken by the customer/user to prevent risks for patients or users

- Pay attention to the Heat Indication Level Icons shown in the Viewing Station to know the temperature of the X-Ray Tank.
- Follow the instructions provided in Annex I of this letter for a safe use of the system.
- Circulate this notice to all users of this device so that they are aware of the issue.
- Place this Field safety Notice with the documentation of the of your system
- Transfer this Field Safety notice within your organization or to any organization, if the affected devices have been transferred.
- Complete the enclosed Customer Reply Form and send it back to confirm that users have reviewed and understood this Urgent Field Safety Notice.

5. Actions planned by Philips IGT Systems to correct the problem

Philips is informing customers through this Urgent Field Safety Notice and providing the Addendum to the Instructions For Use of the BV Endura Release 2.3, BV Pulsera Release 2.3 and Veradius Unity Release 2.1 systems.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

Sincerely,

XXX



Philips' proprietary information. Unauthorized use is prohibited.

Annex I

Addendum to the Instructions for Use

Philips BV Endura Release 2.3, BV Pulsera Release 2.3 and Veradius Unity Release 2.1

This addendum provides information about:

- X-ray source assembly - Addition of note for maximum X-ray tank surface temperature.
- Image detection subsystem- Addition of note for maximum image intensifier/ detector surface temperature.

X-ray source assembly

(Section 9.2.4 of the Instructions for Use of BV Endura R 2.3, BV Pulsera R 2.3 and Veradius Unity R2.1)

The surface temperature of the X-ray tank can reach 60 degrees (Celsius) during prolonged X-ray activation. Take care to avoid contact between the patient/user and the x-ray tank, especially when the tank is above the patient table. Placing protective covers or drapes over the X-ray tank will further reduce the risk of direct contact between the X-ray tank and the patient.

Image detection subsystem

(Section 9.2.6 of the Instructions for Use of BV Endura R 2.3 and 9.2.7 of the Instructions for Use of BV Pulsera R 2.3 and Veradius Unity R2.1)

The maximum temperature observed on the image intensifier /detector surface is less than 45 degrees (Celsius) during prolonged usage.

Philips has provided this Addendum through Customer Information Letter Ref. 2021-IGT-MOS-001

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Addendum to the Instructions for Use, Philips BV Endura Release 2.3, BV Pulsera Release 2.3 and Veradius Unity Release 2.1, 2021-IGT-PUN-001

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Form, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/Postal Code/Country: _____

Customer Actions:

- Pay attention to the Heat Indication Level Icons shown in the Viewing Station to know the temperature of the X-Ray Tank.
- Follow the instructions provided in Annex I of this letter for a safe use of the system.
- Circulate this notice to all users of this device so that they are aware of the issue.
- Place this Field Safety Notice with the documentation of the of your system.
- Please transfer this Field Safety notice within your organization or to any organization, if the affected devices have been transferred.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly reviewed with all users who handle the Philips BV Endura Release 2.3, BV Pulsera Release 2.3 or Veradius Unity Release 2.1

Name of person completing this response form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date
(DD/MM/YYYY): _____

Please send this confirmation form to:
<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx">