

## URGENT Field Safety Notice

### Philips BV Vectra

#### Maximum System Component Surface Temperature

December 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,

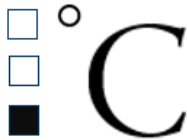


A problem has been identified in the Philips BV Vectra that could pose a potential risk for patients and users. This URGENT Field Safety Notice is intended to inform you about:

#### 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 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 50° C which can cause burns if it 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 console.

The table below shows how the Heat Indication Level Icons relate to the X-ray tank surface temperature:

Heat Indication Level		
		
X-ray tank warm – Level 1 Icon indicates that the X-ray tank is warm, and temperature is between 45° C to 50° C	X-ray tank warm – Level 2 Icon indicates that the X-ray tank is very warm, and temperature is between 50° C to 60° C	X-ray tank warm – Level 3 Icon indicates that the X-ray tank is hot, and temperature is higher than 60° C

- Image Intensifier: The temperature of the image intensifier surface may get up to 48 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 <sup>st</sup> degree burn	2 <sup>nd</sup> degree burn	3 <sup>rd</sup> 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

Table 1. Burn Exposure Chart (antiscald.com)

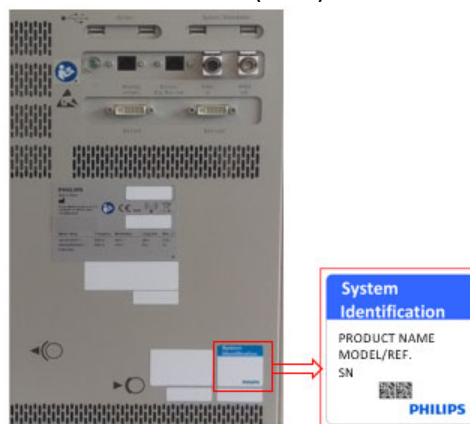
Degree of Burn	Effect
1st	Damage to outer layer of skin. Burn heals on its own.
2nd	First layer of skin burns through, and damage to the second layer of skin occurs. However, burn does not pass through to underlying tissues.
3rd	Involves damage to all layers of the skin.

Table 2. Skin Burn Degree definition

## 3. Affected products and how to identify them

Product Name	Model Numbers
BV Vectra	718400

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 Vectra 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:

**0800 80 3000**

Sincerely,

S. S. Srinivas N.  
Quality and Regulatory



Philips' proprietary information. Unauthorized use is prohibited.

**Annex I****Addendum to the Instructions for Use****Philips BV Vectra**

This addendum provides information about:

- X-ray source assembly - Addition of note for maximum X-ray tank surface temperature.
- Image intensifier and camera - Addition of note for maximum detector surface temperature.

**X-ray source assembly**

(Section 3.1.1 of the Instructions for Use of BV Vectra)

The surface temperature of the X-ray tank can reach 50 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 intensifier and camera**

(Section 3.1.3 of the Instructions for Use of BV Vectra)

The surface temperature of the Image Intensifier can reach 48 degrees (Celsius). Take care to avoid contact between the patient/user and the image intensifier, especially when the image intensifier is above the patient table. Placing protective covers or drapes over the image intensifier will further reduce the risk of direct contact between the image intensifier and the patient.

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 Vectra, 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/State/ZIP/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 Urgent Field Safety Notice with the documentation of the of your system.
- Please transfer this Urgent 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 Notice has been properly reviewed with all users who handle the Philips BV Vectra.

**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:

**dach.cs.pmplanning.gbs@philips.com**