PHILIPS

Field Safety Notice (FSN)

URGENT Field Safety Notice

Inadequate instructions for
Cleaning and Disinfecting the Esophageal/Rectal/Skin Temperature Probes

February 2022

Customer Name
Attn:
Street Address
City, State, Zip Code

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 instructions for use provided with the Philips Esophageal/Rectal/Skin Temperature Probes (autoclavable) that could pose a risk to patients.

These autoclavable, reusable probes are recommended for continuous temperature monitoring in humans. These probes are intended to use with a monitoring system designed to accept 400 series temperature probes and are used in conjunction with extension cables.

This Urgent Medical Device recall is to inform you about the following:

1. **The problem:**
   The Esophageal/Rectal/Skin Temperature Probe's Instructions for Use, (IFU), contain inadequate instructions related to the cleaning and disinfection process for the reusable probes. The IFU instructs the user to clean the product with disinfecting agents but does not specifically instruct the user to first clean with an enzymatic solution (detergent) before disinfecting or sterilizing. Cleaning the probes with a detergent allows for the physical removal of soil and other contaminants. Philips has received 2 complaints related to the cleaning and disinfection of the stated product. However, neither has been reported as being related to an adverse event.

   Effective cleaning mitigates soil transfer from one patient to another or between uses in a single patient, prevents accumulation of residual soil throughout the product's use life; and allows for successful, subsequent disinfection/sterilization steps.

2. **The hazard/harm associated with the issue:**

   a. Not cleaning the probes with a detergent prior to disinfection or sterilization may allow for the transfer of soil, debris, and other contaminants from one patient to another or between uses in a single patient and may cause the accumulation of residual debris throughout the product's use life, which may lead to subsequent infection.

3. Affected products and how to identify them:

Affected products are identified below in **Table 1.**

Table 1

Part #	Product Description	Revision # Number
453564635891	The IFU for the Autoclavable Temperature Probes (Applicable to: Esophageal/Rectal/Skin Temperature Probes model #s: 21075A, 21076A, 21078A, 989803162621, 989803162631, 989803162641)	A

4. Actions planned by Philips to correct the problem:

An IFU addendum (part# 453564978601) was created that provides updated instructions for cleaning, disinfection, and sterilization. This addendum is to be kept with the main IFU (part# 453564635891).

5. Actions that should be taken by the customer to prevent a risk to patients or users:

Prepare and soak in an enzymatic solution (detergent) to remove any debris prior to disinfection or sterilization.

To reduce risk of cross-infection always clean all probes before applying to a different patient. Esophageal/Rectal Probes must be cleaned and sterilized between patient use. To reduce risk of cross-infection always clean all probes (disinfect/sterilize accordingly) before applying to a different patient.

Skin probes can be cleaned and disinfected or cleaned and sterilized between patient use.

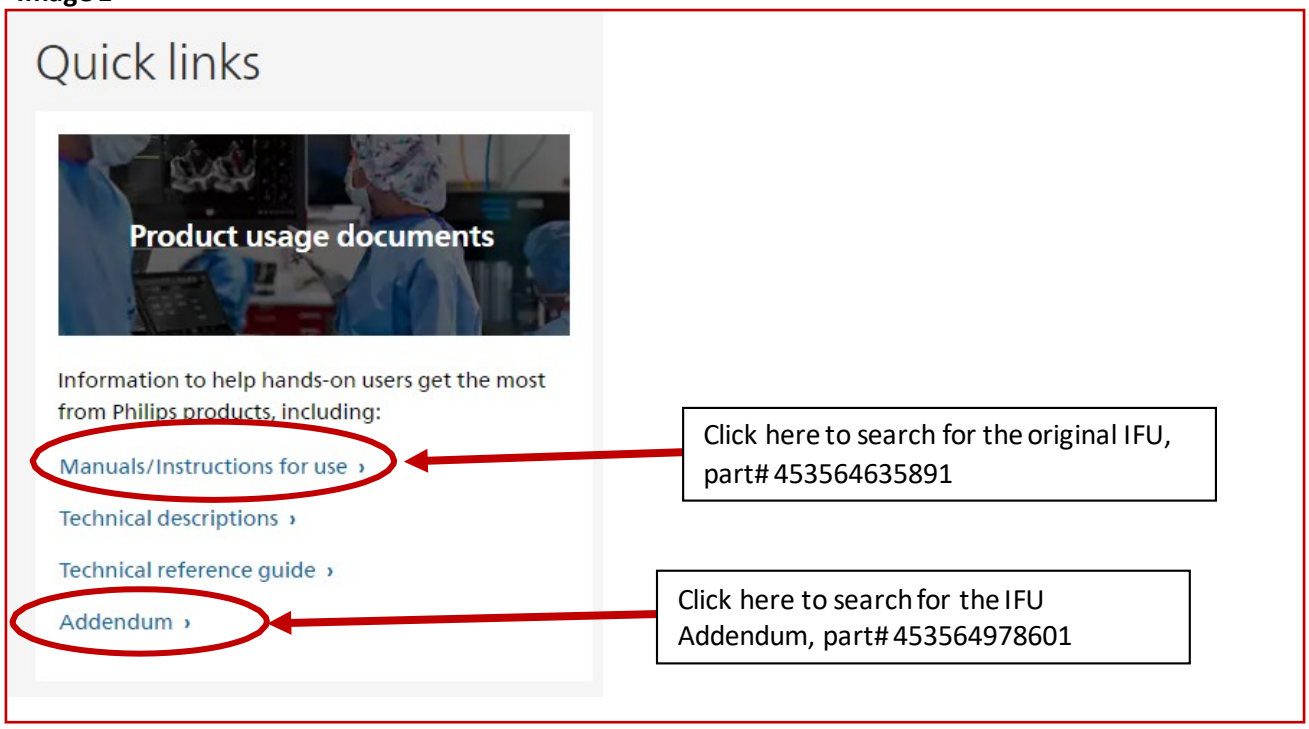
All users, including clinicians, should review the additional important cleaning, disinfecting and sterilizing details, by downloading the IFU Addendum (Part# 453564978601) from the Philips Resource Center at www.philips.com/ifu. Please note, if this link does not take you to the Philips Resource Center, you may need to use an alternative web/internet browser. To download the addendum, follow the instructions below.

Read and understand the IFU for this product. Please note, if the original IFU is not available, you may download it from the Philips Resource Center at www.philips.com/ifu by searching for the part number of the IFU (part# 453564635891). To download the full IFU, follow the instructions below:

In the Resource Center, scroll down until you see the Quick Links section as indicated below in **Image 1.**

1) Click on “Addendum” to search for the Addendum
2) Click “Manuals/Instructions for use” if you want to download the entire IFU.

Image 1



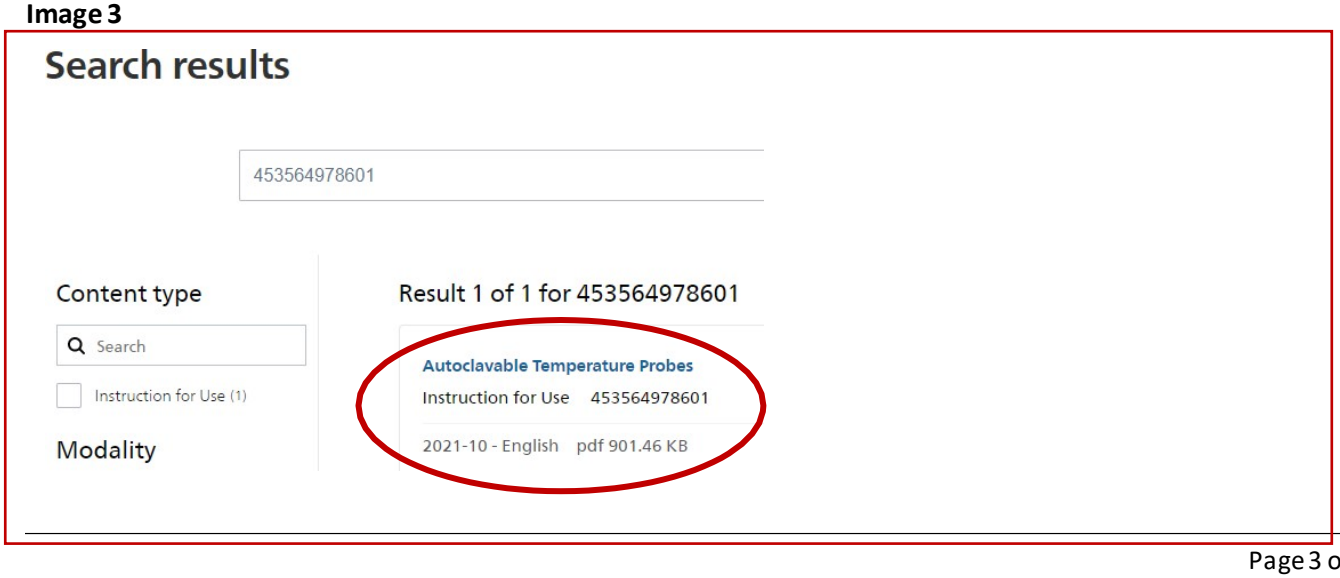
To search for a document, enter the part number into the search field, as shown below in **Image 2**, and hit return:

1) For the addendum the part number is 453564978601
2) For the Instructions for Use, the part number is 453564635891

Image 2

This will bring you to the page shown in **Image 3**. From this location, you can download and print the document.

Image 3



PHILIPS

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If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market>*

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to < *Markets to insert to whom the customer should report;>*.

Philips regrets any inconvenience caused by this problem.

Sincerely,

xxx
Medica! Consumables & Supplies
Philips Healthcare

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Inadequate instructions for Cleaning and Disinfecting the Esophageal/Rectal Temperature Probes

Instructions: Please complete and return this form promptly to Philips and no later than 30 days from receipt. Completing this form confirms receipt of the UREGNT FIELD SAFETY NOTICE understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

To ensure safe use of the product, all clinicians should:

Prepare and soak probes in an enzymatic solution (detergent) to remove any debris prior to disinfection or sterilization.

To reduce risk of cross-infection always clean all probes before applying to a different patient. Esophageal/Rectal Probes must be cleaned and sterilized between patient use. To reduce risk of cross-infection always clean all probes (disinfect/sterilize accordingly) before applying to a different patient.

Skin probes can be cleaned and disinfected or cleaned and sterilized between patient use.

All users, including clinicians should review additional important cleaning, disinfecting and sterilizing details, by downloading the IFU Addendum (Part# 453564978601) from the Philips Reference Center at www.philips.com/ifu. Please see instructions on pages 2-3.

Read and understand the main IFU for this product. Please note, if the original IFU is not available, you may download it from the Philips Reference Center at www.philips.com/ifu by searching for the part number of the IFU (part# 453564635891).

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Esophageal/Rectal Temperature Probes (autoclavable)

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please email this completed form to Philips at: *<Reply form return details to be completed by the KM / country>*