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URGENT – Field Safety Notice
Philips V60/V60 Plus Ventilators

Information regarding High Flow Therapy Option

Dear Customer,

A problem has been detected in the Philips V60/V60 Plus ventilators that could pose a risk to patients or users. All units with High Flow Therapy option enabled are impacted. These ventilators include all V60 Plus ventilators and all V60 ventilators upgraded to enable High Flow Therapy (software version 3.00 and 3.10). 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 to prevent risks for patients or users, and
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and effective 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.

The V60/V60 Plus ventilators equipped with High Flow Therapy option (Software Version 3.00 and Software Version 3.10) are designed with a safety mechanism to limit the amount of pressure that can be delivered to the patient when the ventilator is operating in High Flow Therapy. If the high flow therapy pressure reaches the maximum limit, the ventilator will sound the “Cannot Reach Target Flow” (CRTF) alarm and will reduce the pressure, which will simultaneously decrease the flow rate. In these cases, where flow rate decreases due to device reaching the maximum pressure, patients may experience oxygen desaturation, increased work of breathing and respiratory distress resulting in clinical deterioration needing escalation in medical treatment.

If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips regrets any inconveniences caused by this problem.

Sincerely,

David McGrath
Head of Quality and Regulatory, HRC

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AFFECTED PRODUCTS	Respironics California, LLC V60/V60 Plus ventilators equipped with High Flow Therapy option (Software Version 3.00 or Software Version 3.10)
PROBLEM DESCRIPTION	The V60/V60 Plus ventilators equipped with High Flow Therapy option (Software Version 3.00 and Software Version 3.10) are designed with a safety mechanism to limit the amount of pressure that can be delivered to the patient when the ventilator is operating in High Flow Therapy. In situations where the high flow therapy pressure reaches the maximum limit, the ventilator will sound a low priority, "Cannot Reach Target Flow (CRTF)" alarm and reduces the pressure – which also simultaneously decreases the flow rate to a level below what was set by the clinician for as long as the condition persists. The "Cannot Reach Target Flow" alarm can be identified by the sound of a one (1) second "beep" at a minimum of 55dBA and will pulsate every 20 seconds. When the alarm sounds, the main screen of the ventilator will display "Cannot Reach Target Flow". In the event of a CRTF condition, an audible alarm may also be broadcasted via institutional/central alarm notification systems (where available) and via the screen display of the device. The Philips Remote/Nurse Call alarm will only provide audible notification for high priority and inoperative condition alarms. While using a High Flow Nasal Cannula, potential factors that could contribute but not limited to reaching the maximum high flow therapy pressure limit are: 1. compression of the cannula, 2. kinks in the tubing, 3. mucus plug blocking the flow, 4. patient movement, 5. positioning, 6. coughing, 7. blockage in the gas pathway, 8. and the inappropriate size of the nasal cannula for the flow setting.
HAZARD INVOLVED	When V60 ventilators with HFT option upgrade and V60 Plus ventilators reach the maximum high flow therapy pressure limit, the CRTF alarm will sound and the flow rate will decrease in order to decrease the pressure. In some cases, patients may experience oxygen desaturation as a result of the decrease in flow rate, which can be characterized as moderate or severe hypoxemia.
ACTION TO BE TAKEN BY CUSTOMER / USER	When administering HFT via HFNC the following action must be taken: (1) Monitor the patient's SpO2 continuously; (2) All patients that are dependent on supplemental oxygen, and at risk of clinical deterioration should be under constant and close monitoring by the clinician to prevent dangerous drops in blood oxygen levels, work of breathing and respiratory distress and resulting escalation in medical treatment (3) Respond to all alarms urgently, regardless of alarm priority; (4) If the patient cannot be constantly and closely monitored by the clinician, do not use HFT In addition; (5) Refer to and follow the attached user manual addendum titled "V60 Plus User Manual Addendum: High-Flow Therapy Safety and Alarm

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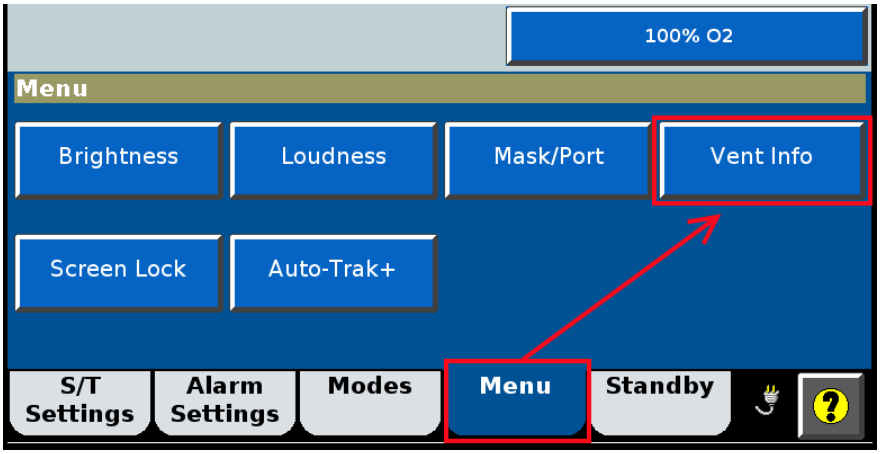
	Features". This user manual addendum provides additional technical details about the CRTF alarm functionality. For additional information and education regarding this issue, please watch the "Understanding HFT" video located at the following link https://www.learningconnection.philips.com/en/V60_V60Plus-education. Complete, sign, and return the Acknowledgment and Receipt Form at the end of this letter.
ACTIONS PLANNED BY PHILIPS	Philips is releasing this Field Safety Notice Letter to make customers aware of the potential High Flow Therapy issues described above and how to address them. The user manual addendum attached to this letter will be included with new V60 Plus Ventilators, and V60 ventilator HFT Field Upgrade Kit. This addendum is also available at www.philips.com/hrcmanuals under the V60/V60 plus link titled "V60 Plus User Manual Addendum - High-Flow Therapy Safety and Alarm Features". Philips is developing a technical correction and will notify customers when the correction is available.
HOW TO IDENTIFY AFFECTED PRODUCTS	All units with High Flow Therapy option enabled are impacted. These ventilators include all V60 Plus ventilators and all V60 ventilators upgraded to enable High Flow Therapy (software version 3.00 and 3.10). Below are two methods in identifying affected ventilators. **Method 1. Check the ventilator for the HFT enabled option.** The review of options installed on the ventilator may be viewed on the display while the ventilator is in operation. Select the **Menu** tab at the bottom of the screen and then select **Vent Info**. (See **Figures 1** and **2**) 

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FIGURE 1: ACCESSING INSTALLED SOFTWARE OPTIONS LISTING FROM ON-SCREEN DISPLAY

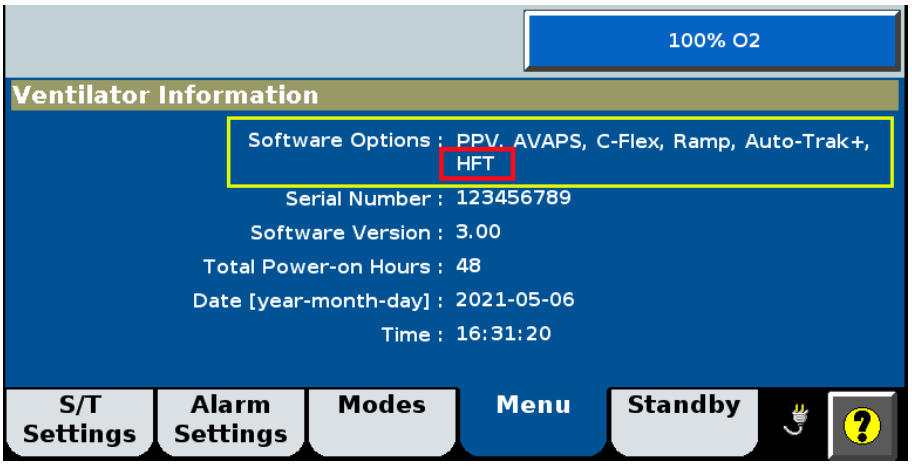

FIGURE 2: LISTING OF ACTIVE OPTIONS INSTALLED AS VIEWED FROM THE VENT INFO SCREEN

Method 2. In the diagnostics mode, check the enabled Software Options listing for HFT. Only those ventilators with HFT (High Flow Therapy) listed are affected.

WARNING: To prevent possible patient injury, do not enter the diagnostic mode while a patient is connected to the ventilator. Ensure that the patient is disconnected from the ventilator being serviced and that the patient is receiving adequate respiratory support from another device, if needed, before proceeding.

1. Press and hold the Accept button on the upper right of the device;
2. While continuing to hold the navigation ring Accept button, press the On/Shutdown button on the user interface;
3. Within 5 seconds of the power up, release both buttons and then press the navigation ring Accept button again to enter the Diagnostics menu (Figure 3).

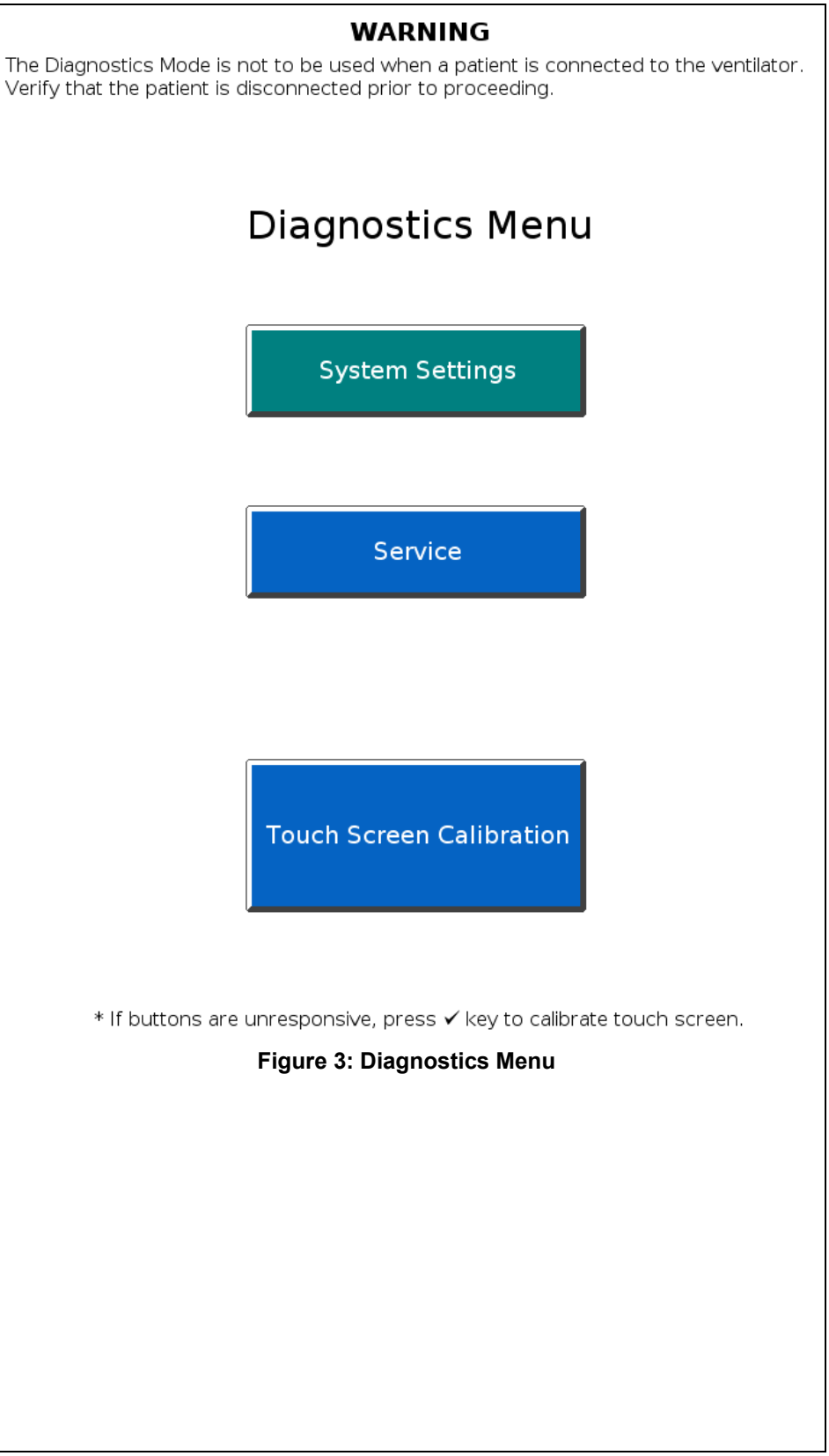

Figure 3: Diagnostics Menu

4. Select the **Service** key. (Figure 4)

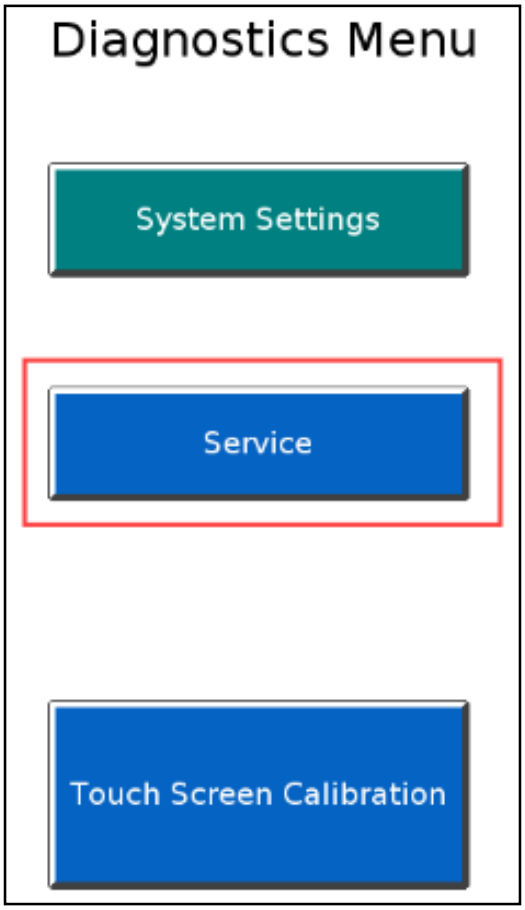

Figure 4: Select Service from the Menu Options

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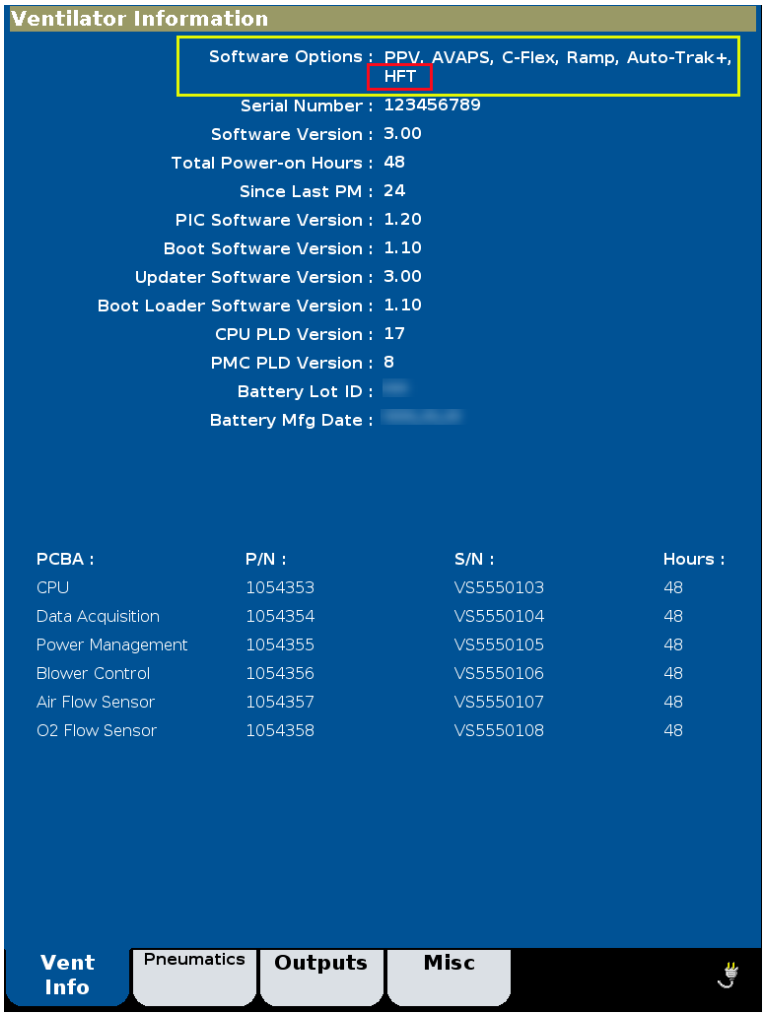
	5. From the **Service** screen (Figure 5), review the **Vent Info** tab information.  **Figure 5: Vent Info tab. Refer to the Software Options list at top of the Vent Info Screen** 6. In the **Software Options:** section of the **Vent Info** screen, look for the option HFT within the list. If HFT option is in the listed, the ventilator is affected.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

URGENT – Field Safety Notice
Philips V60/V60 Plus Ventilators

Information regarding the High Flow Therapy Option

Acknowledgement and Receipt Form
Response is Required

Customer Information:

Form Completed By & Title:	
Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address:	
City, State, Zip Code:	
Country:	

I have read and understand the instructions provided in the notification letter. Yes ☐ No ☐

Signature: _____ Date: _____

Please return the completed and signed reply form to:

dach.cs.pmplanning.gbs@philips.com

If you experience difficulty in carrying out the instructions contained in this communication, contact your local Philips representative:

0800 80 3000