Patient address/ details

# XXXXXX trust name ventilation service – safety alert

Dear **Name**,

# We are writing to all patients under the care of our service who are using a Philips A40, A30 or A40 pro device. There have been two safety alerts regarding these machines released in the UK. The safety alerts are enclosed but we have summarised the key points:

**Safety Alert 1 (Reference: 2023-CC-SRC-039 Revision B)**

**What are the issues and when do they occur?**

There have been reported incidents of people’s ventilators alarming with the message “Ventilator Inoperative.” If it occurs, ventilation will stop, and a constant beeping alarm will sound. The alarm silence button will flash red, and a message will appear on the device screen displaying “Ventilator Inoperative” (shown in appendix C of the safety alert with reference 2023-CC-SRC-039 Revision B).

This is concerning and we are working quickly to put a safe plan in place.

The alert does outline that the likelihood of this issue happening is low with 888 reports globally from 100 million uses (0.0008%) however this has resulted in ten (10) allegations of serious injury, and seven (7) cases reported a patient death associated to this issue.

**Trust next steps**

Set out key actions agreed at XXXX Trust/organisation

For example: We will review all our users and anyone needing to use a ventilator more than 14 hours per day will be contacted to ensure they have a spare machine. If people are using it less than 14 hours, we will arrange for same day replacement if the alarm were to occur.

Provide contact details and any hotline / helpline patients and carers can contact. If your usage / dependency has increased….

# Field Safety Notice 2 (Reference: 2023-CC-SRC-042)

**What the problem is and under what circumstances can it occur?**

There have been reports of a “High Internal Oxygen” alarm occurring. This alarm is intended to detect oxygen accumulation within the ventilator that may occur while supplemental oxygen is being provided to a patient. This sensor can malfunction causing an alarm where there is no elevated oxygen level. The device will continue to provide therapy while the alarm is addressed (in accordance with the User Manual).

This issue can manifest itself in the following forms:

* the device continuously raises the “High Internal Oxygen” alarm, while supplemental oxygen is connected
* the device continuously raises the “High Internal Oxygen” alarm, while supplemental oxygen is not connected

To date, there have been no instances of patient harm or injury reported relating to this alert.

# Actions for patients and carers to take (only required if the issue happens as described):

**If either of the issues happen as described in the alerts and you have a spare machine,** please swap to your spare machine, and contact the home ventilation service immediately so we can arrange for a replacement machine. Between 0800 and 1700 Monday to Friday, please contact xxxxxx xxxxxx, outside of these hours please contact the enhanced high care ward at xxxxxxxx Hospital on xxxxxxxx xxxxxxxx.

**If the issue happens as described in the alert but you do not have a back-up machine**- call the numbers above so we can arrange to get another machine to you, whist waiting you may be able to perform a hard reboot to temporarily restore machine function (as described in appendix C (for ref: 2023-CC-SRC-042) / appendix D (for ref: 2023-CC-SRC-039 Revision B) in the safety alerts which also have pictures). The steps to do this are also included below (without pictures):

1. If a Ventilator Inoperative alarm occurs, the display screen turns red, and the Ventilator Inoperative message appears on-screen. Power off the therapy device.

* Press the Start/Stop button.
* If the ventilator display is operational, the “Power Off” confirmation screen will appear, as shown below.
* Select the button on the right side, “Yes” to shut off the device and silence the alarm.

1. Unplug the power cord from the wall or from the device itself.
2. Remove the battery from the therapy device.

# NHS England logo

# Detachable battery pack

* If the detachable battery pack is used, open the battery compartment at top of the detachable battery module accessory.
* Lift battery out using release lever on top of the battery.

1. Leave the battery disconnected from the ventilator for at least 30 seconds.
2. Reconnect the applicable battery in use.
3. Plug the power cord in to the wall or to the therapy device itself.
4. Power on the device by pressing the Start/Stop button.
5. Once the ventilator powers back on, therapy may be restarted.

If you have any queries or concerns and would like to discuss this further, please **contact us on [xxxxxx xxxxx].**

Once we have more information from the supplier as to next steps, we will write to you again with an update.

Yours Sincerely, xxxx

**Lead clinician details**