

Philips Healthcare

Home Healthcare Solutions

-1/3-

FSN86300028 2008 APR 29

URGENT – Field Safety Notice Motiva Remote Patient Management System

Weight measurements may not transmit as expected

Dear Customer,

A problem has been detected in the Philips Motiva Remote Patient Management system that, if it were to re-occur, could pose a risk for patients or users. 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 in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

If you need any further information or support concerning this issue, please contact your local Motiva Support Organization.

UK - Capex +44 1226 208877, Spain – Joan Valenzuela: +34 696 48 7083, NL – Nick Ebbers: +31 610 362 595, Germany – Udo Goldbach: +49 7031 463 2083.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,


Philips Home Healthcare Solutions Quality & Regulatory Director



Philips Healthcare

Home Healthcare Solutions

-2/3-

FSN86300028 2008 APR 29

AFFECTED PRODUCTS	Motiva Remote Patient Management System, Model 453564036921. Software Version: SATURN_1_1b_20070417/SATURN_1_1b_20070417/04.02bmotiva_saturn/SA Serial Numbers/MAC Address: All devices distributed.
PROBLEM DESCRIPTION	Under specific circumstances, the Motiva Set Top Box does not transmit weight measurement values as expected. This issue occurs if the patient is using a scale, as well as an additional measurement device (e.g. blood pressure unit) and regularly takes Motiva measurements over a long period of time - approximately one year. Patients can recognize this issue, if after having taken their measurements, the weight value does not show up in the Motiva measurement screen on the patient's TV set. Care providers should immediately contact Philips if a weight measurement is not reported in the Motiva clinical software, despite the fact that the patient has taken the measurement.
HAZARD INVOLVED	The missing weight measurement does not represent a direct hazard to the patient. It can however impact the care provider's ability to trend weight values over periods of time. Note: Motiva is not an emergency response system, and patients are always instructed to contact their existing emergency support organization if they need immediate medical assistance.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Set Top Boxes in distribution exhibit the weight transmission problem, after the boxes have been in use for approximately one year. These boxes have an Alwell label on the front cover (left upper corner) of the box.
ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none">• Care providers are requested to inform their patients (e.g. via a Motiva message), that if a weight measurement is not reported on the patient's TV, despite the fact that the measurement has been taken, the patient should immediately inform the care provider, who in turn will contact the local Motiva Support organization.• If the care provider observes that a weight measurement has been taken but is not being displayed on the Motiva clinical user interface software, they should immediately contact the local Motiva Support organization.

PHILIPS

Philips Healthcare

Home Healthcare Solutions

-3/3-

FSN86300028 2008 APR 29

ACTIONS PLANNED BY PHILIPS	<ul style="list-style-type: none">• Philips has established a process to proactively scan all Set Top Boxes and assess if the relevant file in the STB is reaching its capacity limit. If the file is reaching its capacity limit, a service engineer will be dispatched to either replace the STB or clear the file.• Philips is in the process of introducing a new Set Top Box that will replace all currently deployed units. The exchange process is expected to start in June 2008. Care Providers will be contacted by Philips to coordinate the exchange once the new Set Top Boxes are available.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Motiva Support organization.</p> <p>UK - Capex +44 1226 208877, Spain – Joan Valenzuela: +34 696 48 7083, NL – Nick Ebbers: +31 610 362 595, Germany – Udo Goldbach: +49 7031 463 2083.</p>

