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The Difference in Clinical Grade™

ABPM BP+Vitals BP Cuffs OEM NIBP Stress BP Vet BP

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Date 16 April 2020

URGENT: MEDICAL DEVICE RECALL

Oscar 2, Model 250

Attention to Customer:

Kardian D.O.O
Ulica Hindlova 2/9,
Zagreb 10000
Croatia

Dear Customer,

Summary

Purpose of this letter: SunTech, Inc. is voluntarily recalling some Oscar 2, Model 250 systems shipped between November 21st 2019 and February 19th 2020.

Reason for Voluntary Recall: The device display, when activated, can show an incorrect decimal point when the blood pressure reading is a three-digit number and the unit of measure is set for “mmHg.”

Correct display

Incorrect display shows additional decimal places and kPa symbol.

Risk to Health: This failure should not impact risk for users or patients in any way.

Actions to be taken by the Customer/User: Follow provided correction instructions below and download service tool at https://www.suntechmed.com/oscar2-display-update-request**Oscar 2**

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Intended Use

The Oscar 2 System is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro™, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

Optionally, the Oscar 2 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff.

It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects).
Bluetooth wireless connectivity is available as an option.

Reason for the Voluntary Recall:

The display on the device, when activated, can show an incorrect decimal point when the blood pressure reading is a three-digit number and the unit of measure is set for “mmHg.” For example, “120” will be displayed as “12.0”. In addition, both unit of measure indicators are displayed simultaneously. (“mmHg” and “kPa”)

The data displayed in the AccuWin Pro software and subsequent reports is correct. This only impacts the data viewed on the device display while readings are being collected.

- **Frequency of failures and complaints:** We are aware of 1 complaint for this issue and have determine that this occurs in systems manufactured from November 21, 2019 to February 19 2020.

- **Magnitude of the error, if applicable:** This problem results in the unit displaying erroneous values if the display is turned on during the 24-hour BP study. The value of the blood pressure is off by a factor of 10.

- **Adverse events:** There have been no reports of injury or death related to this issue.

Risk to Health:

This failure should not impact users or patients in any way. The data within the device and the reporting software is correct and valid. The reports created from the software are correct and

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valid. The Accuwin Pro software display and printed reports are the data points that the physician uses to diagnose the patient. In most cases, the display on the unit is turned off so the BP data is not visible to the patient during the blood pressure study. At times when the display is active and visible to the patient or practitioner, there is minimal risk of injury and the display error has no impact on user activity or decisions.

How to recognize that the device may fail.
Any time the device is displaying a blood pressure element that is three digits long, the erroneous decimal point will be displayed.

Actions to be taken by the Customer:

Mitigation (what users can do until device is corrected)
Physicians and nurses are encouraged to ignore the readings on the device display and to continue to focus on the Accuwin Pro data for diagnosis. Best practice is to "disable" the device display during unit configuration and to instruct the patient to ignore any data that may be visible on the display. If you do these steps, you may continue to use your device without any issues until it can be corrected.

Correction (how to correct the device display)
When you are ready to correct your device:

- Download service tool at https://www.suntechmed.com/oscar2-display-update-request
- Customers should contact SunTech to confirm the configuration has been corrected at recallcoordinator@suntechmed.com and provide:
    - Contact person
    - Company
    - Serial numbers of corrected devices

Please sign and return the attached form that confirms you have received this letter and are taking the recommended actions.

The letter can be returned by email to recallcoordinator@suntechmed.com

Or can be sent by mail to:

Recall Coordinator
SunTech Medical, Inc.
507 Airport Blvd, suite 117
Morrisville, NC 27560-8200

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Product and Distribution Information:

Our records show we have distributed the following devices to you:

Product	Part Number	Serial Number	Distribution Date
Oscar 2	99-0133-10	SN:00116330	31-Jan-2020
Oscar 2	99-0133-10	SN:00118366	25-Jan-2020
Oscar 2	99-0133-10	SN:00118371	25-Jan-2020
Oscar 2	99-0133-10	SN:00118390	25-Jan-2020
Oscar 2	99-0133-10	SN:00118422	25-Jan-2020
Oscar 2	99-0133-10	SN:00118555	25-Jan-2020
Oscar 2	99-0133-10	SN:00118565	25-Jan-2020
Oscar 2	99-0133-10	SN:00118721	25-Jan-2020
Oscar 2	99-0133-10	SN:00118928	31-Jan-2020
Oscar 2	99-0133-10	SN:00125434	25-Jan-2020
Oscar 2	99-0133-10	SN:00127696	25-Jan-2020

OTHER INFORMATION:

- If you have any questions, please contact SunTech Medical
  - Email: recall coordinator@suntechmed.com
  - Phone: +1-800-421-8626 or 919-654-6128
- Attachments
  - Acknowledgement form

Authorized by:

Name: Charles Setzer

Title: Senior RA/QA Analyst / Recall Coordinator

Contact Information: Monday through Friday 8:00 AM to 5:00 PM Eastern Time
Phone: +1-919-654-2300 ext 128
Toll Free: +1-800-421-8626 ext 128
Email: recallcoordinator@suntechmed.com

Adverse events or quality problems experienced with the use of this product may be reported to your government's Competent Authority, such as:

- The US FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
- United Kingdom, Medicines and Healthcare products Regulatory Agency (MHRA), Yellow Care Scheme online
- France, French Ministry of Health, Signalement-sante.gouv.fr.