

SunTech Medical

December 20, 2019

URGENT: MEDICAL DEVICE RECALL

Bravo Mini, Agilis Mini, NBP On

Dear Device Customer/Distributor,

(1) Purpose of this letter

The purpose of this letter is to advise you that SunTech Medical is voluntarily recalling Bravo Mini, Agilis Mini and NBP One devices, all model 250D.

The Bravo Mini, Agilis Mini and NBP One Systems, Model 250D, are non-invasive oscillometric ambulatory blood pressure monitors that are intended to be used with AccuWin 4 SE, Agilis Mini Software and NBP One software, PC-based computer programs for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. They are 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 systems are only for measurement, recording, and display to assist a licensed physician in making a diagnosis.

Serious injuries could occur due to the failure mode associated with this recall. We have reports of 0 deaths and of 0 serious injuries.

(2) Reason for the Voluntary Recall:

We are aware of 2 complaints in which the batteries in the device overheated to the point that the case was deformed. This situation can occur when the batteries are installed into the device in the incorrect polarity. This situation causes an electrical short circuit and the batteries begin

to overheat. Within two to three minutes, the batteries can reach a temperature at which thermal injuries are possible. This failure mode can occur in all Bravo Mini, Agilis Mini and NBP One devices, model 250D, with serial numbers “00124827” and below. No injuries have been reported at the time of this writing.

(3) Risk to Health:

4a) If the batteries are installed in the reverse polarity, within two to three minutes, depending on the type of batteries used, the temperature of the battery and associated components such as the battery contacts, can reach temperatures in excess of 140 degrees F. Burns to fingers and hands are possible for the patient and/or health care provider.

4b) “How to recognize that the device may fail.” If the unit does not power on successfully when the batteries are installed, this may be an indication that the batteries are in the reverse polarity. Should this occur, immediately remove the batteries from the device. Do not use. Please return to your distributor.

(4) Actions to be taken by the Customer/User:

Please discontinue use of the device immediately.
Please send an e-mail to RecallCoordinator@suntechmed.com acknowledging the receipt of this letter. Include the serial number(s) of the device(s) you have.
A representative of SunTech or your distributor will be in contact with you with further instructions once we have a resolution plan in place.

(5) Product and Distribution Information:

Product and Distribution Information Table

Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Serial Number	Manufacturing/Distribution Dates	Quantity
Bravo Mini 10840935108429	99-0233-00 (Model 250D)	All	24SEP2019 - 23NOV2019	100
Agilis Mini 10840935108740	99-0233-40 (Model 250D)	All	29AUG2019 – 23NOV2019	152
NBP One 10840935108702	99-0233-10 (NBP-ONE-K-00-01) (Model 250D)	All	16JUL2019 – 24OCT2019	132



ABPM



BP+Vtal



BPOufs



IEM NIBI



StressBP



VetBP

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(6) Type of Action by the Company:

In the short term, SunTech plans to replace all units that have been distributed to end users with Oscar 2 systems.

SunTech is developing a new battery contact configuration that will eliminate the problem. Development and validation activities are still underway. We anticipate that a new battery contact design will be available in the coming weeks. This should make rework of all existing units possible, eliminating the hazard. Once production resumes, all units produced will use the new battery contact design.

SunTech is still evaluating long term activities.

- Failure investigations have confirmed the hazard. When batteries are inserted in the reverse polarity, the batteries begin to overheat and will reach hazardous temperatures in 2-3 minutes depending on the type of batteries used. High amperage rechargeable batteries have shown to overheat the quickest.

(7) OTHER INFORMATION:

- Please contact our Recall Coordinator by email at recallcoordinator@suntechmed.com or by phone at 919-654-6128 with any questions.
- Attachments:
 - Acknowledgement Form
 - Product Replacement Forms

Authorized by:

Name:

Signature: xxx

Title: xxx

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.