



June 14, 2019

Urgent Field Safety Notice

Solar Blue
June 14, 2019
Field Safety Corrective Action

Attention: [insert customer name/organization/address]

Dear Customer/Distributor,
This is to inform you that a product correction is being initiated involving the following products.

Details on affected devices:

Solar Blue

U3-1 Solar Blue, Table top
Sales Order(s): [insert SO #'s]
Serial number(s): [insert solar blue device SN]

U3-3 Solar Blue, Laptop integrated,
Sales order(s): [insert SO #'s]
Serial numbers(s): [insert solar blue device SN]

Description of the problem:

This field safety corrective action is being initiated to address a manufacturing with the power supply unit that has been delivered with the device(s). The power supply unit (identified as 'PS-SBL' in the User's Manual) is not correctly labeled, and insulation material used at the low voltage DC end does not meet all applicable flammability rating requirements. Although unlikely, use of this product may lead to a potential fire hazard. While the hazard is unexpected during the lifetime of the power supply, action should be taken to mitigate the risk until your power supply can be replaced.

Medical Measurement Systems B.V.
Colosseum 25, 7521 PV Enschede
P.O. Box 580, 7500 AN Enschede
The Netherlands

Tel.: +31-53-480 37 00
Fax: +31-53-480 37 01
E-mail: info@laborie.com
Internet: www.mmsinternational.com
Internet: www.laborie.com

Vat no.: NL 8019.30.200.B01
K.v.K. no.: Enschede 06070224
IBAN no. €: NL61 INGB 0665 1241 39
IBAN no. \$: NL32 INGB 0021 7998 06
BIC no.: INGBNL2A



Advise on action to be taken by the user:

- **For distributors:**

Immediately examine your inventory and quarantine product subject to recall if that product is not yet at a customer facility. In addition, please identify your customers and notify them immediately of this correction and the steps to mitigate according to the end-user actions listed below. Your notification to your customers may be enhanced by including a copy of this recall notification letter. You will receive a Return Material Authorization for the affected power supply unit(s) and a free of charge Sales Order for new power supply unit(s) within the next 60 days, along with instructions on how to replace the power supplies in the field. You must replace all units at end customers within the next 120 days. We are asking for you to send back the deficient unit(s) or provide evidence of the field correction for the units sold to you.

- **For end-users:**

We advise to not use the product without supervision and to unplug the power supply from the wall socket when not in use.

You will be contacted by the manufacturer or your dealer for replacement of the deficient power supply unit(s) within the next 120 days; however, you can contact Laborie/MMS customer care with any questions, concerns or problems (see contact reference person details below).

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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Acknowledgement Form:

Please complete and return the appended Acknowledgement Form as soon as possible by postal mail or as PDF-attached by email

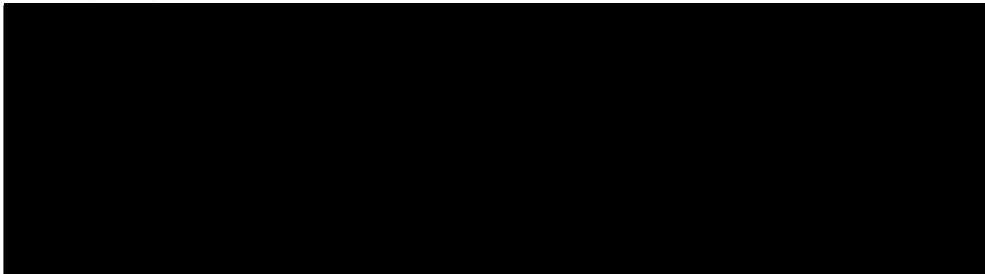
Contact reference person:

Laborie/MMS Customer Care
Medical Measurement Systems B.V.
Colosseum 25
7521 PV Enschede
The Netherlands

[insert customer care person's Name / Phone Number / Email]

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Your assistance is appreciated to prevent any potential harm.



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Acknowledgement Form

Field Safety Notice:

Solar Blue

June 14, 2019

Field Safety Corrective Action

Customer:

Company / institution:

Address:

ZIP code

City:

Country:

Confirmation by customer:

The undersigned herewith confirms to have received, read and understood this Field Safety Notice.

Name:

Signature:

Function/Title:

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