

**Field Safety Notice**  
2020-01-02

**Urgent Field Safety Notice to the market**

**Doc ID ref # 34453**

**Please note that this information must be sent to all end users having any of the below listed instruments.**

**Medonic M-Series/M32 Autoloader with Automatic Barcode Reader**

Boule Medical is sending this letter regarding the Medonic M-Series/M32 Autoloader part number mentioned below.

Part number	Description	Part number	Description
1400011	M-series M16S BD ABR	1400075	M-series M16S BD ABR US
1400012	M-series M20S BD ABR	1420026	Medonic M-series M32S BD AR
1400068	M-series M20S Sarstedt ABR	1420028	Medonic M-series M32S SA AR

<b>ISSUE:</b>	<ul style="list-style-type: none"><li>As a result of internal investigations, it has been determined there is an issue of a mix-up of autosampler tube positions with a possibility of misidentification of sample results.</li><li>A risk of operator injury from an exposed aspiration needle.</li></ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"><li>The misidentification of the sample may impact patient treatment based on unexpected results.</li><li>Exposure to the aspiration needle may result in injury or potential exposure to a bloodborne pathogen.</li></ul>
<b>ACTION:</b>	<ul style="list-style-type: none"><li>Ensure all samples processed on the autosampler are identified by a unique barcode label on the sample tube.</li><li>If barcodes are not available to be placed on the sample tube, do not utilize the sample wheel and process samples in the open tube mode.</li><li>Ensure that all users follow the Operators Manual, section Analyzing the Sample (Autoloader), instructing users to not touch the sample wheel or samples during operation.</li></ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>Boule is working on the corrective action.</li></ul>

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please indicate on the returned Acknowledgement form.

So that we are assured you have received this Field Safety Notice, please respond within 10 days by returning the Acknowledgement Form included with this notice as directed by postal mail or email. If you have any questions regarding this notice, please contact [regulatory@boule.com](mailto:regulatory@boule.com). We apologize for the inconvenience that this caused your laboratory.

## *Field Safety Notice*

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**Urgent Field Safety Notice to the market**

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**Please note that this information must be sent to all end users having any of the below listed instruments.**

### **Swelab Alfa/Alfa Plus Sampler instruments with Automatic Barcode Reader**

Boule Medical is sending this letter regarding the Swelab Alfa/Alfa Plus Sampler part number mentioned below.

Part number	Description	Part number	Description
1400023	Alfa S BD 16p CL MCI QC ABR	1400072	Alfa S Sarst 20p CL MCI QC ABR
1400024	Alfa S BD 20p CL MCI QC ABR	1420046	Swelab Alfa Plus Sampler BD AR
1400071	Alfa S Sarst 16p CL MCI QC ABR	1420048	Swelab Alfa Plus Sampler SA AR

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>As a result of internal investigations, it has been determined there is an issue of a mix-up of autosampler tube positions with a possibility of misidentification of sample results.</li> <li>A risk of operator injury from an exposed aspiration needle.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>The misidentification of the sample may impact patient treatment based on unexpected results.</li> <li>Exposure to the aspiration needle may result in injury or potential exposure to a bloodborne pathogen.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Ensure all samples processed on the autosampler are identified by a unique barcode label on the sample tube.</li> <li>If barcodes are not available to be placed on the sample tube, do not utilize the sample wheel and process samples in the open tube mode.</li> <li>Ensure that all users follow the Operators Manual, section Analyzing the Sample (Autoloader), instructing users to not touch the sample wheel or samples during operation.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Boule is working on the corrective action.</li> </ul>

Please share this information with any laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please indicate on the returned Acknowledgement form.

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