

## Voluntary Recall Notice

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Medical Measurement Systems B.V.  
Colosseum 25  
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The Netherlands  
[www.laborie.com](http://www.laborie.com)

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February 28, 2023

Dear Valued Customers/Importers/Distributors,

This is to inform you that a voluntary product recall is being initiated involving the Flowstar Thermal Printer.

**Affected products:**

The Laborie/MMS Flowstar (U2-1) - see Table 1 below for the specific serial numbers.

**Description of the problem:**

This communication is being issued in response to 3 complaints involving a newly identified software issue. When two measurements are performed in a row without turning off the device where the second measurement has a shorter duration and a smaller volume than the first measurement, the result for voided volume and average flowrate are incorrect.

There is no clinical risk to the patient, and the error is easily detectable. The graphs for the voided volume and the flowrate are always correct, it is just the printed result in the report section that is incorrect. However, if the device is turned off and back on between tests the printed results will be correct.

**Actions:**

Please complete and return the attached Response Card as soon as possible.

Please forward this notice to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

The appropriate competent authorities have been notified of this corrective action. LABORIE is committed to patient and user safety and apologizes for any inconvenience that this may cause. Please contact Technical Support via our service line at +1-800-522-6743 or +31 (0) 53 4803 777, if you have any questions or concerns.

Sincerely,



VP Quality and Regulatory

**Table 1: Affected Serial Numbers**

Serial Numbers	
22347000	22347034
22347001	22347035
22347002	22347036
22347003	22347037
22347004	22347038
22347005	22347040
22347006	22347041
22347008	22347042
22347009	22347043
22347010	22347044
22347011	22347045
22347012	22347046
22347013	22347047
22347014	22347048
22347015	22347049
22347017	22347050
22347018	22347051
22347019	22347052
22347020	22347053
22347021	22347054
22347022	22347055
22347023	22347056
22347024	22347057
22347025	22347058
22347026	22347059
22347027	22347060
22347028	22347061
22347029	22347062
22347030	22347063
22347031	22347064
22347032	22347065
22347033	22347066