

Safety Communication

رسالة سلامة

Issues may result in injury or unexpected results

Device/ Product Description:	Medonic M-Series/M32 Autoloader with Automatic Barcode Reader
	Swelab Alfa/ Alfa Plus Sampler instruments with Automatic Barcode Reader
Part Numbers:	1400011, 1400012, 1400068, 1400075, 1420026, 1420028
	1400023, 1400024, 1400071, 1400072, 1420046, 1420048
Manufacturer:	Boule Medical
Problem:	<ul style="list-style-type: none"> - An issue of a mix-up of autosampler tube positions with a possibility of misidentification of sample results. - A risk of operator injury from an exposed aspiration needle
Recommendation /Actions:	<ul style="list-style-type: none"> - Ensure all samples processed on the autosampler are identified by a unique barcode label on the sample tube. - 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. - 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. <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>

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