



Hamilton Voluntary Correction

MOI 21-01.A.OUS

April 2021

Tissue Preparation System

Tissue Preparation System: Hamilton Heater Shaker Fire Risk

Our records indicate that your facility may have received the following product:

Table 1. Affected Product

Product Name	Siemens Material Number (SMN)	Instrument Serial Numbers
Tissue Preparation System	10701001	All

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and to provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has received the attached Urgent: Medical Device Correction related to the Hamilton Heater Shaker component of the above-indicated product from Hamilton Company, the product manufacturer. As a distributor of the affected product, Siemens is informing our customers as directed by the manufacturer.

Siemens Healthcare Diagnostics will be contacting you to make arrangements to upgrade the Hamilton Heater Shaker component of your Tissue Preparation System.

Risk to Health

Per Hamilton Company evaluation, there is a risk that the Hamilton Heater Shaker can start a fire if flammable liquids contact and enter the device through events such as missing labware during a pipetting step or overflow of fluid from labware or an on-deck fluid handling device.

Actions to be Taken by the Customer:

- Please review this letter with your Medical Director.
- Until the upgrade is performed, the manufacturer advises that it is crucial to observe the following safety best practices:
 - Methods should include labware touch-off presence checks to ensure the labware is ready to receive liquid.
 - On-deck waste and fluid collection devices should be placed at least one track away from Hamilton Heater Shakers or any other heating device.

Tissue Preparation System: Hamilton Heater Shaker Fire Risk

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Tissue Preparation System: Hamilton Heater Shaker Fire Risk

FIELD CORRECTION EFFECTIVENESS CHECK

Tissue Preparation System: Hamilton Heater Shaker Fire Risk

This response form is to confirm receipt of the enclosed Hamilton Voluntary Correction MOI 21-01.A.OUS dated April 2021 regarding *Tissue Preparation System: Hamilton Heater Shaker Fire Risk*. Please read the question below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

I have read and understood the Voluntary Correction instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please send a scanned copy of the completed form via email to **XXXX@XXXX**.

Or to fax this completed form to the Customer Care Center at **XXXXXX**.

If you have any questions, contact your local Siemens Healthineers technical support representative.



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January 14, 2021

URGENT: MEDICAL DEVICE CORRECTION

Dear Hamilton Customer:

This communication is intended to inform you that Hamilton Company is initiating a voluntary correction to all varieties of the Hamilton Heater Shaker to address a potential safety hazard. Please see all Hamilton Heater Shaker part numbers in Appendix A.

There is a risk that the Hamilton Heater Shaker can start a fire if flammable liquids contact and enter the device through events such as missing labware during a pipetting step or overflow of fluid from labware or an on-deck fluid handling device.

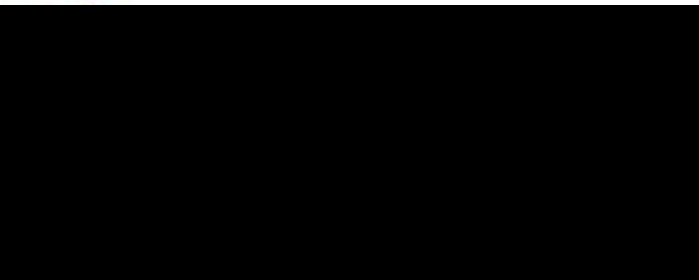
The upgrade consists of a plastic tray within the body of the Hamilton Heater Shaker and a redesigned base plate. These upgrades prevent liquid from reaching the electrical components of the device. This upgrade will be supplied free-of-charge and does not impact the functionality of the device.

Until the upgrade is performed, it is crucial to observe the following safety best practices:

- Methods should include labware touch-off presence checks to ensure the labware is ready to receive liquid.
- On-deck waste and fluid collection devices should be placed at least one track away from Hamilton Heater Shakers or any other heating device.

Recipients of this notice shall forward it to all customers to whom they have sold Hamilton Heater Shakers.

Sincerely,



The Measure of Excellence™

Appendix A – Hamilton Heater Shaker Part Numbers

PART NUMBER	DESCRIPTION
188318	HHS2,2MM ORBIT,CUSTOMIZED
188319	HHS2,3MM ORBIT,CUSTOMIZED
199000	HHS 0.5 MTP FLAT BOTTOM
199001	HHS 2.0 MTP FLAT BOTTOM
199002	PLEASE USE PN: 199034
199007	HHS 2.0 NUNC DWP 96 2ML
199008	HHS 3.0 NUNC DWP 96 2ML
199009	HHS 1.5 MTP FLAT BOTTOM
199011	HHS,1.5MM,NUNC,96DWP,2ML
199027	HHS 1.5 MM SARSTEDT 48X1.5ML
199033	HHS2,2MM ORBIT,MTP FLT BOTTOM
199034	HHS2,3MM ORBIT,MTP FLT BOTTOM
199037	HHS 1.5MM NUNC DWP 96 2ML
199038	HHS2,2MM ORBIT,NUNC DWP96 2M
199039	HHS2,3MM ORBIT,NUNC DWP96 2M
199085	HHS 3.0 FLIPTUBE RACK
199474	HHS 3.0 BIO-RAD DWP FSD
809018	HHS 3.0 AUTOLYS
0201710-001	HHSADVWR40002-012DWP96CON2ML
0202697-002	HHS,RGT TRUGH HOLD FRAME,LID
0203408-002	HHS,199034
188219APE	HHS 3.0MM AMPLITUDE
199033R	HHS2,2MM ORBIT,MTP FLT BOT REF
199034R	HHS2,3MM ORBIT,MTP FLT BTM
65608-01	HHS2,3MM ORBIT, MPT
65608-01R	HHS2,3MM ORBIT, MPT,REFURB
6601885-01	KIT,HHS,3 MM ORBIT,ML PREP
6601885-02	KIT,HHS,2 MM ORBIT,ML PREP
95379-01	HHS2,3MM ORBIT,DWP96,EXACT SCI

