URGENT MEDICAL DEVICE RECALL

Affected Product: NxView 2.0 (NX3302-A)

September 29, 2020

Dear NxStage Customer:

Description of Problem

NxStage Medical, Inc. is voluntarily recalling NxView 2.0 monitors manufactured in March and April of 2020. These monitors have an audible power setting that is not compatible with the internal speakers. As a result, the affected NxView systems may not produce an audible alarm tone during use.

The NxView is a secondary user interface that replicates alarms on the NSO and provides additional treatment information and historical information for the user. NxView 2.0 displays information about the cycler's current operation and logs/ charts this data, including:

- Current alarms
- Warnings and precautions
- Pump rates, volumes, and pressures
- Other cycler parameters

The NxView monitor can receive data from the NxStage cycler, but it cannot control the cycler. Additional information displayed in NxView includes labeling, which assists the user in setup, operation, and troubleshooting the cycler's alarms.

You are receiving this notice because our records indicated that NxStage Medical, Inc. shipped the affected device(s) to your facility.

Potential Risk

There have been no adverse health consequences related to the NxView 2.0 monitors.

The NxStage Cycler has both visual and audible alarms that are not impacted and will continue to work as intended as the primary display of alarm conditions. If the NxView monitor fails to produce an audible alarm during treatment with the NxStage Cycler, it may result in a delay in responding to the alarm condition. It is important to note that although the audible portion of the NxView alarm may fail, the NxView visual alarm indicators are still working Under the circumstances, NxStage believes that the likelihood of any serious adverse health consequences is extremely unlikely.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

What should I do?

1. Confirm you have the affected NxView 2.0 systems in your possession by reviewing the manufacture date(s) on the back of the monitor(s). Only devices manufactured in March and April of 2020 are affected. Refer to attachment A for help in locating the date of manufacture on the device.

2. Ensure all users of NxView 2.0 at your facility are informed of this Product Recall.

3. Follow the instructions on the attached reply form or click on the following link to respond electronically, https://www.nxstage.com/nxviewrecall, to acknowledge your receipt of this notice.

What is NxStage doing?

NxStage will coordinate with your designated representative and send a NxStage representative to your facility to replace the affected NxView 2.0 systems.

Please know that we are committed to continuous improvement in order to provide you and your patients with the best products available and apologize for any inconvenience that this issue may have caused. If you have any questions or comments, please contact NxStage Customer Service at 1-866-NXSTAGE (1-866-697-8243).

Regards,

Todd M. Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs

Attachment A- Locating Date of Manufacture