

**To our customers of
Infinity CentralStation (ICS) VG3 or lower
And Edifier Speaker**

December 2024

Important Safety Notice

The Edifier speakers (Purchased in or after April 2023) do not generate audio when the ICS is configured to analog mode and the speakers revert to USB mode.

Affected Devices: Infinity Central Station (MS26800) VG3.0 or lower and Edifier speakers (MS34036). See Attachment 1 to identify the affected speaker.

Dear Customer,

During our global market surveillance activities, we have become aware of instances where the new Edifier speakers (shipped in or after April 2023) do not annunciate when configured in analog mode which can lead to delayed treatment to the patient. There was no patient injury reported in those instances reported in our post market surveillance activities. The issue occurs after loss of power or power disconnected to the speaker. To continue to operate the speakers in analog mode, the initial setup (i.e., correct order of connection) needs to be repeated. The initial setup is below:

1. Connect USB cable first.
2. Connect Analog Cable.
3. Verify that the green LED is displayed on the speaker. If the LED is not green, then the Analog cable should be disconnected and then reconnected. **See Attachment 2.**

IMPORTANT: This issue is not observed for speakers configured in USB mode.

Actions to be taken:

The issue of no alarm annunciation only occurs when the new Edifier speakers are configured in analog mode with the ICS. The issue occurs when there is a power loss or power cable (USB cable) disconnected and reconnected. To identify if the new Edifier speaker has this issue, first identified if the speaker is configured with the ICS in USB mode or Analog mode. It can be identified by looking at the backside of the speaker. For the speaker set to USB mode, there is no analog cable (aux cable) connected to the speaker with the ICS and the light on frontside of the speaker display red. For the speaker set to Analog mode, there is an analog cable (aux cable) connected to the backside of the speaker and the light on frontside of the speaker display green. **See Attachment 2 and 3.** If the speaker set to Analog mode and display red light instead of green, then the issue of no alarm sound is present.

IMPORTANT: For speaker set to USB mode, ensure a cable is NOT connected to the speaker's rear AUX jack.

If an issue with alarm annunciation occurs while operating the speaker in analog mode as a result of a power loss to the ICS:

- You MUST physically disconnect Analog cable and then re-connect from the speaker to put the device back in Analog mode (Green LED) or else there will be no sound.

If an issue with alarm annunciation occurs while operating the speaker in analog mode as a result of the USB power cable being disconnected, then the USB cable is reconnected, the speaker will default back to USB mode (RED LED) and to restore the speaker back to Analog mode:

- You MUST disconnect and re-connect the Analog cable to restore the speaker to Analog mode (Green LED).

ICS VG4 software and higher have instructions about this issue in the release notes. Until VG4.0 or higher software is installed at your site, please follow the instructions above to restore the speaker functionality in analog mode. This Important Safety Notice is only for customers who has new Edifier speaker which was supplied in and after April 2023. For customers who have old Edifier speaker, in case new Edifier speaker is purchased, please keep this Important Safety Notice until VG4.0 or higher software release note is available at your site.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward them a copy of this information. Kindly complete and return the attached reply card to confirm you received this Important Safety Notice.

Please keep this information at least until all the users get ICS VG4.0 or higher version installed on the site.

Identification of the affected medical devices:

According to our records, you have received at least one affected ICS VG3 or lower (MS26800) manufactured by Draeger Medical Systems, Inc. (European Single Registration Number: US-MF-000020721, UDI: 04049098001878) and have ordered and received the new Edifier speakers (MS34036, UDI: 04048675548027) that may be affected by this issue. The new speakers can be identified by locating a light on the front face and to differentiate between old and new speakers, the old Edifier speaker have a flat façade with no light (see **Attachment 1**).

Draeger Medical Systems, Inc., Telford, PA 18969-1042 USA

Contact:

If you have any questions, please do not hesitate to contact your local representative. The responsible authorities have been notified of this action. We regret any inconvenience this may cause.

Thank you for your support.



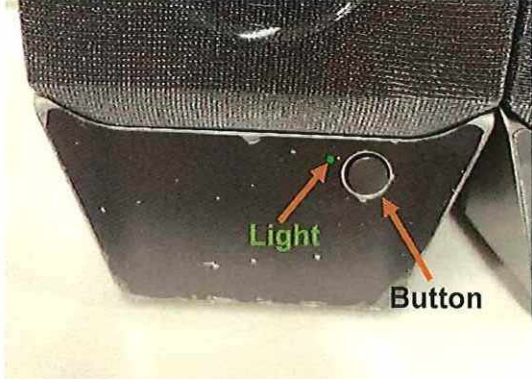
With kind regards

Rafael Zuaznabar
Director of Product Management
Business Unit Patient Monitoring
Draeger Medical Systems, Inc.

Draeger Medical Systems, Inc., Telford, PA 18969-1042 USA

Attachment 1



Attachment 1: Identification of New Speaker and Differentiation Between Old and New Speaker

Old Speakers	New Speakers
	
<p>Note the square bottom, no button, and no light.</p>	<p>Note the angled bottom, button, and red/green light.</p>
	 <p data-bbox="1096 1291 1177 1333">Light</p> <p data-bbox="1234 1354 1331 1396">Button</p>

Draeger Medical Systems, Inc., Telford, PA 18969-1042 USA

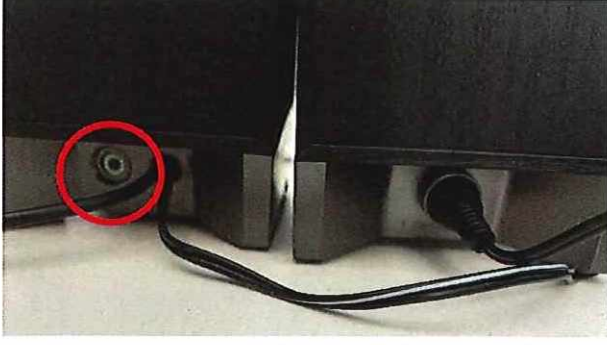
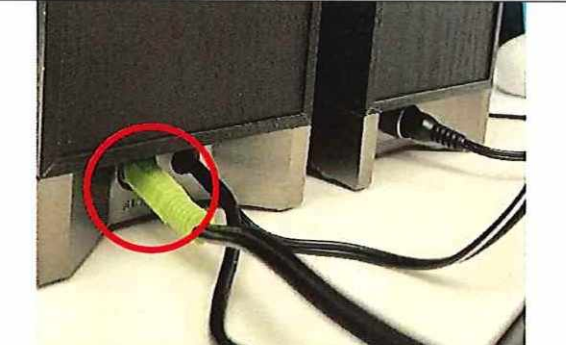
Attachment 2

Attachment 2 : Identification of USB mode and Analog Mode through a color of light on front of the new Edifier Speaker

USB Mode	Analog Mode
	
Red Light – the Speaker is in USB mode	Green Light – the Speaker is in Analog Mode

Attachment 3

Attachment 3: Identification of the new Edifier speaker set to USB mode or Analog mode

USB Mode	Analog Mode
	
No Analog Cable (Aux Cable) Connected	Analog Cable (Aux Cable) Connected

Customer Reply Card

Please fax or e-mail this form to your Dräger representative!

D R Ä G E R	To:	< To be completed by relevant subsidiaries/dealers >		
	Department:	_____		
	Dräger Representative	_____		
	Fax:	_____		
	Phone:	_____		
	E-mail:	_____		
Re: Safety notice on ICS VG3.0 or lower and Edifier Speaker purchased in or after April 2023				
(Please complete)				
C U S T O M E R D A T A	Hospital:	_____		
	Customer name:	_____		
	Phone:	_____	Fax:	_____
	E-mail:	_____		
	Address:	_____		
	Address 2:	_____		
Town/city:	_____	Country:	_____	
Quantity of affected units: _____				
<input type="checkbox"/> We acknowledge receipt of the safety notice and that the information contained therein has been brought to the attention of all affected users.				
<input type="checkbox"/> We confirm that the devices in our hospital have now been taken out of service.				
<i>Please include the device serial numbers relating to the above items in an attachment if possible.</i>				
(Please complete and sign)				
Title/position: _____				
Name: _____ (Please print in capitals)				
Signature: _____ Date: _____				