



Urgent Field Safety Notice
IPELA FHD PTZ TILE KITS

Date: XX Dec 2021

Dear Valued Customer,

You recently received communication of an issue with IPELA FHD PTZ TILE KITS. Our records indicate you have purchased and are currently using at least one of the IPELA FHD PTZ TILE KITS.

As previously communicated Natus is conducting a voluntary field corrective action for the IPELA FHD PTZ TILE KITS. This letter and the attached document *DOC-057825 IPELA FHD PTZ TILE KITS Correction* provide further instruction on how to correct the issue.

This notice needs to be passed to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Intended use of the IPELA FHD PTZ TILE KITS

The IPELA FHD PTZ TILE KITS containing the wall and ceiling mount accessories are intended to be used in combination with Natus Neuroworks/Sleepworks software which allows a qualified medical practitioner trained in electroencephalography or polysomnography to acquire, display, archive, review and analyze physiological signals along with audio and video. It can be used with patients of all ages.

The IPELA FHD PTZ TILE KITS allows one to install and situate a video camera more strategically within a patient environment to optimize the view or perspective of a video recording of a patient. Video recorded with an EEG or PSG study provides more information regarding a patient's well-being and may be helpful with respect to patient care. The IPELA FHD PTZ TILE KITS including wall and ceiling mount accessories is able to support a camera plus any associated power sources, cabling or hardware to facilitate a video recording. Having the ability to install a video camera on a wall or ceiling position in such a way that the equipment and cabling can utilize space and resources efficiently is valuable particularly in a clinical environment. The IPELA FHD PTZ TILE KITS including the wall and ceiling mount accessories helps to protect the equipment and facilitates a more obstruction-free environment for clinicians or patients who move about in a typical room.



Description of the issue:

Natus Field Service Personnel report that the Axis camera ceiling tile is not fitting properly in some domestic institution ceiling tile grids that have a thinner style grid frame.

Affected Items:

Please see below table with details of legal manufacturer and the devices affected in this FCA:

Legal Manufacturer	Part Number	Description
Natus Medical Incorporated, DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle, Oakville, Ontario, Canada	022638	IPELA FHD PTZ TILE KIT
	022663	IPELA FHD PTZ TILE KIT 220V

Hazard associated with this issue:

The ceiling tile may suddenly fall from the ceiling and cause a safety risk to the patient or end user.

Action to be taken:

Only kits, 022638 and 022663 using the Axis camera are affected by this recall. If your installation uses the Sony IPELA camera, please disregard this recall.

How to identify the affected tile kit:

Step 1. Locate the product's label on the tile kit. The label part number should correspond to the affected Natus Part Numbers above. If the part numbers do not match then disregard this recall.



Step 2:

Look through an adjacent ceiling tile to identify the model of the camera installed. The camera model will either be Sony IPELA or Axis. The Axis camera can be identified with the “Axis communications” logo on the side of the camera housing indicated by the green circle in the upper left image below. For reference, image of kits using the Axis camera (showing a ‘✓’) and Sony IPELA camera (showing a ‘x’) are provided below. Note, the kit with an Axis camera also uses a smaller clear dome than the Sony Ipele as shown in the bottom two pictures below.



If you have identified the Sony IPELA camera, please disregard this recall. If you have identified the Axis camera, you are affected by the recall, please proceed to Step 3.

Step 3:

Please follow the correction steps outlined in the attached document DOC-057825 IPELA FHD PTZ TILE KITS Correction.

If you have any questions, please use the contact information provided below.

Please complete and return the customer reply form to Natus at the following address:

Email: FCA@Natus.com

Tel: 800-387-7516

Thank you for your patience and cooperation.



CUSTOMER REPLY FORM
TO BE COMPLETED BY RECIPIENT

Customer Name: _____
Facility Name: _____
Facility Address: _____
City, State Country: _____
Postal Code: _____
Email address: _____
Contact Name: _____
Phone Number: _____
SR number: _____

Please complete for received items

We hereby declare that we are aware of the product recall by Natus Medical Incorporated.

Please mark as appropriate:

- We do not have any of the affected products
 We do have the affected product(s) and have performed the correction as outlined in DOC-057825
IPELA FHD PTZ TILE KITS Correction

List Serial Number(s) of affected device:

Name of Person completing these actions (please print): _____

Signature: _____ **Date:** _____

Title: _____ **Phone:** _____