**Urgent Field Safety Notice**

**IPELA FHD PTZ TILE KITS**

Date: XX Nov 2021

**Dear Valued Customer,**

You are receiving this information as our records indicate you have purchased and are currently using at least one of the IPELA FHD PTZ TILE KITS.

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:

<table>
<thead>
<tr>
<th>Legal Manufacturer</th>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natus Medical Incorporated, DBA Excel-Tech Ltd. (XLTEK)</td>
<td>022638</td>
<td>IPELA FHD PTZ TILE KIT</td>
</tr>
<tr>
<td></td>
<td>022663</td>
<td>IPELA FHD PTZ TILE KIT 220V</td>
</tr>
</tbody>
</table>

**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:**

We request that the affected customers stop using this device immediately. Natus will be in contact in due course with a solution to this issue. Please use the contact information provided below if you have any questions.

Email: FCA@Natus.com

Tel: 800-387-7516

Please be aware that your Competent (Regulatory) Authority has been informed of this communication.

Thank you for your patience and cooperation.