

## Urgent Field Safety Notice

<b>Commercial name of the affected product:</b>	Keeler Wall-plug Power Supply
<b>Part number:</b>	EP29-32777
<b>Scope:</b>	This FSN will only affect Keeler product shipped prior to 1/1/2006
<b>FSCA identifier:</b>	CAPA 1096
<b>MHRA references:</b>	<b>2015/001/012/601/005 &amp; 2015/001/014/081/004</b>
<b>Type of action:</b>	Advisory Notice
<b>Date:</b>	10/2/2015 – issue 1
<b>Attention:</b>	Distributors and Users
<b>Transmission of this Field Safety Notice:</b>	This notice must be passed on to all those who need to be aware within your organisation; This must include: <b>Quality/Regulatory, Theatre, Maintenance</b>

This notice only applies to Wall-plug Power Supplies shipped prior to: **Jan 01 2006 and marked “MADE IN TAIWAN R.O.C.”**

### Description

Keeler has been informed of a single incident in which a Wall-plug power supply which had been subjected to a significant impact had been rendered unsafe and had been found to be the root cause of an electrical shock delivered to a user.

Subsequent investigations into the event have identified a potential weakness in respect of a small proportion of the Keeler Wall-plug Power Supply units which were on sale only between Jan 2001 and Dec 2005. It should be noted that the investigations have confirmed that the devices concerned satisfied all the medical and safety tests prevailing at the time of their shipments.

### Details of affected devices

The Wall-plug Power supplies concerned carry a label as shown below and only those with identical labels and with the marking **“MADE IN TAIWAN R.O.C.”** are of concern to this notice.



### Cause

Following investigations we believe that excessive impact or repetitive external knocks to the housing of the Wall-plug can lead to degradation of the internal insulation protection and/or sudden development of a hazardous electrical fault in the power supply. When subjected to physical damage some Wall-plugs can be rendered unsafe and pose a potential risk of electric shock.

These knocks and impacts are potentially more likely when the power supply is installed on a prolonged basis in positions making them prone to being hit by instrument / patient trolleys or any other room furniture.

In order to check if your Wall-plug power supply is one of those covered by this notice, please undertake the following steps:

- i) Check the label on the reverse side of the wall-plug. Only power supplies with an identical label to the above and with the marking "MADE IN TAIWAN" are of concern.
- ii) Check the physical appearance of the housing for any sign of damage, scratches, etc. The housing is of strong plastic type so even slight signs of damage are undesirable and would require replacement of the power supply.
- iii) Ensure that your test engineers carry out their regular Electrical Appliance safety tests. Replace the power supply if it fails the Isolation Resistance test.

### Risk:

Potential hazardous electrical shock in the event of physical knock and damage to the unit.

## Advice on action to be taken by user

### Your responsibility:

- 1- Ensure your EP 29-32777 plug-in power units do not show any sign of physical damage.
- 2- Ensure that the power unit is plugged into a safe place and is not prone to knock and physical damage by moving trolleys, people and other equipment.
- 3- Ensure that the Portable Appliance Test is carried out on your equipment by qualified engineers at specified regular intervals defined by your local policy.
- 4- Ensure that old and/or damaged equipment is replaced with the latest standard equivalent

### Vigilance Information:

This voluntary safety and recommendation information will be reported to MHRA, FDA, and other Competent Authorities.

We are committed to upholding the highest standards of safety, quality workmanship and reliability for all of our products and apologise for any inconvenience this advisory safety notice may cause you. We thank you in advance for your cooperation and patience.

Please keep Keeler informed of any adverse events associated with the use of any of our products.

## Remedy

If you are concerned that your unit may be affected, please speak to your local Keeler representative to discuss replacing it. Investigations have confirmed that only power supplies marked with “**MADE IN TAIWAN R.O.C.**” are affected. You can contact Keeler directly:

Address: Clewer Hill Road, Windsor SL4 4AA, UK

Tel: +44 (0) 1753 827 116

Email [replacement@keeler.co.uk](mailto:replacement@keeler.co.uk)

You can also find more information at our web site at <http://www.keeler.co.uk/>

## Keeler Contact for this notice

### Phil Burridge

Keeler Ltd

Clewer Hill Road

Windsor

Berkshire

SL4 4AA

United Kingdom

Tel: +44 (0) 1753 827155

The undersigned confirms that this notice has been forwarded to the appropriate Regulatory Agency



### Phil Burridge

Senior Quality Engineer

## What are FSNs and FSCAs?

A Field Safety Notice (FSN) is an important communication about medical device safety sent to affected customers by a device manufacturer, or their representative. FSNs outline actions to be taken to reduce the risk of death or serious injury associated with the use of a medical device. These actions are referred to as Field Safety Corrective Actions (FSCAs).

If you receive a Field Safety Notice from a manufacturer, always act on it.

**Do not wait** for a communication from the MHRA.

It is important that your organisation takes the actions detailed in the FSN and replies to the manufacturer, acknowledging receipt of the FSN.

Your organisation's reply is the evidence that the manufacturer, and subsequently the MHRA, needs to monitor the progress of the FSCA.

Without this reply the manufacturer cannot properly verify the completeness of the FSCA and the MHRA may need to issue a Medical Device Alert.