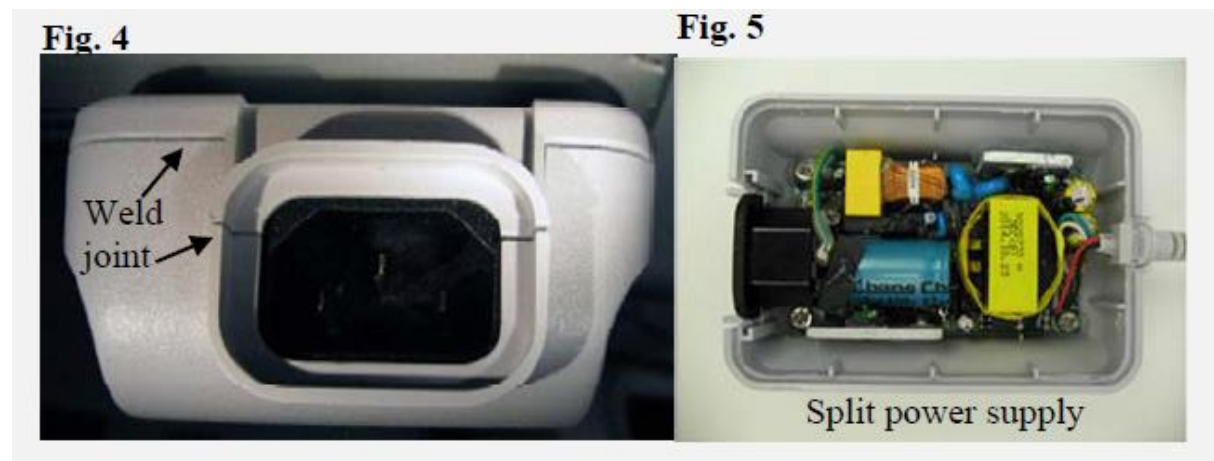


<p>Welch Allyn®</p> <p>Welch Allyn Limited, NavanBusinessPark, Dublin Road, Navan, Co. Meath, Ireland.</p>	<p>URGENT:Field Safety Notice</p>	<p>WA16-01-01</p>
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**Applies to Welch AllynMS3 Connex Spot Classic Mobile Stand & Power Supply
Welch Allyn Ref: WA16-01-01**

Dear Welch Allyn Customer,

It has been brought to the attention of Welch Allyn via customer complaints in the UK that under certain circumstances the power supply casing at the weld joint (housing) can separate which, as a result, exposes electrical components. (See Fig. 4 & 5 below).



The root cause of the failure of the ultrasonic weld on the power supply unit (PSU) casing halves is the excessive lateral load that is being applied to both the PSU power cord socket and the power cord strain relief in circumstances of incorrect / unintended use practices with the device, while installed on its mobile stand. This occurs in the specific circumstance where an attempt is being made to move the device on its mobile stand by grabbing the stand by one of its basket sides and pulling the mobile stand assembly in a “sideways” direction, while the device power cord is still plugged into the electrical wall socket (the power supply is attached to a MS3 mobile stand).

Moving the mobile stand at such an acute angle with the power cord still plugged in can generate enough force on the PSU power cord socket to separate the PSU casing halves, which if they separate completely, can result in exposed wiring while still connected to the electrical mains supply. While it is not expected that customers would move the mobile stand in just such a manner and without un-plugging the unit, we are now aware that there have been a few instances where this appears to be what has happened.

Please continue to ensure that users of these devices take the following precautions:

- As per your Instructions For Use, routinely check your devices for physical damage to the power cords & transformers.
- Do not use damaged power cords and transformers, and report such damage to Welch Allyn and request replacements as necessary.
- Always ensure your device is unplugged from the wall before you move the stand.
- If you identify exposed wires on your power cords/transformers, do NOT make physical contact with it. Switch off the plug at the wall and contact your Biomedical/Clinical Engineering department.

The device PSU has met all of its required testing (e.g. drop test) for electrical certification. Working with its PSU supplier, Welch Allyn has introduced further improvements to the PSU ultrasonic welding process. In the interim, Welch Allyn have also designed a Power Supply Bracket Kit (PN 411626) to retrofit to the mobile stand to further prevent the power supply from splitting apart.

Should you wish to order a Power Supply Bracket Kit (free of charge) then please send an e-mail request to xxxx stating your contact details. One Kit will be supplied for each Mobile stand.

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

• A&E departments	• In-house maintenance staff
• Adult intensive care units	• IV nurse specialists
• All wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Oncology units
• Day case theatres	• Paediatric intensive care units
• EBME departments	• Risk managers
• Equipment stores & Libraries	• Supplies managers
• Health and safety managers	• Theatres

If you are a distributor, please notify your customers who have received these products of this information.

Where applicable, this notice has been communicated to your local Regulatory Agency.

We greatly appreciate your cooperation in this matter.

Yours sincerely,

Paul Reynolds
Director, International Quality Assurance & Regulatory Affairs