

URGENT FIELD SAFETY NOTICE

MANUFACTURER

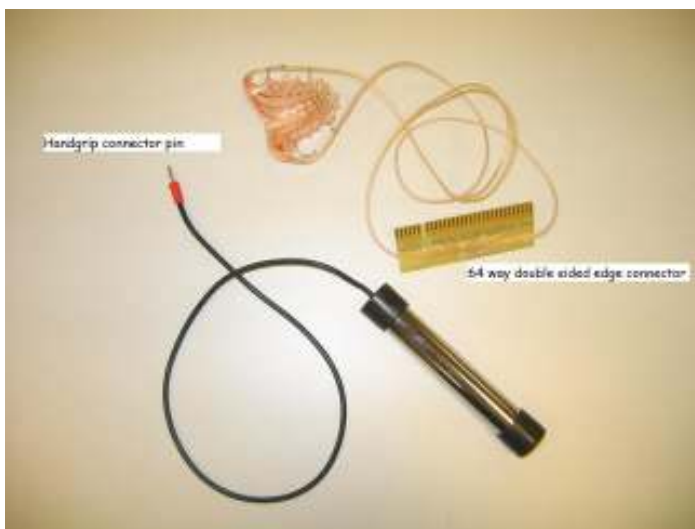
Articulate Instruments Ltd

AFFECTED MEDICAL DEVICES

WinEPG and PTU electropalatographs (All models)

ISSUES

- Patient Applied Parts have exposed conductive connections.
Electropalate is terminated with an un-shrouded copper board; the chrome handgrip has an un-shrouded connection pin. These are both intended for connection to the multiplexer unit. If these parts are held or worn while unconnected this poses a risk of accidental contact with hazardous voltages or accidental earthing of patient.

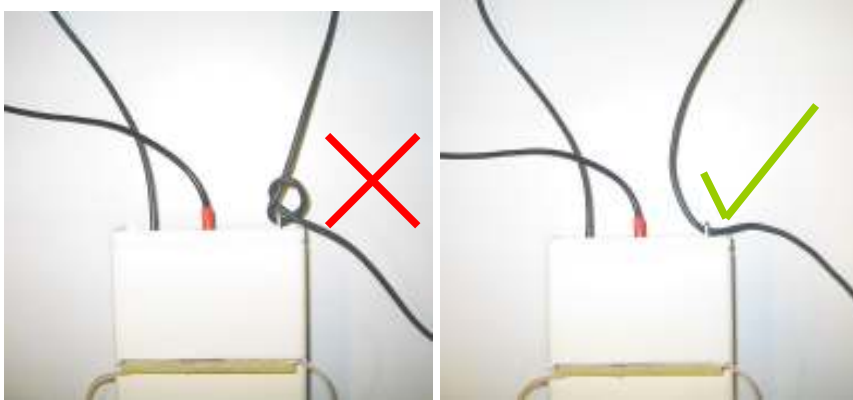


- Medical Isolation Transformer incorrectly labelled
Labelled 'CONNECT TO MEDICAL EQUIPMENT'. However, it is essential* (as stated in the user manual) that the WinEPG, the computer, which is a non-medical device, and any peripheral mains powered devices (monitor, printer, disk drive etc) are powered via this transformer.



* This is to ensure the patient is not exposed to leakage currents above the limits of those specified for Electro-medical devices in standard EN60601-1.

- Lanyard
There is a length of multi-strand sheathed cable protruding from the front panel of the multiplexer – this has no conductive connection to the circuit within. It is to be utilised as a lanyard for feeding around the neck, and is secured by terminating to the bracket also affixed to the front panel. If the lanyard were to be tied off when in place around a patient's neck, this could pose a strangulation hazard.



IMMEDIATE ACTION

1. Ensure that the WinEPG and associated computer and its peripherals (monitor, printer, external disk drive, etc) are powered by the Medical Isolation Transformer provided as part of the system. Ensure the patient/user area is free of all other electrical equipment.
2. Always connect the electropalate to the multiplexer BEFORE the palate is positioned within the patient's mouth and DO NOT REMOVE PALATE CONNECTOR WHILST THE PATIENT IS IN CONTACT WITH THE APPARATUS. Connect the handgrip to the multiplexer before handing it to the patient.
3. Dispose of all earlier manual revisions and replace with *WinEPG users manual 1.16* and *PTU users manual 1.18* or later revisions. It is important that all users read the revised instructions and take note of all warnings.
4. Ensure that the multiplexer lanyard is NOT TIED OFF when placed around a patient's neck as this could pose a strangulation hazard. Never, walk around with the multiplexer worn around the neck.
5. Make sure children and adults with incapacity are supervised when using EPG.

DISTRIBUTION REQUIRED

Please bring this safety notice to the attention of all who need to know or be aware of it. This will include distribution to clinical engineering departments within hospitals and all staff using WinEPG and PTU electropalatography units with patients.

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

BACKGROUND

This safety notice has been issued following a safety review initiated by independent inspection of the devices by a clinical engineering laboratory.

ENQUIRIES

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The undersigned confirms that this notice has been notified to the appropriate regulatory authority.



Alan Wrench
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