

URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

PENTAX Auto Leakage Tester SHA-P6

To:

«CUSTOMER_NAME»
«STREET_ADDRESS»
«POST_CODE» «CITY»,
«COUNTRY»

RE: Field Safety Notice PENTAX Auto Leakage Tester SHA-P6

Dear esteemed user, this letter is to inform you that PENTAX Medical ("PENTAX") is conducting a Field Safety Corrective Action (FSCA) concerning all **PENTAX Auto Leakage Tester SHA-P6**.

This FSCA was initiated in order to alert you on the **potential risk of an electric shock** resulting from the **AC Adapter Model UM312-7516** (Manufacturer: Nihon Seimitsu Sokki Co. Ltd., Japan) which is intended to be used for recharging the battery of the **PENTAX Auto Leakage Tester SHA-P6**. The AC adapter may also left stay connected permanently with the SHA-P6.

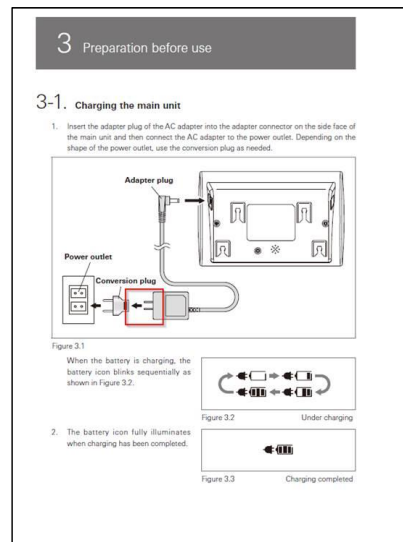
Description of the risk:

When disconnecting the AC adapter from the wall socket while pulling the AC adapter outwards and holding the AC adapter only, the conversion plug (wall socket adapter) did not keep attached to the AC adapter. A user did grab the AC adapter unintentionally in such way that his finger touched the metal connector of the AC adapter, which still was partly inside the conversion plug – and carrying mains voltage of 230VAC. As consequence, the user did suffer from a short electric shock. The earth leakage circuit breaker (RCCB, Residual Current operated Circuit Breaker) at the house installation was functioning correctly and tripped immediately, preventing further (personal) damage. In this case, no serious deterioration in the user's state of health was reported. This risk is independent from individual serial numbers and does affect all AC adapters delivered with leakage testers SHA-P6. The picture and extract from the Instructions for Use provide below shall illustrate critical parts.

AC adapter and conversion plug:



Extract from the Instruction for Use of the SHA-P6



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MEDICAL

Please note the Auto Leakage Tester SHA-P6 itself did **NOT** contribute to this incident at all.

Advice to the user:

For the time being, please make sure that you are not touching the metal connectors when disconnecting the AC adapter from the wall socket. In order to disconnect, please grab the AC adapter in such way that you avoid any contact with the metal connectors under any circumstance. Alternatively, you can leave the AC adapter connected permanently with the wall socket. PENTAX will provide you with additional information as soon as further advice will become available.

Customer Instructions:

Enclosed with this letter you will receive a Field Safety Corrective Action Response Form. Please complete this form, and return it to PENTAX Medical using the e-mail address or fax number listed below.

Incidents experienced with the use of this product must be reported immediately to PENTAX at vigilance.emea@pentaxmedical.com. Independent from this, incidents must be reported to national Competent Authorities as per the Regulation (EU) 2017/745 ("EU-MDR") and / or local Medical Device Regulation by the user facility.

PENTAX regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. Please be assured that maintaining safety and quality is our utmost priority.

Contact Information:

In case you may have any questions regarding this Field Safety Corrective Action, please feel free to contact your local PENTAX Medical representative at:

Tel:

Email:

Sincerely,

PENTAX Europe GmbH
Dr. Stephan Lunau

Leader Regulatory Affairs EMEA
Person Responsible for Regulatory Compliance

Attachment:

Customer Response Form, Ref.: FSCA-PMJ-21-01