

MEDICAL DEVICE FIELD SAFETY CORRECTION

<Business name>

<Address>

<City, State>

<Country>

<Date (include prior to the initiation of the distribution of the letter in the country/region)>

To: <Customer Address>

RE: **Notification of Error Correction in Instructions for Use**

Dear Valued Customer,

PENTAX Medical has become aware of an error in the description of an Instructions for Use of PENTAX ULTRASOUND VIDEO BRONCHOSCOPE EB-1970UK. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Affected Product details:

PENTAX ULTRASOUND VIDEO BRONCHOSCOPE EB-1970UK

Number of Instructions for Use: Z870

Revision No.: R10-R12

Safety issue:

WARNING

The errors in the instructions for use (IFU) shown in the following table are corrected in the right column. Following to the erroneous description in the IFU may result in ineffective reprocessing, posing the risk of cross-contamination and/or anaphylactic shock.

Safety Instructions:

Although no incidents have been reported, please be informed about the following errors and correction:

Page	Error	Correct
Sec.4-2-4-4. p51	6) Inject the <u>disinfecting solution</u> into the channel.	6) Inject the <u>air</u> into the channel <u>to remove the remaining disinfecting solution</u> .
Sec.4-3-1-4. p61	6) Using a 10 mL syringe, inject 3 mL or more of clean water into the injection tube (OE-B5) to rinse the cleaning detergent while it is immersed in the <u>detergent solution</u> .	6) Using a 10 mL syringe, inject 3 mL or more of clean water into the injection tube (OE-B5) to rinse the cleaning detergent while it is immersed in the <u>water</u> .
Sec.4-3-2-2. p63	4) Using a 10 mL syringe, inject 2 mL or more of disinfecting solution into the injection tube (OE-B5) while it is immersed in the <u>detergent</u> solution.	4) Using a 10 mL syringe, inject 2 mL or more of disinfecting solution into the injection tube (OE-B5) while it is immersed in the <u>disinfecting</u> solution.

Sec.4-3-2-3. p63	6) Using a 10 mL syringe, inject 3 mL or more of clean water into the injection tube (OE-B5) to rinse the disinfecting solution while it is immersed in the <u>detergent solution</u> .	6) Using a 10 mL syringe, inject 3 mL or more of clean water into the injection tube (OE-B5) to rinse the disinfecting solution while it is immersed in the <u>water</u> .
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Contact information:

<Describe how the customer – consignee can contact PENTAX Medical with any question. Contact name with phone number, email address>

We sincerely regret any inconvenience caused by this action and appreciate your immediate attention to this matter.

Please be assured that maintaining a high level of safety and quality is our highest priority.

If you have any question regarding this action, please feel free to contact your local office of PENTAX Medical.

Sincerely,

PENTAX Europe GmbH

[Redacted signature line]

[Redacted contact information]