WATER BOTTLE ASSEMBLY OS-H4

1. INTENDED USE
The PENTAX water bottle assembly, OS-H4 is intended to be used with compatible PENTAX flexible endoscopes and PENTAX air sources (video processor, light source, etc.) for delivery of air and/or water during endoscopic procedures. NEVER use the water bottle for any purpose other than that for which it has been designed.

Since endoscopic accessories, including the water bottle are designed to be used in conjunction with other medical devices, the effectiveness of an accessory especially a reusable one, is dependent upon a number of factors, including the condition of the endoscope and the care and maintenance of the accessory and related devices.

WARNING:
The water bottle assembly identified in this manual is a reusable medical device. Since it is packaged nonsterile, it must be sterilized BEFORE initial patient use. Subsequently, it should be subjected to an appropriate cleaning and sterilization process at least on a daily basis or more frequently depending upon the patient and/or type of endoscopic procedure.

2. NOMENCLATURE

NOTE:
If the water bottle assembly has been handled roughly, the water feeding tube inside the hose may be damaged or disconnected at the A/W connector for the endoscope. To test, remove the cap and using a syringe, inject water into the water feeding stem. If the water comes out of both the center hole of the A/W connector and the series of holes around the center hole, the water feeding tube is disconnected. Use another water bottle assembly.

3. DIRECTIONS FOR USE
1) Fill the bottle approximately 2/3 full with sterile water.
2) Screw the bottle cap snugly onto the bottle.

NOTE:
Do NOT use the new PENTAX OS-H4 water bottle cap with the older OS-H2 water container/bottle. Although the cap may appear to fit onto the bottle, air may escape resulting in insufficient pressure and flow of air and water during the endoscopic procedure. Both the PENTAX water bottle cap and bottle/container are identified by their appropriate model designation. Ensure that an OS-H4 cap is used only with the OS-H4 water container/bottle. Do NOT over-tighten the bottle cap. Over-tightening can cause the bottle cap to break.

3) Set the Air/Water - Drain lever to A/W position.
4) Insert the air pipe stem into the processor or light source and press until the water bottle ‘clicks’ into position.
5) Insert the A/W connector into the holder on the bottle cap until the endoscope is connected.

NOTE:
Always disconnect the water bottle assembly before moving the video processor (or light source) into a position not common to normal use. Always disconnect the water bottle before packing the unit for shipment.

6) Properly inspect and connect the endoscope to the video processor (or light source) as per the detailed instructions supplied with each device.

7) Connect the A/W connector of the water bottle directly to the Air/Water port (receptacle) located on the endoscope’s umbilical connector.

8) Proceed to inspect and test the endoscope’s air and water delivery functions as per the endoscope owner’s manual.

NOTE:
When removing the Air/Water hose from the endoscope, always grasp the metal A/W connector to avoid damage or disconnection of the rubber tubing.

4. CARE AFTER USE

To maintain maximum performance and a patient safe device, proper care after use is important. Each water bottle assembly should be cleaned and sterilized at least on a daily basis or more frequently depending upon the patient and/or type of endoscopic procedure.

As with all endoscopic accessories, prior to sterilization, entire water bottle assembly should be thoroughly cleaned. Failure to do so could result in incomplete or ineffective sterilization.

NOTE:
Take care in handling the water bottle. DO NOT carry the bottle assembly by the A/W Connector or the hose. When the bottle cap has been removed from the bottle, be careful in handling the water feeding stem.

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1) Immediately after use, the entire water bottle assembly (bottle, cap and tubing) should be washed with fresh detergent solution and a dampened gauze or scrub brush. Complete immersion in a detergent solution should be used for soiled items. Internal surfaces of the water bottle assembly may be exposed to the detergent by injecting the detergent into the air pipe stem using a syringe. The A/W-Drain lever should be set to the A/W position to ensure contact with all internal tubes.

2) Ultrasonic cleaning of the entire water bottle assembly is recommended to access difficult to reach areas. Use an operating frequency of 44 kHz ±6% or higher for a period of at least 5 minutes.

3) After washing with the cleaning solution, all surface areas of the water bottle assembly should be thoroughly rinsed and dried. Gauze or lint-free cloth can be used to wipe dry most surfaces. Compressed air and 70% alcohol may be used to facilitate drying of hard to reach areas.

4) After cleaning and thoroughly rinsing, the water bottle assembly can be sterilized. Before any attempt is made to sterilize the water bottle assembly, ensure the cleaning process has been completed and all items are thoroughly dry. For sterilization, autoclaving can be performed.

NOTE:
The sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated. Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer. For more detail, refer to the manual supplied with the PENTAX endoscope.
Steam Sterilization (Autoclaving)

PENTAX water bottle assemblies, Model OS-H4 have been designed to withstand high-pressure steam sterilization procedures providing the following parameters are adhered to:

- Sterilizer Type: Prevacuum
- Temperature: 132 ~ 135 °C (270 ~ 275 °F)
- Time: 5 minutes

During steam sterilization, ensure that the cap and tubing section have been removed from the water bottle container. Make sure that the drain lever on the water bottle cap has been set on the A/W position (upright).
Explanations of the symbols used in the operating manual, on the devices or on the packagings.

Symbol for "MANUFACTURER"

Symbol for "DATE OF MANUFACTURE"

Symbol for "AUTHORISED REPRESENTATIVE"

Symbol for "SERIAL NUMBER"
In the case of endoscopes the serial number is either on the control body or the light guide connector. The serial number always has 6 digits preceded by a letter.

Symbol for "BATCH CODE"

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

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