

Instructions for use

Product name / Trade name

HydroCheck-E

Available in sizes: 1.0, 1.7, 2.8, 3.8, 5.0 mm

Product Description / Intended Purpose

The devices HydroCheck-E are used for detection of residual water in flexible endoscope channel.

The devices are used by medical professionals and trained CSSD staff in CSSD departments of Hospitals and medical practices.

Instructions for use



Gloves must be worn throughout the test procedure to avoid contamination of the test.

Do not open HydroCheck-E test before use.

The size of the swab must be compatible to the diameter of the endoscope channel.

1. Insert the EndoSwab into the channel to be tested and push it all the way through, once only.
2. Immediately after swabbing cut the EndoSwab 2cm behind the tip with scissors and place into the test vial. Close and shake at least 3 times.
3. A colour change to purple on the EndoSwab indicates residual water in the tested channel.
4. Small amount of residual water on the EndoSwab will be indicated by a small purple spot. Large amount of water can turn the whole test to purple.



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1.0	77080-06X
1.7	77080-06A
2.8	77080-06B
3.8	77080-06C
5.0	77080-06D

Performance characteristics

HydroCheck-E: Detection of residual water in endoscope channel.

The test kit can detect 0.05 µL of residual water in an endoscope channel.

In the event of malfunction / performance changes

Flexible endoscopes must be stored dry. Residual water indicated by HydroCheck may jeopardize safe storage.

Precautions:

- Open package carefully and handle with care.
- Don't eat and drink at work. No smoking. Keep away from food.
- Avoid contact with skin and eyes.
- Store protected from moisture.
- Use eye protection (Chemical splash goggles).
- Wear chemical resistant gloves.
- Inhalation protection in case of dust.
- Don't use twice.
- Use only for the intended purpose.
- Read the instructions carefully before interpreting the results.

Safe combinations with devices / equipment

Use only swabs supplied with HydroCheck-E. Do not open HydroCheck-E test before use.

Restrictions on combinations

Contact to any source of moisture, for example a fingerprint, can give a false positive result. If the EndoSwab is not tested immediately, it might dry and give a false negative result.

Each test kit consists of:

6 x single use tests for the detection of residual water in endoscope channels.

- o HydroCheck-E test
- o EndoSwab

Special storage and/or handling condition

- Store at RT (15°C- 25°C).
- Store in closed original packaging.
- Store in a dry place.

Side effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are located.

Significant residual risks:

After use always check if the swab is still intact. After the test, the endoscope needs to be reprocessed / disinfected again.

Safe disposal of device

Dispose of HydroCheck-E in accordance with valid local regulations.

Version and date of the issuance of the IFU.

Version: 2.0 Date: 22.07.2025