



Edition 01, April, 2026



Thank you for choosing AMA RUT Expert with CubePlus 840, the test-system for semi-quantitative detection of *H. pylori* in gastric biopsies. Please follow these recommendations carefully and the test-system will help to diagnose your patients better and save your time.



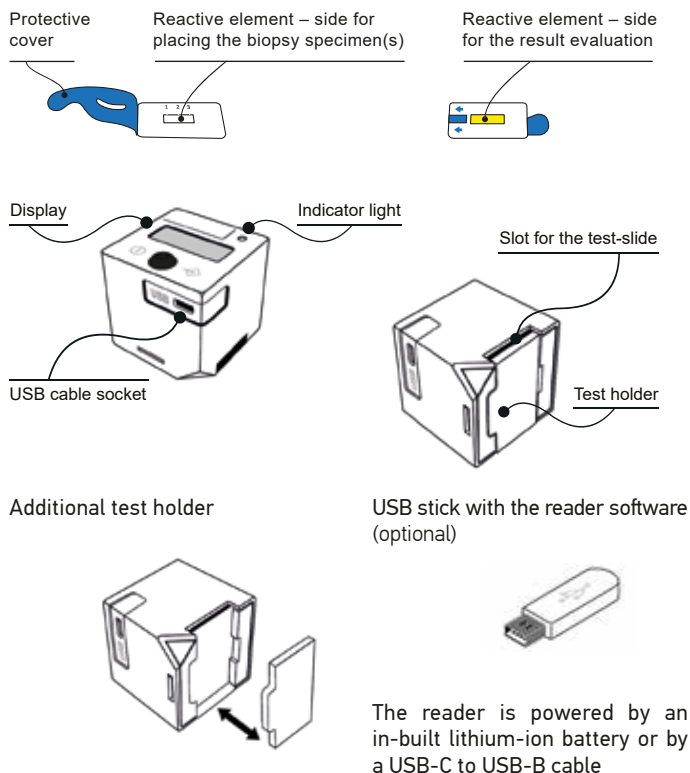
Before using the product, please read and follow instructions for use of both AMA RUT Expert and CubePlus 840.

INTENDED USE AND PRINCIPLE OF OPERATION

The test-system consists of a single use test AMA RUT Expert (hereinafter referred to as test or test-slide) and the reader "CubePlus 840" (hereinafter referred to as reader). The principle of operation is based on the color change of the indicator after the biopsy specimen(s) placed on the reactive element of the test-slide. In the event of urease activity in the biopsy specimen(s), a red or magenta spot appears on the test-slide. The reader is used as a visualization tool that takes multiple readings to check if the spot appeared. The higher the urease activity is, the faster the detection time. The reader stops as soon as it detects a spot or proceeds up to the maximum exposure time (14 minutes) to confirm the absence of the spot and thus the negative result. The result is indicated on the display and saved.

DESIGN OF THE TEST-SYSTEM

The test-slide is a rectangular-shaped polymer basement with the reactive element hermetically sealed by a protective cover.



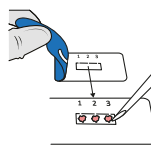
PREPARATION BEFORE THE TEST

- Put on the gloves;
- Open the package of the test.

THE PROCEDURE



1. If you use AMA RUT Expert in blocks, separate one test along the perforation lines and put it on a flat surface.



2. Open the protective cover, but do not pull hard not to tear it off.

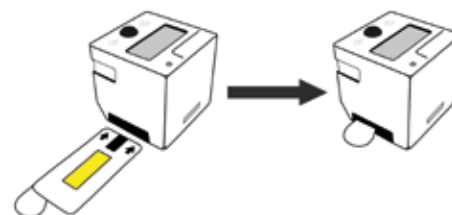
3. Place one, two or three biopsy specimen(s) on the white reactive element, but not beyond.



4. After the last biopsy is placed, reseal the cover. Gently smooth the cover with your finger around the perimeter of the test.

5. Turn the test-slide upside down so that the yellow reactive element positions above.

6. Insert the test-slide into the slot on the bottom side of the reader as far as it can go.



The test-slide should be inserted with the yellow reactive element and the arrows upside. Make sure the period between the biopsy placement onto the test-slide and the first reading is as short as possible. Should the period exceed 1 minute, the result is interpreted as qualitative only, please see Limitations.

7. Then, if previous readings have been taken, an audible alarm beeps and the display shows last saved result as a scrolling message. Press the button to continue, the audible alarm beeps and the display shows "ON".

ON

8. To start the test, press the button again. The display shows "RFID/TEST". Confirm the start of the test by pressing the button.

RFID/TEST

9. The reader first checks if the test-slide is properly inserted into the slot and if yes, the first reading is taken and the display shows "RUN".

RUN

If the display shows "<---" or "ERROR", it means the reader cannot find the test-slide in the slot.

< ---

ERROR

Make sure the test-slide is inserted as far as it can go and the result evaluation side up. Press the button to restart the procedure from step 9.

After the first reading, the CubePlus 840 either stops the procedure with the positive result, or continues with a countdown showing time until the next reading.

00:25

After the counter reaches zero, the next reading is taken, and the display shows "RUN" again. The countdowns and the readings repeat automatically until the test-slide is interpreted as positive or until total time reaches **14 minutes**. The display then shows the result as a scrolling message.

Period of exposure since the biopsy placement	Result on the screen	Urease activity appropriate for the number of bacterial <i>H. pylori</i> cells*
0 and 1 st minute	HP +++	High, as in ~10 ⁶ CFU and more
3 rd to 4 th minute	HP ++	Moderate, as in ~10 ⁵ CFU
9 th to 14 th minute	HP +	Low, as in ~10 ⁴ CFU

*The approximate values are for indicative purposes only, these are based on the microbiological research.

AMA RUT Expert does not in any way measure the number of the *H.pylori* cells. Inserting the slide into the reader with delay from the moment of biopsy placement increases the exposure time, thus the low or moderate urease activity cases may indicate as the "HP++" results. The "1", "2", "3" in the scrolling message of the positive indicated result specify the biopsy placement area(s) where the spot has appeared the fastest, for example "HP++ 1,2". The absence of the spot on the 14th minute means the absence of the urease activity. The "HP-" on the screen indicates the negative test result.

There is no button to switch the device off. The reader continues beeping for 30 seconds, and then shuts down automatically if no actions are made. The results are saved and shown as a scrolling message at next switch-on.

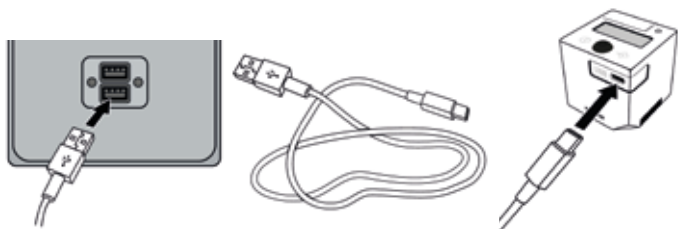
TRANSFERRING THE TEST RESULTS

The reader memory can store 86 test results. When the memory is full, old data is replaced with the new.



To avoid data loss, transferring the test results from the reader to the PC is recommended weekly.

To transfer test results, the reader must be successfully connected to the software.



You can get the user software recorded on a USB stick (optional) or as a link from the distributor. Please see Installing the software in the manual "Cube-DataReader-Software" by "opTricon".

1. After the installation has been successful, press the button of the reader until its display shows "ON", connect the reader to the PC via the provided USB cable, then launch the software.



When the reader is connected to the PC via the USB cable, it is powered by the USB port and doesn't discharge the batteries. There is no auto-shutdown until the reader is unplugged.

2. As soon as the reader is ready for operation the software will automatically try to connect to the reader. This automated process operates preconfigured after installing the software and can be switched off later. In such case, it is possible to connect the reader manually by pressing the **Connect** button. If the reader is connected successfully, the button turns to **Disconnect**.

Menu Setup Language Info

1. [USB] Cube plus (840-2613-0002) v

Connect

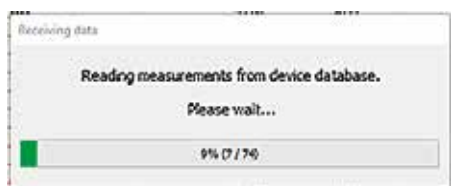
3. Click the **Read data from device**. The software will receive the entries from the memory of the reader and display them in the main window.

Menu Setup Language Info

1. [USB] Cube plus (840-2613-0002) v

Disconnect

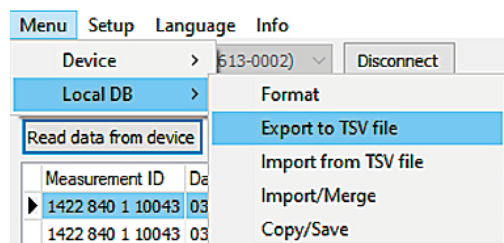
Read data from device



Data presentation format:

Measurement ID	Date / Time	Test name	Lot number	Distributor/Manufacturer	User comments	Temperature (°C)	Voltage(mV)
1432 840 1 10043	04/07/2026 01:26 PM	RUT-E		ANA		19.52	3674
1432 840 0 65390	04/07/2026 01:26 PM	RUT-QC		ANA		19.68	3674
1432 840 1 10043	04/07/2026 11:55 AM	RUT-E		ANA		21.27	3983
1432 840 0 65390	04/07/2026 11:55 AM	RUT-QC		ANA		20.92	3986
1432 840 1 10043	04/07/2026 11:59 AM	RUT-E		ANA		21.74	3996
1432 840 0 65390	04/07/2026 11:57 AM	RUT-QC		ANA		21.74	3996

4. To save the transferred test results click on **Menu, Local DB** and **Export to TSV file** in the menu bar. The saved file with ".tsv" extension (tab separated values) can be opened by the reader software and by other applications, for example Microsoft Excel.



5. After transferring the test results is finished, press the **Disconnect** button and then unplug the reader from the PC.

Menu Setup Language Info

1. [USB] Cube plus (840-2613-0002) v

Disconnect

LIMITATIONS

Not recommended:

- testing at an ambient temperature below 17 °C and above 35 °C;
 - eating legumes a day before testing;
 - drinking carbonated beverages 2-3 hours before testing.
- All these factors can affect the reliability of test results, in addition, false negative results may occur if:
- the concentration of *H.pylori* in the sample taken during the biopsy is below the sensitivity threshold of the test;
 - the sample does not contain *H.pylori* due to the uneven distribution of bacteria in the gastric mucosa (in 1-5% of patients, the bacteria is present in the body/corner of the stomach, and not in the antral part, and conversely);
 - if the sample contains bacillary forms of *H.pylori* cells below 10% of the total number of cells;
 - the biopsy stick or forceps contaminated before testing;
 - taking antibiotics that inhibit *H.pylori* 4-6 weeks before the test;
 - PPIs or H₂ receptor antagonists, analgetics, antiseptics agents, anti-inflammatory agents, bismuth compounds have an anti-*H.pylori* activity and decrease the load of *H.pylori* leading to false negative results, an interval of 2 weeks is required.

The test results must be interpreted by the physician based on the patient's clinical presentation. If there is a discrepancy with other diagnostic parameters, it is recommended to make additional tests using other methods. Semi-quantitative results of AMA RUT Expert are based on kinetic evaluation of the urease activity. For this, it is important to fix the period from the moment the biopsy specimen(s) carefully placed on the reactive element until the possible spot appearance. The time fixation is carried out by the reader automatically, but it is important to start the reading no longer than 1 minute after the biopsy specimen(s) have been placed on the reactive element of the slide. The semi-quantitative result is valid only in this case. Otherwise, if the delay is longer than 1 minute, the test results should be interpreted as qualitative only. As with any diagnostic procedure, the test results indicated on the screen are interpreted in the light of the patient's clinical presentation and any other information available to the physician.

ORDERING INFORMATION

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