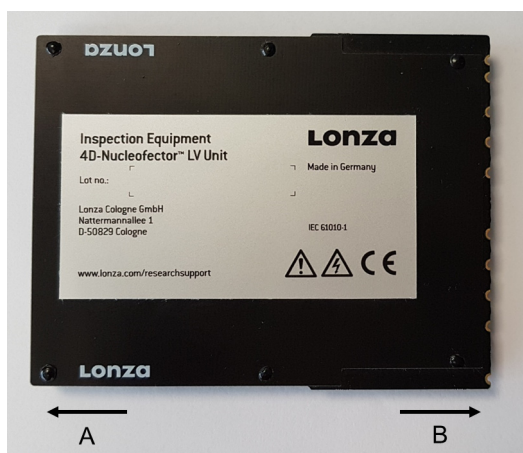


Inspection Equipment for 4D-Nucleofector™ LV Unit

This inspection equipment is a fixed resistor cartridge (560 Ω resistor) that can be used to check the functionality (electrical performance) of the 4D-Nucleofector™ LV Unit prior to use.



AXP-1005

Inspection Equipment 4D-Nucleofector™ LV Unit
Test cartridge orientation: External part for handling (A)
and internal part for insertion into cartridge slot (B).



Test cartridge inserted into 4D-Nucleofector™ LV unit

Instructions for use:

1. Switch on the 4D-Nucleofector™ System. If already turned on go back to the home screen
2. Select "LV Unit" and then "1 mL cartridge"
3. Insert inspection equipment
4. Select any solution code (needs to be done first to be able to select a pulse code)
5. Select the first pulse code setting indicated in the table below (CA-100) and press OK
6. Press START
7. Observe the LEDs on the front of the inspection equipment
8. Check the result window on the screen (for expected results see table below)
9. Repeat steps 5-8 for remaining program codes (EN-200, FF-100 and CA-137). Press the "Back" Button to enter different program code

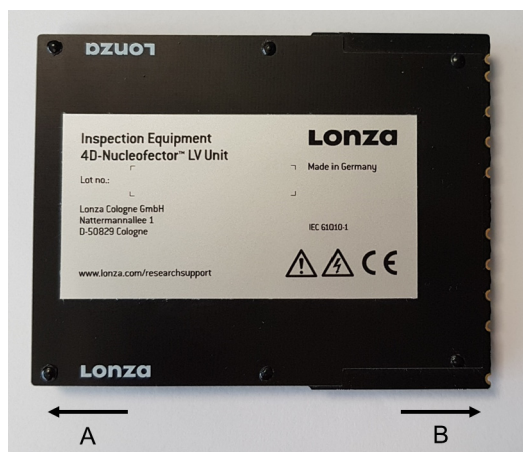
Pulse code	Expected Result
CA-100	The six LEDs do not flash up. No error message.
EN-200	The six LEDs flash up twice each for more than 1 sec. No error message.
FF-100	The six LEDs flash up twice each for less than 1 sec. No error message.
CA-137	The six LEDs flash up twice each for less than 1 sec. No error message.

IMPORTANT NOTE: Please do not use other pulses as the ones indicated as this may damage the test equipment. If you want to use another pulse for a certain reason, please contact Lonza to verify whether that pulse might be suited.

Note: For a full IQOQ of the device, please refer to the respective IQOQ protocol.

Quality Certification

Inspection Equipment 4D-Nucleofector™ LV Unit



AXP-1005

Inspection Equipment 4D-Nucleofector™ LV Unit

Test cartridge orientation: External part for handling (A) and internal part for insertion into cartridge slot (B).

Hereby Lonza Cologne, Germany confirms that this Inspection Equipment for the 4D-Nucleofector™ LV Unit has passed a quality control procedure comprising:

- ✓ Optical check
- ✓ Mechanical check
- ✓ Electronic check
- ✓ Safety Check

Standards

The Inspection Equipment 4D-Nucleofector™ LV Unit was tested by TÜV Rheinland Product Safety GmbH and found to be in compliance with the following standards:

– IEC 61010-1

Declaration of Pack Material

For packing materials, no natural wood is used.

For further details regarding technical specifications and technical standards, please refer to the use instructions (page 1) or contact your local representative.



Dr. Rainer Hammermann
Head of Quality