

Product Information

Fixture for Testing of Medical Small-Bore-Connectors for Liquids and Gases to ISO 80369

CTA: 235886 235887



Applications

ISO 80369 describes a test method for small-bore connectors for liquids and gases in healthcare applications. These can be used with cannulas, syringes, catheters and infusion tubes.

The connectors must be tested for the following stresses:

- Leakage by pressure decay
- Falling drop positive-pressure liquid leakage
- Subatmospheric-pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing = I

Advantages and features

- Compliance with the contents of standards
ISO 80369 - 1
ISO 80369 - 7
ISO 80369 - 6
ISO 80369 - 20
- Fully integrated test sequence via a semi-automated assembly process with subsequent test sequence. This minimizes error influences and saves on both time and costs.
- Calibrated pressure and vacuum device for leakage testing of gases and liquids.
- Standard-compliant reference gauges for mechanical and physical testing of the medium.
- The variable gripping system allows for testing of various specimen geometries.
- testXpert III integrated test program to ISO 80369 with all benefits including, for example expanded traceability to 21 CFR Part 11 and EU GMP Annex 11.

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The following machine configuration is the basic recommendation for testing Luer lock connections:

| Description | ArticleNumber |
|--|---------------|
| zwickiLine Z2.5 TN+ | 1039527 |
| Enlarged base for zwickiLine with torsion drive | 1041715 |
| Emergency stop link (2x) | 1023870 |
| Ethernet switch for 10/100/1000 MBit | 1026425 |
| I/O module for analog and digital signal processing | 029448 |
| Torsion drive, 2 Nm or higher | 1020233 |
| Alignment fixture for axial offset and angle correction | 3006208 |
| Adjustment rod for alignment fixture | 3006211 |
| Xforce HP 500 N load cell | 069529 |
| Torque transducer, 2 Nm | 069536 |
| testXpert III basic program | 1035154 |
| testXpert III advanced control mode | 1035959 |
| testXpert III test program correction curve/calibration, torsion | 1042159 |
| Personal computer | 1076395 |
| TFT monitor | 028997 |
| Documentation, English | 347188 |
| Spare parts lists, English | 354856 |

Optional:

| Description | ArticleNumber |
|---|---------------|
| Safety device | 059078 |
| Increase rotation speed | 063785 |
| Safety door link tCII (2x) | 1041273 |
| testXpert III expanded traceability to 21 CFR Part 11 and EU GMP Annex 11 | 1035624 |

Test fixture components

Software

| Description | ArticleNumber |
|--|---------------|
| testXpert III test sequence to ISO 80369 | 3008477 |

Test device, upper

| Description | ArticleNumber |
|---|---------------|
| Compensation device for specimens with threaded closure | 1082919 |

Test device, lower

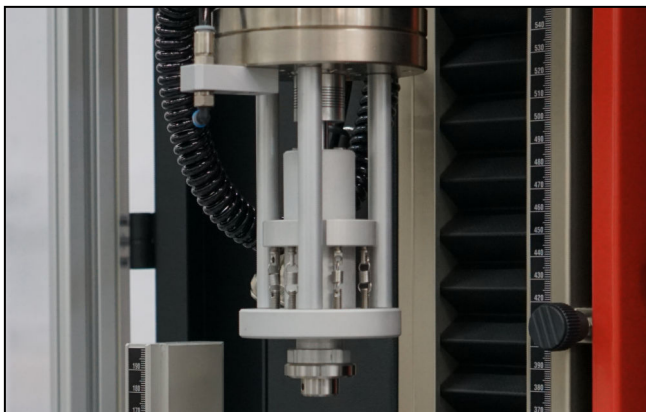
| Description | ArticleNumber |
|---|---------------|
| Universal holder for Luer lock connectors | 3008461 |
| Specimen jaws with non-slip surface for specimen with \varnothing 5-12 mm | 1088183 |

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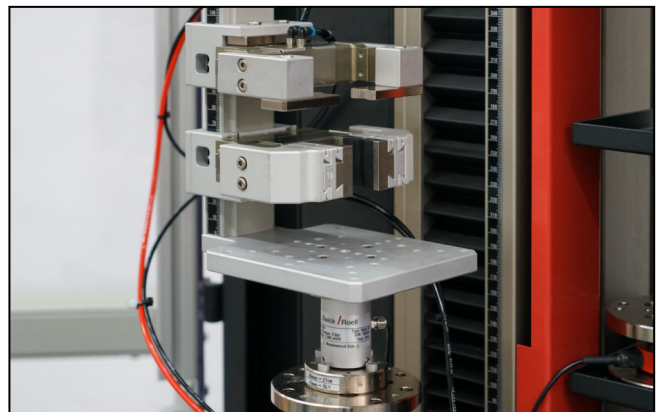
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| Description | ArticleNumber |
|--|----------------|
| Specimen jaws with non-slip surface for specimen with \varnothing 12-35 mm | 1088184 |
| Pneumatic control unit with inching mode | 057427 |

CTA: 235888,235889



Compensation device for 8 mm locking pin



Universal holder for Luer lock connectors including specimen jaws with non-slip surface

Pressure / vacuum control unit

| Description | ArticleNumber |
|---|----------------|
| Control unit for pressure and vacuum test Pressure range: -0.8 to 5 bar | 3008469 |
| Pressure sensor with sensor plug Measurement range: -0.8 to 5 bar Accuracy: 0.05 % of the end value | 3008467 |

CTA: 235890



Vacuum / pressure control unit including sensor

All data at ambient temperature.

Subject to change in the course of further development.

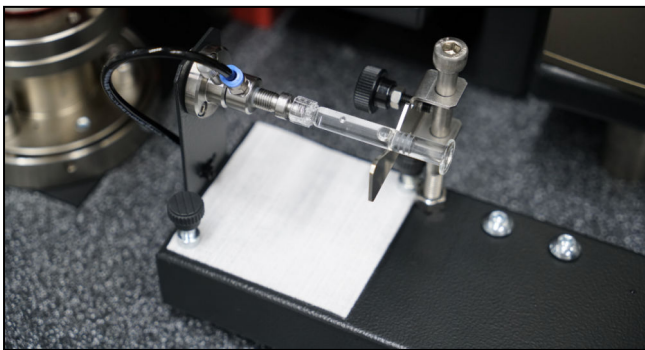
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Testing device for falling drop positive-pressure liquid leakage test

| Description | ArticleNumber |
|---|----------------|
| Testing device for falling drop positive-pressure liquid leakage test Specimen adaptation via 8 mm locking pins. Including magnets to hold blotting paper. | 3008463 |

CTA: 235891



Various metal luer connectors Fig. C1 - C6 are available for the respective sample geometry. If the sample material to be tested made of glass, the plastic luer connector is required for the leakage test.

| ISO 80369 | Specimen material plastics | | | | | | | Specimen material glass | | | | | | |
|---------------|----------------------------|----------|----------|--------------|----------|----------|----------|-------------------------|----------|----------|--------------|----------|----------|----------|
| | Mechanical Test | | | Leakage Test | | | | Mechanical Test | | | Leakage Test | | | |
| | F | G | H | B | C | D | E | F | G | H | B | C | D | E |
| -20 Annex | | | | | | | | | | | | | | |
| Fig. C1 | | -6 -7 | | -6 -7 | -6 -7 | -6 -7 | -6 -7 | | -6 -7 | | | | | |
| Fig. C2 | -7 | | | -6 -7 | -6 -7 | -6 -7 | -6 -7 | -7 | | | | | | |
| Fig. C3 | -6 -7 | | -6 -7 | | | | | -6 -7 | | -6 -7 | | | | |
| Fig. C4 | | -6 -7 | | -6 -7 | -6 -7 | -6 -7 | -6 -7 | | -6 -7 | | | | | |
| Fig. C5 | -6 -7 | | -6 | -6 -7 | -6 -7 | -6 -7 | -6 -7 | -6 -7 | | -6 | | | | |
| Fig. C6 | -7 | | -7 | | | | | -7 | | -7 | | | | |
| Luer plastics | | | | | | | | | | | -6 -7 | -6 -7 | -6 -7 | -6 -7 |

| | Description | 80369-20 | 80369-6 | 80369-7 |
|-----------------|--|----------|---------|---------|
| Leakage Test | Leakage by pressure decay | B | 6.1.2 | 6.1.2 |
| | Falling Drop fluid leakage | C | 6.1.3 | 6.1.3 |
| | Subatmospheric-pressure air leakage | D | 6.2 | 6.2 |
| Mechanical Test | Stress cracking | E | 6.3 | 6.3 |
| | Resistance to separation from axial load | F | 6.4 | 6.4 |
| | Resistance to separation from unscrewing | G | 6.5 | 6.5 |
| | Resistance to overriding | H | 6.6 | 6.6 |

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Luer connectors¹⁾ to ISO 80369-6

| Description | ArticleNumber |
|---------------------------------------|----------------|
| Luer connector to ISO 80369-6 Fig. C1 | 3014264 |
| Luer connector to ISO 80369-6 Fig. C2 | 3014265 |
| Luer connector to ISO 80369-6 Fig. C3 | 3014266 |
| Luer connector to ISO 80369-6 Fig. C4 | 3014267 |
| Luer connector to ISO 80369-6 Fig. C5 | 3014268 |

Luer connectors¹⁾ to ISO 80369-7

| Description | ArticleNumber |
|---|----------------|
| Luer connector to ISO 80369-7 Fig. C1 | 3008475 |
| Luer connector to ISO 80369-7 Fig. C2 | 3008474 |
| Luer connector to ISO 80369-7 Fig. C3 | 3008473 |
| Luer connector to ISO 80369-7 Fig. C4 | 3008472 |
| Luer connector to ISO 80369-7 Fig. C5 | 3008471 |
| Luer connector to ISO 80369-7 Fig. C6 | 3008470 |
| Luer plastic connector for performance of pressure and vacuum tests on glass syringes | 1087884 |

Adapter for Luer connectors²⁾

Required to mechanically connect the Luer connectors to the upper test device. With the pressure and control unit, internal pressure can be applied to the connecting elements via an integrated air channel.

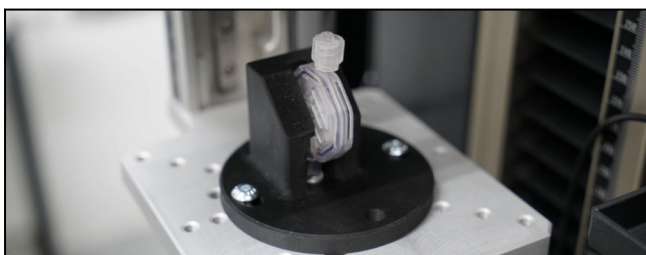
| Description | ArticleNumber |
|---|----------------|
| Adapter (8 mm locking pin) for ZwickRoell Luer connectors | 1084432 |
| Adapter (8 mm locking pin) for Enersol Luer connectors | 1084433 |

Customized mounting for complex / asymmetrical specimen geometries

For asymmetrical specimen geometries the connectors can be centrally aligned by using special specimen grips and specimen grip inserts. For this, the specimen data (STEP files) of the outer contour are required. Production is carried out via additive manufacturing processes. Using the standardized drill pattern on the universal holder, the specimen is positioned in the axis and secured.

| Description | ArticleNumber |
|--|----------------|
| Mounting for complex Luer lock geometries. | 3008462 |

CTA: 235692



¹⁾ One adapter (Item No. 1084432) required per Luer connector

²⁾ One adapter is required per connector.

All data at ambient temperature.

Subject to change in the course of further development.