

## 4040 Examination Method of Luer Conical Fitting of Prefilled Syringes

This method is used to examine the fitness of the Luer conical fitting of a prefilled syringe.

### Reference connector

Reference connector is the standard connector that fits with the Luer conical fitting of the prefilled syringe during examination.

Reference connectors used to test the glass barrel of the prefilled syringe shall be manufactured from semi-rigid materials, and those used to test the plastic barrel shall be manufactured from corrosion-resistant rigid materials with a surface roughness value  $R_a$  not exceeding  $0.8\mu\text{m}$  on critical surfaces. Semi-rigid material is the material with a modulus of elasticity in flexure or in tension between 60MPa and 3433MPa. Rigid material is the material with a modulus of elasticity in flexure or in tension greater than 3433MPa.

Reference connector specified in Fig. 1 is used to test the Luer non-locking connector. Reference connector specified in Fig. 2 is used to test the leakage, separation from screwing, stress cracking of the Luer lock connector. Reference connector specified in Fig. 3 is used to test the separation from axial load, overriding of the Luer lock connector.

Dimensions in millimeters

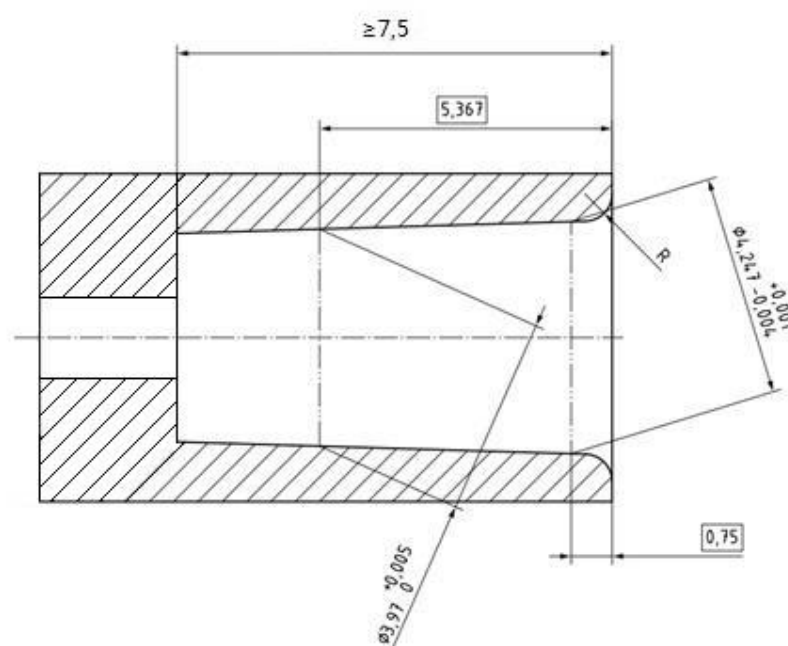
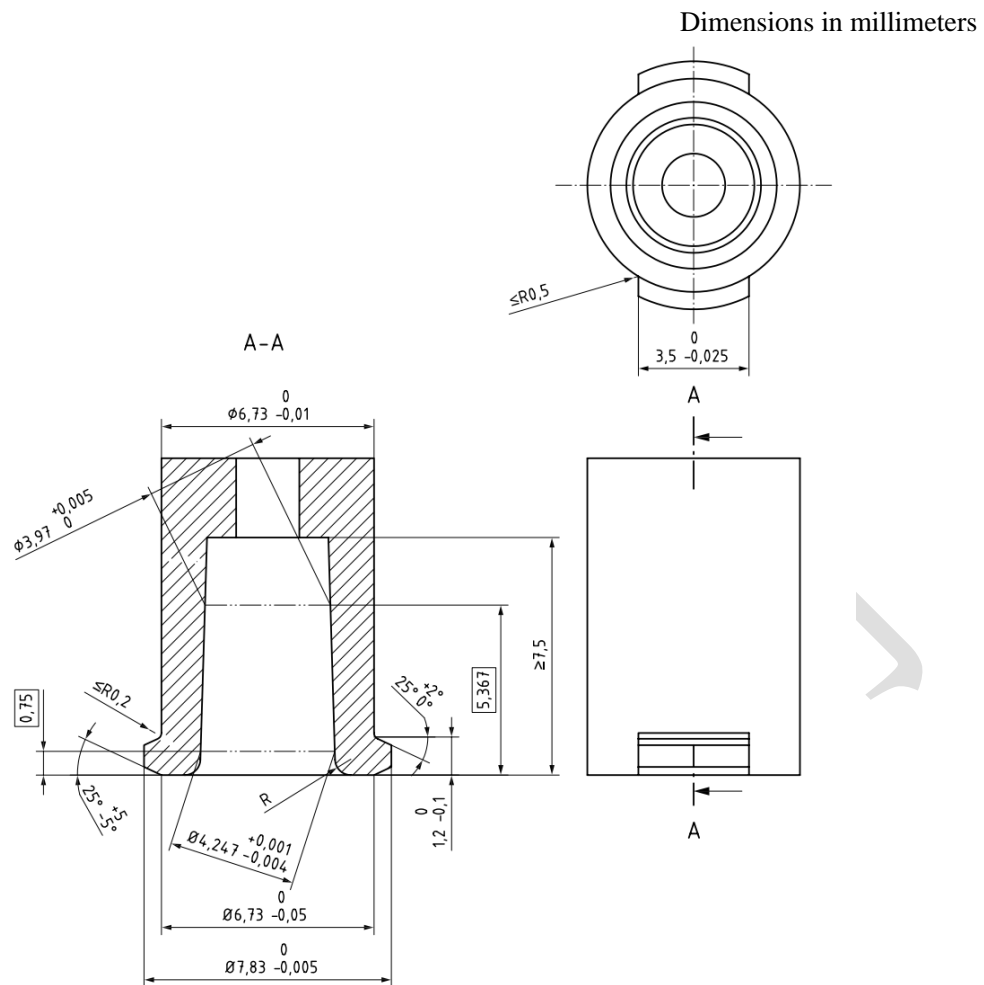


Fig. 1 Reference connector for Luer non-locking connector tests

- 19 Note1: R is the radius or chamfer not to exceed 0.5mm.
- 20 Note2: Conical taper 0.06:1.



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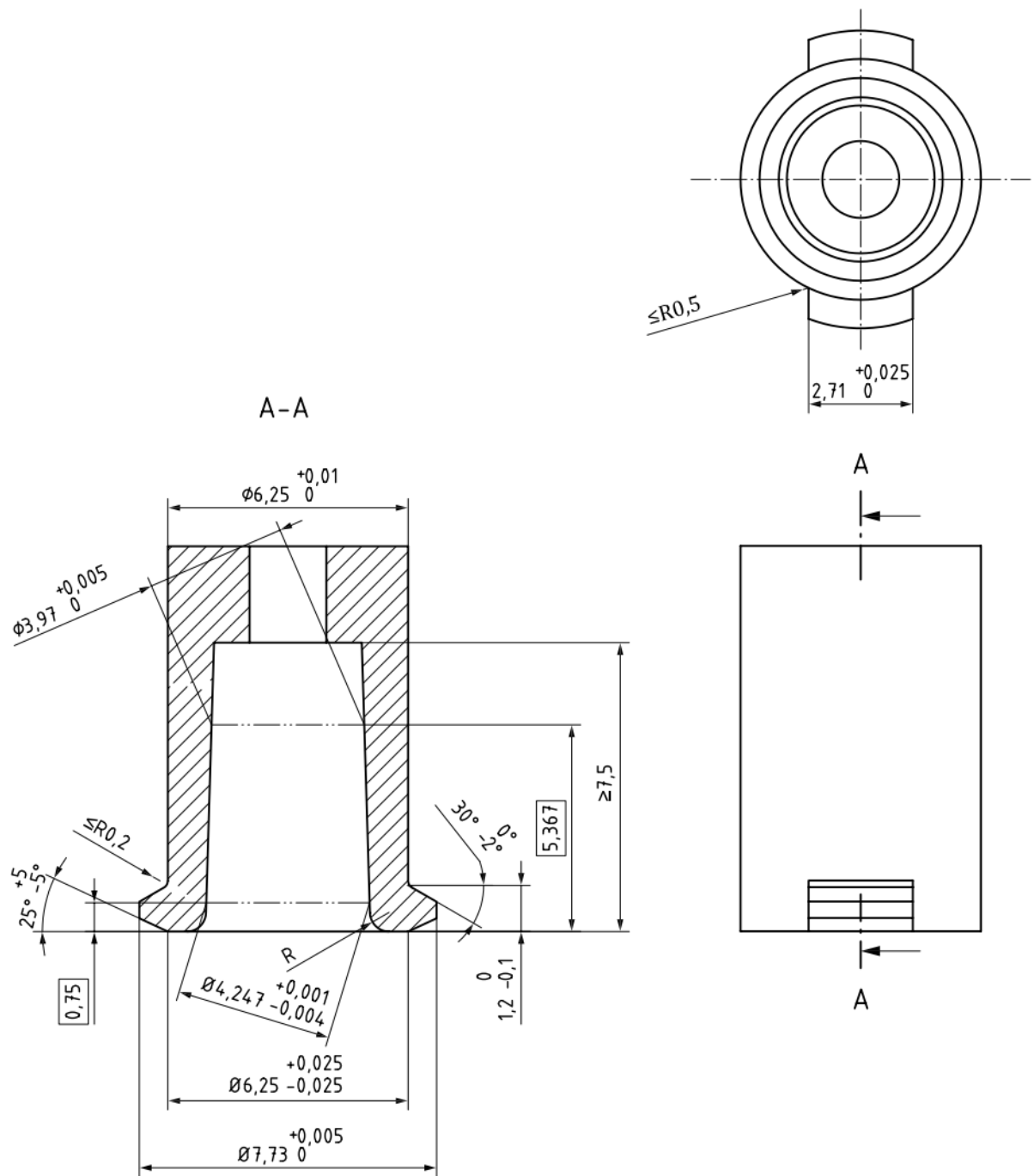
23 Fig. 2 Reference connector for leakage, separation from screwing and stress cracking test of  
 24 Luer lock connector

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26 Note: All outside edges of lug or thread form shall have a radius between 0.15mm and  
 0.20mm. R is the radius or chamfer not to exceed 0.5mm.

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Dimensions in millimeters



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Fig. 3 Reference connector for separation from axial load and overriding test of Luer lock connector

Note: All outside edges of lug or thread form shall have a radius between 0.15mm and 0.20mm. R is the radius or chamfer not to exceed 0.5mm.

33 **Environmental test conditions**

34 Perform tests at a temperature within the range of 15°C to 30°C and at a relative humidity  
35 between 25% and 65%.

36 **1. Positive-pressure liquid leakage test**

37 **Instruments**

38 Reference connector, see Fig.1 or Fig.2.

39 Assembling device, which can simultaneously apply an axial force and torque to assemble  
40 Luer conical fitting and reference connector.

41 Pressure gage, measuring the applied pressure with a minimum accuracy of 0,3%

42 Timer, with an accuracy of  $\pm 1s$ .

43 **Examination method**

44 a) Introduce water of about a quarter nominal volume into the prefilled syringe, dry the  
45 outside of the connector after exhausting the air in it.

46 b) For a Luer non-locking connector, assemble by applying an axial force of between  
47 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of  
48 between  $0.08N \cdot m$  and  $0.10N \cdot m$  or a rotation not exceeding  $90^\circ$ .

49 c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and  
50 27.5N for 5s to 6s while rotating the connector under test to a torque of between  $0.08N \cdot$   
51  $m$  and  $0.12N \cdot m$ .

52 d) With the axis of assembled connector horizontal, position the plunger stopper by the  
53 plunger rod to avoid the movement of the plunger stopper by pressurizing.

54 e) Apply a pressure between 300kPa and 330kPa through the small bore of the reference  
55 connector, hold a period of 30s to 35s. Visually inspect the connection.

56 **Result determination**

57 The test is passed if there is no falling drop of water.

58 **2. Stress cracking test**

59 **Instruments**

60 Reference connector, see Fig.1 or Fig.2.

61 Assembling device, which can simultaneously apply an axial force and torque to assemble  
62 Luer conical fitting and reference connector.

63 Pressure gage, measuring the applied pressure with a minimum accuracy of 0,3%

64 Timer, with an accuracy of  $\pm 1s$ .

65 **Examination method**

66 a) Dry the sample and the reference connector.

67 b) For a Luer non-locking connector, assemble by applying an axial force of between  
68 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of  
69 between  $0.08N \cdot m$  and  $0.10N \cdot m$  or a rotation not exceeding  $90^\circ$ .

- 70 c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and  
71 27.5N for 5s to 6s while rotating the connector under test to a torque of between  $0.08\text{N}\cdot\text{m}$   
72 and  $0.12\text{N}\cdot\text{m}$ .  
73 d) Leave the sample and reference connector assembled for not less than 48h.  
74 e) Inspect visually, then do the positive-pressure liquid leakage test.

#### 75 **Result determination**

76 The test is passed if there is no visible cracks in the sample connector and positive-pressure  
77 liquid leakage test has passed

### 78 **3. Resistance to separation from axial load test**

#### 79 **Instruments**

80 Reference connector, see Fig.1 or Fig.3.

81 Assembling device, which can simultaneously apply an axial force and torque to assemble  
82 Luer conical fitting and reference connector.

83 Timer, with an accuracy of  $\pm 1\text{s}$ .

84 Loading device, which can apply at least  $35\text{N}$  axial separation force

#### 85 **Examination method**

- 86 a) Dry the sample and the reference connector.  
87 b) For a Luer non-locking connector, assemble by applying an axial force of between  
88 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of  
89 between  $0.08\text{N}\cdot\text{m}$  and  $0.10\text{N}\cdot\text{m}$  or a rotation not exceeding  $90^\circ$ .  
90 c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and  
91 27.5N for 5s to 6s while rotating the connector under test to a torque of between  $0.08\text{N}\cdot\text{m}$   
92 and  $0.12\text{N}\cdot\text{m}$ .  
93 d) Apply an axial force in a direction away from the test fixture at a rate of approximately  
94  $10\text{N/s}$ . For Luer non-locking connector, the axial force is between 23N and 25N. For  
95 Luer lock connector, the axial force is between 32N and 35N. Hold the axial force for  
96 10s to 15s. Do not apply any supplementary force in other directions.  
97 e) Inspect whether the connectors have completely detached at the interface between the  
98 connectors.

#### 99 **Result determination**

100 The test is passed if the connectors have not completely detached at the interface between the  
101 connectors.

### 102 **4. Resistance to separation from unscrewing test (only applicable to Luer lock** 103 **connector)**

#### 104 **Instruments**

105 Reference connector, see Fig. 2.

106 Assembling device, which can simultaneously apply an axial force and torque to assemble  
107 Luer conical fitting and reference connector.

108 Timer, with an accuracy of  $\pm 1$ s.

109 Loading device, which can apply a torque between  $0.018\text{N}\cdot\text{m}$  and  $0.020\text{N}\cdot\text{m}$ .

110 **Examination method**

111 a) Dry the sample and the reference connector.

112 b) Assemble the sample and the reference connector by applying an axial force of between  
113  $26.5\text{N}$  and  $27.5\text{N}$  for 5s to 6s while rotating the connector under test to a torque of  
114 between  $0.08\text{N}\cdot\text{m}$  and  $0.12\text{N}\cdot\text{m}$

115 c) Apply an unscrewing torque between  $0.018\text{N}\cdot\text{m}$  and  $0.020\text{N}\cdot\text{m}$  over a hold period  
116 between 10s and 15s.

117 d) Inspect whether the connectors have completely detached at the interface between the  
118 connectors.

119 **Result determination**

120 The test is passed if the connectors have not completely separated at the interface between  
121 the connectors.

122 **5. Resistance to overriding test (only applicable to Luer lock connector)**

123 **Instruments**

124 Reference connector, see Fig.3.

125 Assembling device, which can simultaneously apply an axial force and torque to assemble  
126 Luer conical fitting and reference connector.

127 Timer, with an accuracy of  $\pm 1$ s.

128 Loading device, which can apply a torque between  $0.15\text{N}\cdot\text{m}$  and  $0.17\text{N}\cdot\text{m}$ .

129 **Examination method**

130 a) Dry the sample and the reference connector.

131 b) Assemble the sample and the reference connector by applying an axial force of between  
132  $26.5\text{N}$  and  $27.5\text{N}$  for 5s to 6s while rotating the connector under test to a torque of  
133 between  $0.08\text{N}\cdot\text{m}$  and  $0.12\text{N}\cdot\text{m}$ .

134 c) Apply a screwing torque between  $0.15\text{N}\cdot\text{m}$  and  $0.17\text{N}\cdot\text{m}$  over a hold period between 5s  
135 and 10s. Do not apply any supplementary force or torque in other directions.

136 d) Inspect whether the threads or lugs of the reference connector have not completely  
137 extended past the threads or lugs of the connector under test.

138 **Result determination**

139 The test is passed if the threads or lugs of the reference connector have not completely  
140 extended past the threads or lugs of the connector under test.

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