

QUALITY ASSURANCE TESTING, EQUIPMENT AND SERVICES



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## Guidance to the required reference connectors and equipment for testing small-bore connectors for Enteral applications

ISO 80369-3:2016 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 80369-3 Clause	ISO 80369-20 Annex	Enersol equipment required	Requried Enersol reference connectors for testing Enteral small-bore connectors
Clause 6 - all sub-clauses	The test methods require the test sample is assembled with the appropriate reference connector, using a specified force and/or torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors listed below
Clause 6.1.1 - Fluid leakage requirement	Evaluate using EITHER leakage by pressure decay, or positive pressure liquid leakage. It is inferred the same method is used after the stress cracking conditioning.		
Clause 6.1.2 - Leakage by pressure decay	Annex B - Leakage by Pressure Decay	S77 or S77B - Automated pressure decay tester	S63 - Fig. C.1 - SC for testing CC S65 - Fig. C.3 - CC for testing SC
Clause 6.1.3 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S63 - Fig. C.1 - SC for testing CC S65 - Fig. C.3 - CC for testing SC
Clause 6.2 - Stress cracking	Annex E - Stress cracking	Use S15B and; S16B for positive pressure liquid leakage or S77/S77B for pressure decay	S63 - Fig. C.1 - SC for testing CC S65 - Fig. C.3 - CC for testing SC
Clause 6.3 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S64 - Fig. C.2 - SC for testing CC S66 - Fig. C.4 - CC for testing SC
Clause 6.4 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S63 - Fig. C.1 - SC for testing CC S65 - Fig. C.3 - CC for testing SC
Clause 6.5 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S64 - Fig. C.2 - SC for testing CC S66 - Fig. C.4 - CC for testing SC
Clause 6.6 - Disconnection by unscrewing	Annex I - Disconnection by unscrewing	S79 - Disconnection by unscrewing tester	S63 - Fig. C.1 - SC for testing CC S65 - Fig. C.3 - CC for testing SC
KEY: SC = Socket (Female) Connector CC = Cone (Male) Connector			