



QUALITY ASSURANCE TESTING, EQUIPMENT AND SERVICES

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<https://www.gagecrib.com/>

Guidance to the required reference connectors and equipment for testing Enteral reservoir connectors

ISO 18250-3:2018 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 18250-3 Clause	ISO 80369-20 Annex	Enersol equipment required	Required Enersol reference connectors for testing Enteral Reservoir 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 6.2 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S88 - Fig. C.1. - CP for testing XC (E1R) S90 - Fig. C.3. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.3 - Subatmospheric pressure air leakage	Annex D - Subatmospheric pressure air leakage	S78A - Automated subatmospheric pressure air leakage tester (for subatmospheric pressures close to atmospheric pressure)	S88 - Fig. C.1. - CP for testing XC (E1R) S90 - Fig. C.3. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.4 - Stress cracking	Annex E - Stress cracking	Use S15B and S16B	S88 - Fig. C.1. - CP for testing XC (E1R) S90 - Fig. C.3. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.5 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S89 - Fig. C.2. - CP for testing XC (E1R) S91 - Fig. C.4. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.6 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S88 - Fig. C.1. - CP for testing XC (E1R) S90 - Fig. C.3. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.7 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S89 - Fig. C.2. - CP for testing XC (E1R) S91 - Fig. C.4. - XC for testing CP (E1R) S92 - Fig. C.5. - CC for testing SC (E2R) S93 - Fig. C.6. - SC for testing CC (E2R)
Clause 6.8 - Disconnection by unscrewing	Annex I - Disconnection by unscrewing	S79 - Disconnection by unscrewing tester	S88 - Fig. C.1. - CP for testing XC (E1R) S90 - Fig. C.3. - XC for testing CP (E1R) (Test not required for E2R connectors)

KEY: CP = Cross-port connector XC = Cross connector SC = Socket (Female) Connector CC = Cone (Male) Connector