ISO/TS 23810:2018-07 (E)

Cardiovascular implants and artificial organs - Checklists for use of extracorporeal circulation equipment

Contents

Page

Foreword vi

Introduction vii

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Preoperative requirements 1
4.1 Patient information 1
4.1.1 Rationale 1
4.1.2 Patient interview 2
4.1.3 Patient identity 2
4.1.4 Medical record number 2
4.1.5 Allergies 2
4.1.6 Blood bank numbers 2
4.1.7 Blood type and antibodies 2
4.1.8 Chart 2
4.1.9 Procedure 2
4.2 Equipment and Instructions for Use 3
4.2.1 Rationale 3
4.2.2 Equipment 3
4.2.3 Instructions for Use 3
4.3 Sterility/cleanliness 3
4.3.1 Rationale 3
4.3.2 Component package integrity/expiration dates 3
4.3.3 Serial/lot numbers 3
4.3.4 Equipment 3
4.3.5 Heat exchanger(s) 3
4.3.6 Maintenance 4
4.4 Pumps 4
4.4.1 Rationale 4
4.4.2 Electrical 4
4.4.3 Batteries 4
4.4.4 Roller pumps 4
4.4.5 Centrifugal pumps 5
4.5 Cardioplegia 5
4.5.1 Rationale 5
4.5.2 Solutions 5
4.5.3 Method of delivery 6
4.5.4 Heat exchanger leaks 6
4.5.5 Temperature control 6
4.5.6 Bubble removal 6
4.5.7 Leak-free 6
4.6 Medical gas supply 6
4.6.1 Rationale 6
4.6.2 Circuit gas line(s) connection(s) 6
4.6.3 Source(s) and connections of gas(es) 6
4.6.4 Flow meter/gas blender 6

4.6.5 Hoses 6
4.6.6 Gas exhaust 7
4.6.7 Inhalational gas scavenge line 7
4.6.8 Oxygen sensor 7
4.6.9 Operating pressures for gas sources 7
4.6.10 Gas filter 7
4.7 Vacuum supply 7
4.7.1 Rationale 7
4.7.2 Vacuum line connections 7
4.7.3 Vacuum source connections 7
4.7.4 Vacuum source pressures 7
4.8 Components 7
4.8.1 Rationale 7
4.8.2 Connections/stopcocks/caps 8
4.8.3 Tubing and shunts 8
4.8.4 Tubing direction 8
4.8.5 Tubing lengths and kinks 8
4.8.6 One-way valve(s) 8
4.8.7 Bubble removal 8
4.8.8 Leaks 8
4.8.9 Patency of arterial line/cannula 8
4.9 Safety mechanisms 8
4.9.1 Rationale 8
4.9.2 Alarms 8
4.9.3 Arterial filter/bubble trap 9
4.9.4 Cardiotomy/hard-shell venous reservoir(s) 9
4.9.5 Venous line occluder 9
4.9.6 Devices attached to console 9
4.9.7 Arterial line occluder 9
4.9.8 Vent(s) and suctions 9
4.9.9 Level sensor for dynamic priming 9
4.10 Assisted venous return 9
4.10.1 Rationale 9
4.10.2 Positive pressure-relief valve 9
4.10.3 Negative pressure-relief valve 9
4.10.4 Vacuum regulator 9
4.10.5 Kinetic-assisted venous drainage 10
4.11 Monitoring 10
4.11.1 Rationale 10
4.11.2 Temperature probes 10
4.11.3 Pressure transducers/monitors 10
4.11.4 Flow probe(s) 10
4.11.5 In-line sensor(s) 10
4.12 Anticoagulation 10
4.12.1 Rationale 10
4.12.2 Monitoring devices 10
4.12.3 Time and dose 10
4.12.4 Anticoagulation tested and reported 10
4.13 Temperature control 11
4.13.1 Rationale 11
4.13.2 Water source(s) 11
4.13.3 Temperature range(s) 11
4.13.4 Water lines 11
4.14 Supplies 11
4.14.1 Rationale 11
4.14.2 Tubing clamps 11
4.14.3 Drugs 11
4.14.4 Solutions 11
4.14.5 Blood products 11
4.14.6 Sampling syringes/laboratory tubes and supplies 12
4.14.7 Inhalational anaesthetic 12

4.15 Backup 12
4.15.1 Rationale 12
4.15.2 Hand cranks or uninterruptible power supply 12
4.15.3 Emergency lighting 12
4.15.4 Backup oxygen tank with flow meter 12
4.15.5 Duplicate circuit components and hardware 12
4.15.6 Ice 12

5 Weaning and termination 12
5.1 Rationale 12
5.2 Inhalational anaesthetic 12
5.3 Assisted venous return 13
5.4 Cardiotomy/venous reservoirs 13
5.5 Shunt(s) 13
5.6 Vent(s) 13
5.7 Gas flow 13
5.8 Extracorporeal flow with centrifugal pump 13

6 Post-extracorporeal circulation 13
6.1 Rationale 13
6.2 Termination 13
6.3 Clamping 13
6.4 Bubble removal 13
6.5 Suction 13
6.6 Patient haemodynamics 13

7 Emergent re-initiation of extracorporeal circulation 14
7.1 Rationale 14
7.2 Anticoagulation 14
7.3 Circuit volume 14
7.4 Bubble removal 14
7.5 Medical gas supply 14
7.6 Alarms and alerts 14
7.7 Water supply 14
7.8 Tubing 14

8 Peri-procedural 14
8.1 Entrainment of air into the ECC 14
8.2 Reservoir level 14
8.3 ECC parameters 14
8.4 Water supply 15
8.5 Fluid balance 15
8.6 Personnel 15

9 Documentation 15
9.1 Rationale 15
9.2 Completion of the checklist and procedure record 15
9.3 Retention of the checklist 15
9.4 Expiration date 15
9.5 Operator's manuals 15

10 Devices or equipment not part of the extracorporeal circuit 15
10.1 Rationale 15

11 Annotations to the Bibliography 16

Bibliography 17