

## Appendices

### Appendices

- **In Appendix A** - Meaning of Alarms, there is a table with the messages displayed in alarm conditions and the meaning of each message. This Appendix may also contain a table with the meaning of technical error codes.
- **In Appendix B** - Troubleshooting, a table with problems, possible causes, and suggested actions for correction is presented. For instance, problems may include failure of tests performed automatically by the ventilator, lack of precision in the control of variables, and failure to trigger alarms. It is recommended to list the potential causes from the most to the least likely to occur. After the corrective action, ventilator performance tests should be carried out.
- **Appendix C** - Part List provides a list of parts and components of the ventilator that can be replaced by service personnel with their identifications (Part Number). Some manufacturers may also provide preventive maintenance kits that contain the parts to be replaced according to the preventive maintenance schedule. In addition to the part description and its Part Number, the table may also contain photos of the parts to facilitate identification by the service personnel. If the list of spare parts is not provided, the service manual must include a statement that the manufacturer will make the list of equipment components available upon request (requirement for technical description, subsection 7.9.3.3, ABNT NBR IEC 60601-1:2010 Amendment 1:2016).
- **In Appendix D** - Diagrams, the ventilator's electrical/electronic and pneumatic circuit diagrams are provided. Some manufacturers may also provide a functional block diagram of the ventilator to facilitate understanding its operation. According to the normative requirements, if circuit diagrams are not provided, the technical description must contain a statement that the manufacturer will make circuit diagrams available upon request (requirement for the technical description, subsection 7.9.3.3, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). The service manual should indicate the ventilator's pneumatic diagram, including a diagram for operator detachable parts of the ventilator breathing system, provided or recommended in the instructions for use (requirement for technical description, subsection 201.7.9.3.1.101 b), ABNT NBR ISO 80601-2-12:2014).
- **In Appendix E** - Operational Verification Report, a form is provided to be filled out during the operational verification procedure of the ventilator for test documentation purposes. Subsection 6.1 of ABNT NBR IEC 62353:2019 guides the data that should be included in the test documentation, such as the identification of the organization responsible for the tests, the person(s) who performed the tests, the equipment (e.g., type, serial number, inventory number) and accessories tested, the tests and measurements, date, type and conclusion/results of visual inspections, measurements (measured values, measurement method, measurement equipment), functional tests, evaluation completed, date and confirmation of the professional who performed the evaluation. If electronic documentation is used, an assignment to the inspector/evaluator must be established. A table of equipment marking symbols and descriptions of their meanings is provided.
- **In Appendix F** - Meaning of Symbols. The service manual must contain all applicable ratings specified for protection against electric shock, protection against harmful penetration of water or particulate matter, sterilization method, oxygen-enriched environment, continuous or non-continuous operation. Also, Appendix F should provide any warnings, safety notes, and explanation of safety signs, marked on the equipment, all identification marks (manufacturer's name or trademark and model or type reference), reference to accompanying documents, identification of accessories (manufacturer's name or trademark and model or type reference), model or type reference of the equipment from which it receives power (if applicable), and IP (Ingress Protection) rating (requirements for the technical description, when separate from the instructions for use, subsections 7.2 and 7.9.3.1, ABNT NBR IEC 60601-1:2010 Amendment 1:2016).
- **In Appendix G** - Warranty, the warranty conditions are specified, and instructions are given for sending the equipment to Technical Assistance and filling out a form describing the problem.