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Proposal of a Service Manual Structure for Maintenance of Critical Care Ventilators

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ABSTRACT

In this work, we propose a structure of a service manual as a reference to assist the clinical engineering team of hospitals in the acquisition and maintenance of critical care ventilators and new manufacturers of this class of medical equipment. The structure of the service manual was built upon service manuals from eight commercial mechanical ventilators and the standard requirements of ABNT NBR IEC 60601-1:2010 Amendment 1:2016, ABNT NBR ISO 80601-2-12:2014 and ABNT NBR IEC 62353:2019. The structure encompasses seven sections (Introduction to the Manual, Pulmonary Ventilator's Operation, Disassembly and Assembly, Ventilator Performance Test, Service Procedures, Preventive Maintenance, and Operational Check Procedures) and seven appendices (Meaning of Alarms, Troubleshooting, Replacement Parts, Diagrams, Operational Check Report, Meaning of Symbols, and Warranty). All sections of the proposed service manual were presented with examples of description and main elements found in the references. Also, descriptions of respective standards related to the topic were included when applicable.Results indicated the need to establish procedures for recurrent tests of critical care ventilators aiming at the proper functioning of the equipment within the normative technical requirements and patient safety.

Introduction

Medical electrical equipment is electrically powered equipment that exchanges energy to diagnose, treat, or monitor patients. They are complex devices that require several measures to ensure their safety and performance [1]. Among the medical electrical equipment, mechanical ventilators stand out. Mechanical ventilator is a class of medical electrical equipment that helps patients in the process of pulmonary ventilation, controlling, and monitoring parameters such as pressure and flow in the airways [2]. Critical care ventilators are used for patients dependent on mechanical ventilation, and their failure may lead to death [3]. In Brazil, ANVISA [4] is responsible for medical electrical equipment certification before its commercialization. For ventilators, there are specific standards that must be met to ensure safety and essential performance, with the general and particular requirements provided by ABNT NBR IEC 60601-1 [1,3]. Although the current Brazilian medical electrical equipment certification process

ensures safety and performance before commercialization, there is no enforcement to evaluate medical electrical equipment after the sale [5]. The lack of a proper maintenance policy can result in a significant rate of inoperative medical devices, with estimates between 20-40% of the total Brazilian medical equipment park in 1986 [6]. Also, inadequate maintenance policies preclude the equipment in use to comply with the requirements necessary for its essential performance and safety. Functional tests on operating and reactivated mechanical ventilators have shown deviations from configured values of essential ventilation parameters, such as the volume delivered per ventilation [7] and the fraction of oxygen in the air inspired by the patient [8].

The clinical engineering group is responsible for medical equipment procurement and maintenance [9,10]. The elaboration of an effective medical electrical equipment maintenance policy involves both maintenance procedures (corrective and preventive) and recurrent tests to evaluate the equipment's performance [11,12]. The standardization of the ventilators in the same medical-hospital equipment pool would make maintenance management straightforward since the equipment incorporates new functions over time and there are differences in models from different manufacturers for the same class of equipment [13,14], but this is not what happens usually. The study by Bassani, et al. [15], based on data from ten different Brazilian public hospitals in 2020, showed that ventilators were unevenly distributed among 20 manufacturers and about half aged more than 11 years. The maintenance of critical care ventilators deserves special attention in a hospital's medical electrical equipment system, not only because of the criticality of its function but also because of its budgetary relevance. Mechanical ventilation can increase the daily cost of an intensive care unit patient by 60% [16], and ventilators maintenance expenses can represent about 10% of a hospital's total maintenance budget [15].

The urgent demand of ventilators during the SARS-CoV-2 disease pandemic (COVID-19) led to the emergency development of new ventilators [2] and the reactivation of old equipment. Especially in this context, clinical engineering groups must obtain from manufacturers the information needed for maintenance management to ensure the safety and performance of ventilators in hospitals over the years after the equipment has been incorporated. Commercially, medical electrical equipment documentation consists of the user manual, usually intended for those who will use the equipment in the hospital, and the service manual, which provides information for the maintenance technical team. ANVISA recommends, as a good practice in the incorporation process, that the institution maintains the service manual of the acquired medical electrical equipment [4]. The service manual of a medical electrical equipment provides information on troubleshooting, calibration, performance tests, and part list for replacement. As such, the service manual can represent an essential tool for clinical engineering groups in training technical maintenance staff, defining preventive maintenance schedules, and evaluating medical electrical equipments during their lifetime. The pandemic of COVID-19 revealed the importance of ventilators and, in particular, the maintenance processes. In this context, the objective of this work was to propose a service manual structure as a reference to assist the clinical engineering team of hospitals in the process of acquisition and maintenance of ventilator and new manufactures of this class of equipment in the construction of its documents.

Methods

The Center for Biomedical Engineering (Campinas, Brazil), which is responsible for maintaining the ventilators installed at the Clinics Hospital of University of Campinas and provides technical advice for the technological incorporation of medical devices, established a technical committee with expertise in Biomedical Engineering and ventilators maintenance to develop the critical care ventilator service manual structure. Initially, the service manuals from eight commercial ventilators were reviewed and used to define the overall structure. The structure of the service manual was developed considering the requirements for the technical description of a medical electrical equipment and a critical care ventilator, particularly with references to the standards ABNT NBR IEC 60601-1:2010 Amendment 1:2016 (Brazilian Association of Technical Standards, 2016) and ABNT NBR ISO 80601-2-12:2014 (Brazilian Association of Technical Standards, 2014), respectively. We considered that the normative requirements for

1. Use instructions (which should include essential data for operation, storage, and safe transport),
2. Necessary steps or conditions for the installation of the equipment, and
3. Preparation for use (Subsection 7.9.3.1, Brazilian Association of Technical Standards, 2016), would be fulfilled by the user's manual, while the service manual would fulfill the requirements for the technical description. The ABNT NBR IEC 62353:2019 standard was used as a reference for the development of the sections related to preventive maintenance and ventilators performance testing (Brazilian Association of Technical Standards, 2019). The final structure was consolidated based on the service manuals from commercial equipment, the standards' requirements, and the technical committee's experience that considered the relevance of the information from the point of view of service personnel and the clinical engineering group.

Results

Chart 1 shows the proposed structure of the service manual for a critical care ventilator, with an overview of the contents of each section and the requirements provided by the standards used as reference. The following subsections provide a brief description of the contents of each part of the proposed service manual.

Chart 1: Structure of a service manual for a critical care mechanical ventilator.

Section	Content	Reference
1 – Introduction to the manual	Presentation of the manual structure, definitions, general warnings and alerts, manufacturer contact information.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirements for technical description, subsections 7.9.1 and 7.9.3.1. ABNT NBR ISO 80601-2-12:2014: requirements for technical description, subsection 201.7.9.1. Commercial ventilator service manuals
2 – Ventilator's Operation	Description of the ventilator, technical specifications, identification of external ventilator's parts, theory of operation.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirements for technical description, subsections 7.2.6, 7.3.1, 7.9.3.1, 7.9.3.2, 7.9.3.4, 8.4.4 and 16.3. ABNT NBR ISO 80601-2-12:2014: requirements for technical description, subsections 201.5.101.3, 201.7.9.3.1.101 and 201.7.9.3.101. Commercial ventilators service manuals
3 - Disassembly and Assembly	Step-by-step ventilator's disassembly and parts replacement procedures.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description, subsection 7.9.3.2. Commercial ventilators service manuals
4 – Ventilator Performance Test	Procedures for functional verification.	ABNT NBR ISO 80601-2-12:2014: requirement for technical description, subsection 201.7.9.3.101. Commercial ventilators service manuals
5 – Service Procedures	Procedures for common ventilator repairs, calibration, and software update.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description, subsection 7.9.3.3. Commercial ventilators service manuals
6 – Preventive Maintenance	Preventive maintenance schedule, spare part exchange procedures.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description, subsection 7.9.3.1. ABNT NBR IEC 62353:2019. Commercial ventilators service manuals
7 – Operational Verification Procedures	Procedures for complete ventilator inspection.	ABNT NBR IEC 62353:2019. Commercial ventilators service manuals
Appendix A - Meaning of the Alarms	Table with the presented alarms and description of the meanings.	Commercial ventilators service manuals
Appendix B - Troubleshooting	Table with problems, probable causes, and suggested action.	Commercial ventilators service manuals
Appendix C - Replacement Parts	Identification of spare parts.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description, subsection 7.9.3.3. Commercial ventilators service manuals
Appendix D - Diagrams	Pneumatic and electrical diagrams for the ventilator.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description, subsection 7.9.3.3. ABNT NBR ISO 80601-2-12:2014: requirement for technical description, subsection 201.7.9.3.1.101, item b. Commercial ventilators service manuals
Appendix E - Operational Verification Report	Report being completed during the Operational Verification Procedure.	ABNT NBR IEC 62353:2019, subsection 6.1. Commercial ventilators service manuals

Appendix F - Meaning of Symbols	Table with ventilators markings and their meaning.	ABNT NBR IEC 60601-1:2010 Amendment 1:2016: requirement for technical description when separate from instructions for use, subsections 7.2 and 7.9.3.1. Commercial ventilators service manuals
Appendix G - Warranty	Warranty Conditions.	Commercial ventilators service manuals

Introduction to the Manual

The "Introduction to the Manual" (Section 1) should provide the definitions that will be used throughout the document, as well as warnings and cautions relevant to the maintenance of the ventilator and the contact information of the manufacturer. A "Table of Contents" subsection should also be included. Additionally, in Section 1, the manufacturer should provide information about the equipment model or type reference (requirement for technical description, Subsection 7.9.1 - ABNT NBR IEC 60601-1:2010 Amendment 1:2016), the unique service manual version identifier (e.g., issue date), the minimum qualifications for service personnel, and a warning statement that addresses the hazards that may result from unauthorized modification of the equipment (requirements for technical description, Subsection 7.9.3.1, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). Finally, the first section of the service manual must include the manufacturer's name or trade name and address or a local authorized representative (requirement for technical description, Subsection 201.7.9.1 - ABNT NBR ISO 80601-2-12:2014).

Ventilator's Operation

Under "Ventilator's Operation" (Section 2), a description of the ventilator, its main functions, ventilation modes, and safety properties should be given. Technical information should be provided, including control and monitoring variables, specifications of the pneumatic and electrical supplies, an overview of the ventilator with identification of its parts, and the theory of operation of the ventilator. This section should briefly describe the equipment, its operation, and its most significant physical and performance characteristics (requirement for technical description, Subsection 7.9.3.1, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). Specifically, regarding the operation of ventilators, the service manual should indicate the automatic checkup tests for the functioning of the alarm system. A description should be included about the processing of measured variables displayed or used for ventilators control, along with the method for initiating and terminating the inspiratory phase in each ventilation mode (requirements for technical description, subsection 201.7.9.3.1.101 and 201.7.9.3.101- ABNT NBR ISO 80601-2-12:2014).

Regarding the operating conditions of the ventilator, the second section must provide:

1. The permissible environmental conditions for use, transport, and storage;
2. Any special installation requirements related to the power supply, such as the maximum permissible apparent impedance, the declared voltage, and declared frequency; and
3. A complete specification of fuses (requirements for technical description, subsections 7.2.6, 7.3.1, 7.9.3.1 and 7.9.3.2, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). Any procedure used to conform to the requirements of power supply network isolation should be identified. Moreover, a disclosure on the large transient currents of the medical electrical system and specification of the non-automatic discharge device for internal capacitors are required (requirements for technical description, subsections 7.9.3.4, 8.4.4, and 16.3 – ABNT NBR IEC 60601-1:2010 Amendment 1:2016). Concerning the medical electrical equipment specifications, this section must encompass all characteristics, including the range(s), accuracy, and precision of the values shown in the manual or an indication of where they can be found (requirement for technical description, Subsection 7.9.3. 1, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). As a requirement for ventilators, Section 2 must indicate the uncertainty for each tolerance disclosed and, if applicable, the essential technical characteristics of each recommended respiratory system filter (requirements for technical description, Subsections 201.5.101.3 and 201.7.9.3.1.101- ABNT NBR ISO 80601-2-12:2014).

Disassembling and Assembling

Under "Disassembling and Assembling" (Section 3), the instructions for disassembling and assembling the ventilators should be given, starting with the elements on the outside up to the exchange of printed circuit boards. For a better understanding, pictures or illustrations must accompany the instructions. Warnings regarding precautions to be taken should be explicit, as should instructions for post-repair or assembly procedures. This section should provide instructions for the correct and safe replacement of detachable or interchangeable parts that the manufacturer specifies as replaceable by the service personnel, including instructions for correct connection and anchoring of non-detachable flexible power cord (if the service personnel can replace the flexible power cord),

and appropriate warnings that identify the nature of the hazard where replacement of a component could result in an unacceptable risk (requirements for technical description, subsection 7.9.3.2 - ABNT NBR IEC 60601-1:2010 Amendment 1:2016).

Ventilator Performance Test

Under "Ventilator Performance Test" (Section 4), a ventilator performance test or pre-use test is described, which makes sure that the ventilator's main functions and alarms are correctly operating when connected to a new patient. This test should be performed each time the ventilator is connected to a new patient and, for that reason, appears sometimes only in the user's manual. However, this test should also be performed after service procedures, such as calibrations and repairs, which may appear in service manuals. This section should indicate a method for checking the function of the alarm system for each of the alarm conditions specified in ABNT NBR ISO 80601-2-12:2014, if the check is not performed automatically during the startup (requirement for technical description, subsection 201.7.9.3.101 - ABNT NBR ISO 80601-2-12:2014).

Service Procedures

Under "Service Procedures" (Section 5), a description is given for the procedures required during common ventilators repairs, e.g., exhalation valve diaphragm replacement, internal filters, oxygen cell replacement, component calibration, and software upgrade. Suppose the service manual does not contain calibration instructions. In that case, it must include a statement that the manufacturer will make available the calibration instructions or other support information (for the service personnel while repairing the serviceable parts of the ventilator) upon request (requirement for technical description, subsection 7.9.3.3 – ABNT NBR IEC 60601-1:2010 Amendment 1:2016).

Preventive Maintenance

Under "Preventive Maintenance" (Section 6), the maintenance procedures that should be performed preventively by trained technicians to avoid damage to the equipment are described. Typically, a schedule is specified describing a pattern of "routine" maintenance that can be performed at shorter intervals (e.g., every 1,500 operating hours or six months), and detailed maintenance, involving a complete inspection of the equipment followed by an operational verification procedure, at longer intervals (e.g., every 5,000 operating hours or annually). The manufacturer may offer to sell kits for this maintenance. Routine preventive maintenance should include changing filters, changing o-rings, exhalation valve diaphragm, and internal filters. The inspection procedure may cover, in addition to the routine preventive procedures, battery replacement, gas supply regulator calibration, verification of the integrity of the internal tubes that make up the pneumatic system, and the operational verification procedure. The service manual must provide the expected performance, and any regular essential performance and basic safety tests required, including details of recommended features, methods, and frequency (requirement for technical description, subsection 7.9.3.1, ABNT NBR IEC 60601-1:2010 Amendment 1:2016). The latter tests can also serve as criteria that allow the responsible organization to determine when the equipment is approaching the end of its lifespan (in addition to the lifespan information provided by the manufacturer; ABNT NBR IEC 60601-1:2010 Amendment 1:2016). Annex F of the ABNT NBR IEC 62353:2019 standard guides that the testing interval be established between 6 to 36 months, taking into account the degree of risk of the equipment and the frequency of use, among other factors. However, since an critical care ventilator is an medical electrical equipment for artificial respiration, the interval should not exceed 24 months (Brazilian Association of Technical Standards, 2019).

Operational Verification Procedure

In "Operational Verification Procedure" (Section 7), the tests that should be performed in preventive maintenance to verify the operating conditions of the ventilator are described. These tests include the electrical safety tests, testing of alarms, and functional tests with a calibrated analyzer to verify that the controlled and monitored parameters are within the proper tolerance range. Electrical safety tests should also be performed after component replacement. The ABNT NBR IEC 62353:2019 standard proposes that the tests before putting into service, periodic tests, and tests after repairments follow the sequence:

1. Visual inspection,
2. Ground resistance test for protection,
3. Leakage current test,
4. Functional test,
5. Report of results,
6. Evaluation, and
7. Preparation for regular use.

The results of these tests have to be documented according to Appendix E.

Appendices

Discussion

In general, a service manual for a critical care ventilator should provide information about its operation, corrective maintenance procedures, and preventive maintenance. When the first medical equipment maintenance groups were created in Brazil, the manufacturers no longer provided their technical documentation, with the intention that maintenance could only be performed by the manufacturers and their representatives [6]. Today, in addition to the information required by standards, the quality of the technical documentation can be negotiated with suppliers [6] and, therefore, the results proposed here serve as supporting material for comparison. A survey with 40 biomedical technicians showed that medical equipment service manuals are mainly used for troubleshooting and equipment familiarization [17]. The latter shows the importance of Sections 2 (Ventilator's Operation), 3 (Disassembly and Assembly), and 5 (Service Procedures) of the service manual. The referred study also showed that tables and lists provide relevant information quickly, such as the Table of Contents (suggested as part of Section 1), the Troubleshooting (Appendix B), and the part list (Appendix C), are significant for daily-based maintenance. Moreover, the diagrams (Appendix D) are a point of improvement in service manuals because they are often insufficient and small, not offering easy viewing and good usability [17].

A service manual for a critical care ventilator should contain standard corrective maintenance procedures, replacement kits, and resources needed for preventive maintenance. It allows better sizing of the resources needed for maintenance and the associated costs, essential factors for the clinical engineer that should be considered when purchasing the medical electrical equipment [18]. In addition, Sections 4, 6, 7, and Appendix E are particularly important for defining the preventive maintenance policy, as they relate to procedures and documentation of preventive maintenance, testing, and inspections of the ventilator. ABNT NBR IEC 62353:2019 standard provides essential guidance on medical electrical equipment tests, recommending the tests proposed by the manufacturer and/or the performance tests established by the standards to be taken as reference. Despite recommending the general standard and the particular standards as a reference for testing, ABNT NBR IEC 62353:2019 emphasizes that there should be differences between recurrent testing and testing in the certification process of medical electrical equipment. The tests for the certification process can damage the equipment, and it is acceptable that routine tests have different limits than those recommended in the certification tests since wear and tear are expected from the use of the equipment [19].

ABNT NBR ISO 80601-2-12:2014 tests for evaluating the performance of ventilators are planned to verify monitoring errors and control accuracy of end-expiratory phase pressure, the fraction of oxygen in inspired air, and the control variable (pressure in pressure control mode, and volume in volume control mode) for 21 test lung and ventilation parameter settings. On the other hand, manufacturers' trials vary, and ventilators are usually tested with fixed test pulmonary parameters. In this vein, establishing a standard procedure for post-market functional evaluation of ventilators could facilitate and standardize testing and ensure ventilator performance under different conditions. Currently, it is more common for hospitals to maintain systems that centralize all the data related to the maintenance of their equipment, called Computerized Maintenance Management Systems (CMMS) [20]. The CMMS data makes it possible to design optimized testing and inspection policies based on historical equipment maintenance data [11]. However, an appropriate management system does not reduce the importance of the information provided by the medical electrical equipment manufacturer about test frequency and methods since this is a starting point for defining maintenance procedures and should be followed when there is no history of the equipment [18].

The importance of clinical engineering groups accessing the technical documentation of ventilators should be stressed, especially in the context of the COVID-19 pandemic. Authorizations for emergency use due to the pandemic may pose a high risk in the case of critical care ventilators, causing death or severe harm [21], and, in general, the ventilators are considered a high priority for preventive maintenance of the hospital's equipment park [22]. A study based on almost 3,000 work orders from 60 countries showed that unmaintained medical electrical equipment was out of service due to the lack of trained personnel, not the lack of spare parts [23]. The importance of trained staff and the availability of service manuals can also be noted by observing that in the Center for Biomedical Engineering of the University of Campinas, about 80% of the maintenance of the medical equipment park was performed in-house in 2020, and only obsolete ventilators were out of service before the pandemic. Therefore, the structure of the service manual proposed in this work can be used as a guide, providing relevant information for the maintenance and clinical engineering groups, and can also help reduce the ventilators downtime and ensuing financial losses. The service manual structure proposed here can be easily adapted to other medical electrical equipment by replacing the requirements of the 80601-2-12 standard with the requirements for the specific medical electrical equipment. Likewise, the result of this work is not limited to the national application since the Brazilian standards represent the translation of international standards. It is worth noting the scarcity of work related to the subject. A future study would validate the proposed service manual structure in different technical groups through an updated version of the study by Goffin & Price [17].

Conclusion

After reviewing the service manuals from commercial critical care ventilators, the difference between the documents from different manufactures was evident. The requirements in the ventilator certification standards ensure that critical information for maintenance is present in the documentation. However, there is still a gap between the information that should be mandatory in the medical electrical equipment documents and enough information for clinical engineering groups to establish maintenance procedures that ensure the performance and safety of critical care ventilators in hospitals. In this regard, a generic structure of a service manual was presented as a reference for clinical engineering groups to evaluate the documentation provided by manufacturers in the procurement process for new equipment and by critical care ventilator manufacturers. The importance of establishing a standardized test to assess the expected performance of ventilators in service is also highlighted, which is especially critical in the current context of the COVID-19 pandemic.

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Statements and Declarations

Conflict of Interest

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