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Annual Maintenance of Respiratory Humidifier

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Abstract

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This thesis work was carried out for the medical engineering department of HUS Logistics which is part of the Hospital district of Helsinki and Uusimaa.

Target of this thesis work was divided into two parts. First part was to create a comprehensive report template for annual maintenance of two different respiratory humidifiers manufactured by Fisher & Paykel Healthcare. As it is required by regulations and Finnish law, maintenance procedure must be carried out in accordance with manufacturers` manual so any additional information on maintenance improvement were acquired from engineering personnel and actual device testing.

Second part was to unify the cost of the maintenance service for both humidifiers as the differences in cost charges differed greatly from each other. This was to be achieved by comparing the length of multiple timed maintenance and averaging the duration of them.

Thesis work resulted in tested maintenance template and unified cost of said service for one of the humidifiers. Unfortunately, due to newness and availability of the other device, it was possible to create only a preliminary version of the template, which also meant that no set maintenance time to base the cost off of was not achieved.

Keywords: humidifier, annual maintenance, template, cost

Contents

List of Abbreviations

EMC:	Electromagnetic Compatibility
HYKS:	Helsingin seudun yliopistollinen keskussairaala
ICU:	Intensive Care Unit
IEC:	International Electrotechnical Commission
ISO:	International Organization for Standardization
MAC:	Media Access Control
MDR:	Medical Device Regulation
PCB:	Printed Circuit Board
PEMS:	Programmable Electrical Medical System
WHO:	World Health Organization

1 Introduction

Any malfunction that occurs in a medical device presents a risk of injury to patients or personnel, and in the worst case even fatality. To ensure that the given device operates correctly, annual maintenance is required. This process is intended to help foresee possible decline in the operation and to prolong the service life of the device. Service is always done in accordance with manufacturer's service manual.

To assure that the service is done each time in the same manner regardless of the person performing it and to improve traceability of the results, the need to create an annual maintenance report template arose.

Goal of this thesis work was to create standardized report templates that will be used during each annual service of Fisher & Paykel Healthcare respiratory humidifier MR850 and its successor, F&P 950. The template is to provide step by step instruction on the service process that will be helpful even to experienced service workers. Said template is then uploaded to medical device registry Mequsoft, where it will be easily accessible for future use.

To ensure that the same amount of performed work hours is charged each time, it was decided to generate a unified time frame needed to perform the maintenance, regardless of workstation and person performing the task.

2 Hospital District of Helsinki and Uusimaa

Hospital district of Helsinki and Uusimaa, commonly known as HUS, is Finland's largest hospital district. With nearly 27,000 employed professionals, HUS is also Finland's leading healthcare provider and the country's second largest employer. It consists of five hospital areas: HYKS, Hyvinkää, Lohja, Porvoo, and Västra Nyland. [1.]

However, some specialist medical care services are provided across hospital district borders, being based on the specific catchment areas of university hospitals. The Helsinki University Hospital specific catchment area includes in addition to HUS itself

also the South Karelia, Kymenlaakso, and Päijät-Häme hospital districts with a total of 2.2 million residents. [1.]

HUS is responsible for the special medical care of the residents of 24 member municipalities. Figure 1 shows the area of responsibility and member municipalities. HUS also provides centralized care for rare and severe diseases on a nationwide level. [1.]

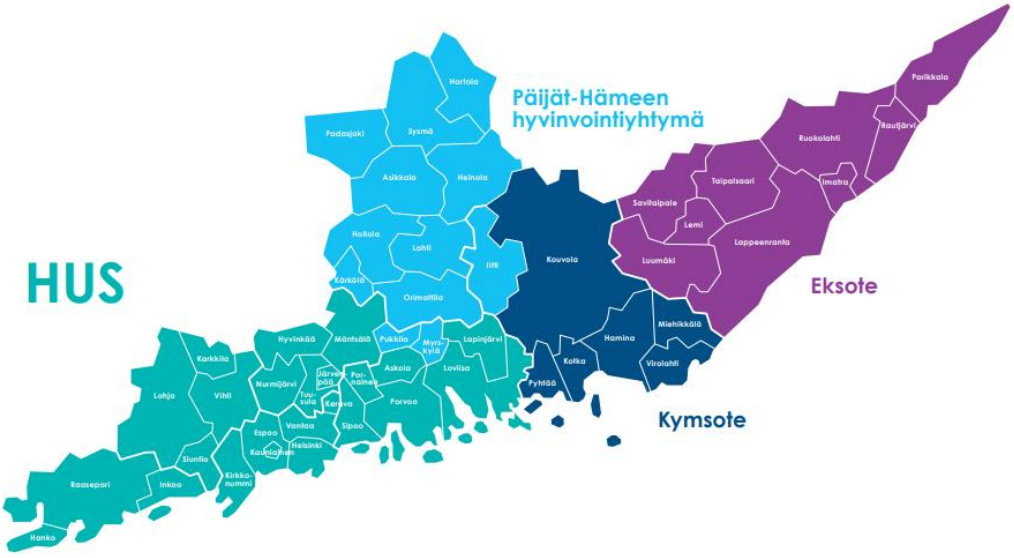

Figure 1 Responsibility areas and member municipalities [2]

2.1 HUS Logistics

HUS Logistics is one of the profit areas of HUS that provides non-medical support services. Services provided include supply logistics, goods transport, refill services, nursing logistics and medical engineering.

In addition, HUS Logistics provides services to the HUS member municipalities as well as the Helsinki University Hospital specific catchment areas that have signed a service agreement.

In 2020, turnover of HUS Logistic was about EUR 298 million and it had 509 employees. [3.]

2.2 Medical Engineering

Medical engineering is part of HUS Logistics that specializes in healthcare technology throughout HUS. Primary customers of medical engineering are all units within the HUS member municipalities in need of technical services as well as municipal customers such as the City of Helsinki.

In order to comply with national and EU standards and regulations, medical engineering provides continuous training of its personnel, uses quality systems and the latest tools and information systems. Amongst main responsibilities of medical engineering is management of medical equipment's life cycle, which consist of acceptance inspections of new equipment, annual maintenance, repairs, or removal of the device from use. Paid rental service on certain devices is also provided. Customer support, procurement and contract management are other examples responsibilities of the medical engineering department.

3 Regulations and Standards

To ensure that the device does not endanger the safety or health of the patient, of the user or of other persons, only medical devices that conform with existing regulations and standards can be placed on the market in Finland. As a rule, the device must have CE-marking that indicates conformity with requirements. [4.]

3.1 Regulations

Regulation (EU) 2017/745 (on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC) lays down rules concerning the placing on the market, making available on the market, or putting into service of medical devices for human use and accessories for such devices in the European Union. This Regulation

also applies to clinical investigations concerning such medical devices and accessories conducted in the European Union.

According to the Article 2 of this Regulation the definition of medical device is:

> any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
>
> - Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease
> - Diagnosis, monitoring, treatment, alleviation of, or compensation for and injury or disability
> - Investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state
> - Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations,
>
> and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> - The following products shall also be deemed to be medical devices:
> - Devices for the control or support of conception
> - Products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4). [5.]

The MDR is less focused on the pre-approval stage of medical device manufacturing, and instead, promotes a life cycle approach to medical device regulation. Also, it newly specifies types of products that need to obtain CE-marking, including products used to clean, sterilize, or disinfect medical devices and devices used to control and support conception.

Mandate for Unique Device Identification (UDI) is included in the new MDR. It is intended to ease traceability of all medical devices sold in the region. Devices must be marked

with a device identifier (ID) and each production series of the product will be marked with production identifier (PI). [6.]

In Finland, The National Law on Medical Devices 719/2021, entered into force on 19 July 2021. This law supplements the EU regulations on medical devices.

3.2 Standards

Medical devices are subject to a rather complex set of safety requirements. Design and manufacture, including mechanical, electrical, and software matters are greatly affected by compliance regulations.

Standards, regulations, and verification are closely connected. Standardized technologies that are tested and certified for safety, quality, and performance contribute to overall risk management. They also help improve processes and the understanding of device interactions.

Different interested parties including manufactures, healthcare providers, clinicians, or regulators contribute to the development of international medical standards. To ensure that international healthcare standards work together, IEC technical committees collaborate with other committees of the IEC, ISO, WHO, and other organizations, based on the expertise each organization characterises. As the majority of regulations of medical devices still takes place at national level, many national regulatory authorities actively participate in the development of IEC and ISO International Standards. [7.]

3.2.1 IEC 60601-1 Medical Electrical Equipment

The IEC 60601-1 is a set of technical standards that ensure the effectiveness and safety of medical electrical equipment. The first edition of IEC 60601-1 was published in 1977. The second edition focusing on device safety in the proximity of a patient was followed in 1988. The third edition which was expanded to explore the means of protection both for patients and equipment operators was released in 2005. Edition 3.1 was released in 2012. It was an extensive update to the third edition and addressed several ambiguities caused by the evolution of medical equipment technology. This version is used in most parts of the world, e.g., Europe, USA, Canada, and Japan. [8.]

Edition 3.1 of the standard consists of thirteen annexes and fourteen main sections. The main sections are as followed: general requirements, general requirements for testing ME equipment, classification of ME equipment, equipment identification and marking, protection against mechanical hazards, protection against radiation hazards, protection against excessive temperatures, accuracy of controls, hazardous situations, and fault conditions, PEMS, construction of ME equipment, ME systems, and EMC.

Medical electrical equipment is described by this standard as having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular supply mains

b) intended by its manufacturer to be used:

1) in the diagnosis, treatment, or monitoring of a patient or
2) for compensation or alleviation of disease, injury, or disability

And medical electrical system as combination, specified by its manufacturer, of items of equipment, at least one of which is medical electrical equipment to be inter-connected by functional connection or by use of a multiple socket-outlet. [9.]

The requirements for ME equipment and systems are different from those for other kinds of electrical equipment. This is because of the relationship of ME equipment or system to the patient, the operator, and the surroundings. Listed below are some of the aspects that play an important role in this relationship: [9.]

- the inability of the patient or operator to detect the presence of certain hazards, such as ionizing and non-ionizing radiation
- absence of normal protection to currents provided by the patient's skin, if this is penetrated or treated to obtain a low skin-resistance
- support or replacement of vital body functions, which depends on the reliability of ME equipment or ME system

- the application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs.

As symbols are often used on medical devices instead of words due to limited space and to ease understanding and omit language differences, new and improved safety signs and symbols have been introduced in the new version of this standard. Figure 2 shows examples of symbols used on medical devices.

No.	Symbol	Reference	Title
7		IEC 60417-5017	Earth (ground)
8		IEC 60417-5021	Equipotentiality
9		IEC 60417-5172	CLASS II equipment
10		ISO 7000-0434A	Caution In case of application as a safety sign, the rules according to ISO 3864-1 are to be adhered to. See safety sign ISO 7010-W001 (Table D.2, safety sign 2).
11		ISO 7000-1641	Operating instructions
12		IEC 60417-5007	"ON" (power)

Figure 2 Example of symbols [9]

Examples of safety signs are shown in Figure 3, where red colour marks the change in the definition of the sign.

No.	Safety sign	Reference	Title
1		ISO 3864-1, Figure 3	Template for constructing a warning sign NOTE Background colour: yellow Triangular band: Black Symbol or text: Black
2		ISO 7010-W001	General warning sign
3		~~IEC 60878~~ ~~ISO 3864-B.3.6~~ ISO 7010-W012	~~Warning: dangerous voltage~~ Warning, electricity
4		ISO 7010-P001 and ISO 3864-1, Figure 1	General prohibition sign and Template for constructing a prohibition sign NOTE Background colour: white Circular band and slash: red Symbol or text: black
5		ISO 7010-P017	Pushing prohibited
6		ISO 7010-P018	Sitting prohibited

Figure 3 Example of safety signs [9]

3.2.2 IEC 62353 Medical Electrical Equipment – Recurrent Test and Test After Repair of Medical Electrical Equipment

The IEC 62353 was introduced in 2007 in response to observations of IEC 60601 that have pointed out that these standards overlook the need for periodic testing of the equipment after it entered the field. As IEC 62353 was designed for testing equipment in the field, it is, in those circumstances, safer, more practical, and more effective than IEC 60601. [10.]

The IEC 62353 standard applies to devices or systems and their components that comply with IEC 60601 standards. Devices in a certain proximity of the patient must also comply with these standards. [10.]

Testing before first start up, after repair and regularly is required by this standard. Testing is to be carried out only by a qualified person that has received proper technical training, has practical experience and is familiar with standards and local regulations. Also, the manufacturer of the devices is obligated to provide information on the testing of the device, with which the person doing the testing should comply. All tests performed need to be properly documented. Following list shows the entries that need to be included in the documentation:

- Designation of the test location (e.g., department)
- Name of the person(s) who performed and evaluated the test
- Designation of the tested device and accessories (e.g., type, serial number, inventory number)
- Executed tests including measured values, measuring methods, and utilized measuring instruments
- Function test
- Final evaluation
- Date and signature of the person who prepared the evaluation
- Identification of the tested device (if required by the operating service provider) [10.]

3.3 Medical Device Registry

The National Law on Medical Devices 719/2021 chapter 4 34§ states that the social and health care unit and any other professional user who is a legal entity or who uses medical devices as a self-employed person must have a monitoring system to ensure the safety of the devices and their use. The monitoring system must record information required for traceability of the equipment used by the functional unit, handed over or otherwise under control as well as patient-mounted devices and information related to hazardous situations arising in connection with the use of the device. [11.]

To comply with regulations, the medical device registry Mequsoft was taken into use in 2006. Mequsoft is an application for management of medical devices created by software company Sofor Oy. This application records all information related to the acquisition and life cycle of the device, such as service labels, service costs and history, as well as periodic measures and warranty information.

Each newly acquired device must undergo an acceptance inspection that is carried out by a medical engineering employee. During this inspection, information such as manufacturer's name, serial number, warranty duration and annual maintenance interval are written to Mequsoft. Some devices are also fitted with a location tag. In this case, tag`s MAC address is to be written to Mequsoft as well. At this stage, all devices are provided with a unique identification number, referred to as L-tunnus, which is used to search for said device inside Mequsoft. This number is printed out on a sticker in a form of bar code and is then attached onto the device. Sticker with the date of the next scheduled maintenance and contact information of Help Desk is also added. Part of the acceptance inspection, depending on the device, might be an electrical safety test, software set up or something as simple as insertion of batteries. Also, devices that are provided to HUS for a trial run need to be added to the registry.

Medical engineering provides Mequsoft Web-medical device register as a service for HUS departments and other customers. Through the interface, customers can follow maintenance history and costs of their registered devices. Furthermore, they are able to perform inventory of the equipment with the use of bar code readers or create maintenance or repair requests. Be it repair or maintenance request, a short description of the problem is required to ease up the process. It also allows medical engineering employees to place the device to the correct work queue, which minimizes the time that the device is out of use.

3.4 Effector

The Effector system is used in addition to Mequsoft. It is used to record the patient's personal aids and medical devices that are used at home. Comparably to Mequsoft it helps to monitor the lifecycle of devices - including reporting functions for borrowing and procurement of aids, return prompts on overdue loans and periodic maintenance. This

system is currently used in 18 hospital districts and in 85% of health centres in Finland. Unlike Mequsoft, Effector also has a mobile application that can be used in the field. [12.]

4 Respiratory Humidifiers

Heat and moisture exchange is one of the most vital functions of the respiratory system. The nose is responsible for warming inspired air, amplifying its humidity carrying capacity. When the upper airway is circumvented during invasive mechanical ventilation, the respiratory system loses its ability to heat and moisten inhaled gas. This inflicts a strain on the lower respiratory tract, which is not designed for the humidification process. As a result, delivery of partially cold and dry medical gases can potentially damage the respiratory epithelium. Damage caused by such gases can manifest itself by increased work of breathing, collapse of one or more areas in the lung, thick and dehydrated secretions, and cough or bronchospasm. When the upper airway is not bypassed (non-invasive mechanical ventilation), humidification is recommended to improve patient`s comfort. [13.]

Humidity is the amount of water vapour that is present in the air and humidifiers are devices that add water molecules into the gas. To warm and humidify gases that are administered to mechanically ventilated patients, two systems are available. Passive and active humidification. Passive humidification utilizes the patient’s own heat and moisture from the exhaled gas that is stored and then released into the inhaled gas. Active humidification uses external sources of water and heat. [14.]

4.1 Passive Humidifiers

Passive humidifiers do not depend on external water supply or power source. The working principle for these devices is based on their capacity to retain heat and humidity during expiration and to deliver at least 70% of them to the inhaled gas during subsequent inspiration. [15.]

According to ISO standards, the appropriate passive humidifier should have efficiency of at least 70% while providing at least 30 mg/L of water vapor. These humidifiers are

placed between the Y piece and the patient as shown in Figure 4, where HME stands for Heat and Moisture Exchanger. [15.]

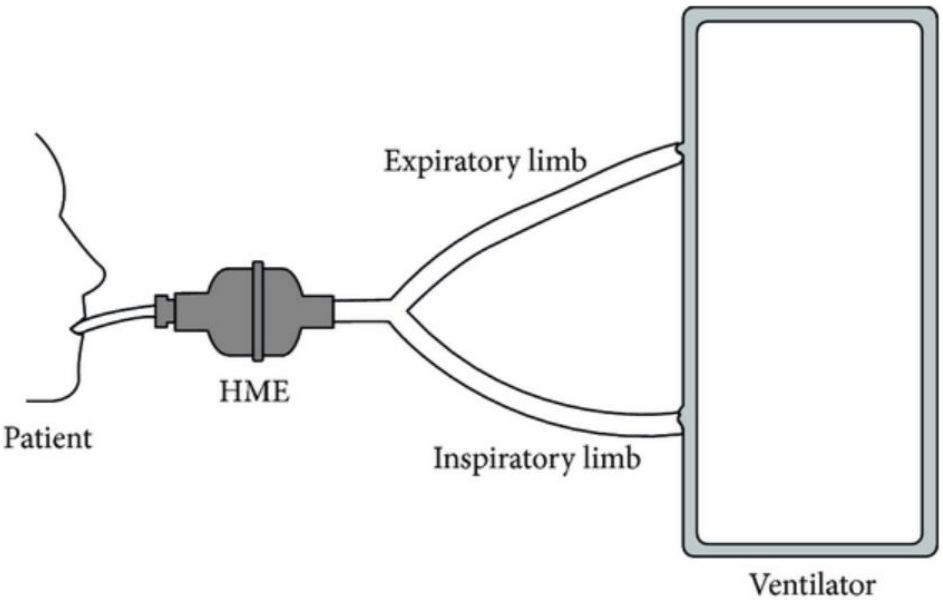

Figure 4 Ventilator circuit with heat and moisture exchanger (HME) [13]

Depending on the mechanism used to achieve passive function, humidifiers are further divided as followed:

Heat and Moisture Exchangers (HME)

Simple condensers composed of elements made of disposable foam, synthetic fiber, or paper, with a substantial surface area that can produce an effective temperature gradient through the device delivering heat on each inspiration. [15]

Hygroscopic Condenser Humidifiers (HCHs) or Hygroscopic Heat and Moisture Exchangers (HHMEs)

Made with synthetic fiber coated by a hygroscopic chemical product (calcium chloride or lithium chloride), which absorbs expired water vapor and carries it to the inspired gas, improving the delivery of humidity. [15.]

Heat and Moisture Exchangers with Filter

Material used to make this type of moisturizers differs by the working principle – hydrophobic or hygroscopic. Furthermore, they contain an electrostatic filter. Filters are flat layers of modacrylic or propylene fiber material that functions as a barrier to the gas flow. The filtration performance is enhanced by applying material with electrostatic charge. [15.]

Combined Heat and Moisture Exchangers

Hygroscopic and hydrophobic components are used in combination to create a combined HME. In terms of absolute humidity, the performances between combined heat and moisture exchangers and hygroscopic condenser humidifiers. [15.]

Several models of passive humidifiers can be converted to an active humidifier by adding an active heated water source, resulting in increased humidification capacity. These devices will still operate as passive if the external water source runs out.

Passive humidifiers are cheaper than active ones. They are lightweight and easily available in ICUs and their use is simple. However, they increase instrumental dead space due to their placement in the circuit. They are contraindicated in some clinical conditions. Also, passive humidifiers are less efficient if compared to active humidifiers. [15.]

4.2 Active Humidifiers

Active humidifiers, also known as heated humidifiers, are devices that comprise of a plastic humidification chamber with a metallic base, containing sterile water, that is placed on top of an electric heater plate. When the chamber`s base is warmed, the water temperature increases by convection. Certain active humidifiers are self-regulated with the help of heating wire that helps to keep the gas temperature constant while it passes through the breathing circuit and a wire with two temperature sensors connected to the heater exit and to a part of the breathing circuit close to the patient, to control the system temperature. [15.] The MR850 humidifier is an example of a device that supports a heater-wire system.

Depending on the techniques used for humidification active humidifiers are further classified as:

Bubble Humidifiers

The gas in bubble humidifiers is forced to the bottom of a water container through a tube. When the gas exits the distal end of the tube that is under the surface of the water, bubbles will be formed. As the bubbles rise to the surface, they gain humidity. A number of these humidifiers have a diffuser at the distal end of the tube that helps to break the gas into smaller bubbles. The smaller the bubbles, the larger the gas-water interface allowing for higher water vapor content. [13.]

Pass-over Humidifiers

Air flow passes over a heated water chamber transporting water vapor to the patient through the breathing tube. Water temperature in the reservoir is a deciding factor for humidity. There are two variants of pass-over humidifiers. Wick humidifier, where gas enters a reservoir and passes over a wick that acts as a sponge which has its distal end immersed in water. The wick pores provide more gas-water interface allowing for more humidification compared to simple pass-over humidifiers. And the hydrophobic membrane humidifier, where dry gas passes through a membrane. Nonetheless, its hydrophobic characteristic only allows passage of water vapor, stopping liquid water from passing through it. [13.]

Counter Flow Humidifiers

After the water is heated outside of the vaporizer, it is pumped to the top of the humidifier where it enters through small diameter pores, then it flows down on a large surface area. The gas flows in counter direction. The air is moisturized and warmed to body temperature while it passes through the humidification chamber. [13.]

Inline Vaporizer

Inline vaporizer uses a small sized plastic capsule in which water vapor is injected into the gas inside the inspiratory limb of the breathing circuit close to the patient wye. A small heater disk inside the capsule supplements the heating of the gas.

Active humidifiers are more efficient and can deliver accurate temperatures. They do not have contraindications and have an alarm system. The presence of water in the circuit can limit the airflow. Monitoring is required to ensure correct performance. [13.]

5 MR850 Respiratory Humidifier

The MR850 respiratory humidifier, created by Fisher & Paykel Healthcare, was selected for this thesis work as it is the most common model of humidifier currently used throughout HUS. While this thesis work was being conducted, there were 347 active devices spread across 36 departments.

5.1.1 Humidifier Operation

The MR850 is an active humidifier designed to be used in intensive care units of hospitals and has both invasive and non-invasive modes. The heater-plate of the humidifier heats the water inside the humidification chamber which adds moisture and heat to respiratory gases that pass through it before being administered to the patient. Temperature of the gas is monitored by the chamber probe located at the outlet of the humidification chamber. To retain the set-point of the chamber, the power delivered to the heater-plate is controlled by the humidifier. Non-invasive mode heats the gas to 31 °C and the invasive mode to 37 °C. The MR850 has two different heating systems: heater-wire and non-heater-wire. [16.]

5.1.2 Heater-wire Operation

Humidified gas passes through the inspiratory limb in which the temperature of the gas must be maintained to prevent condensation. This is accomplished with a heater-wire within the inspiratory limb. Optionally, a second heater-wire can be located in the expiratory limb to minimise condensate in it. Typical heater-wire set-up is shown in figure 5 below.

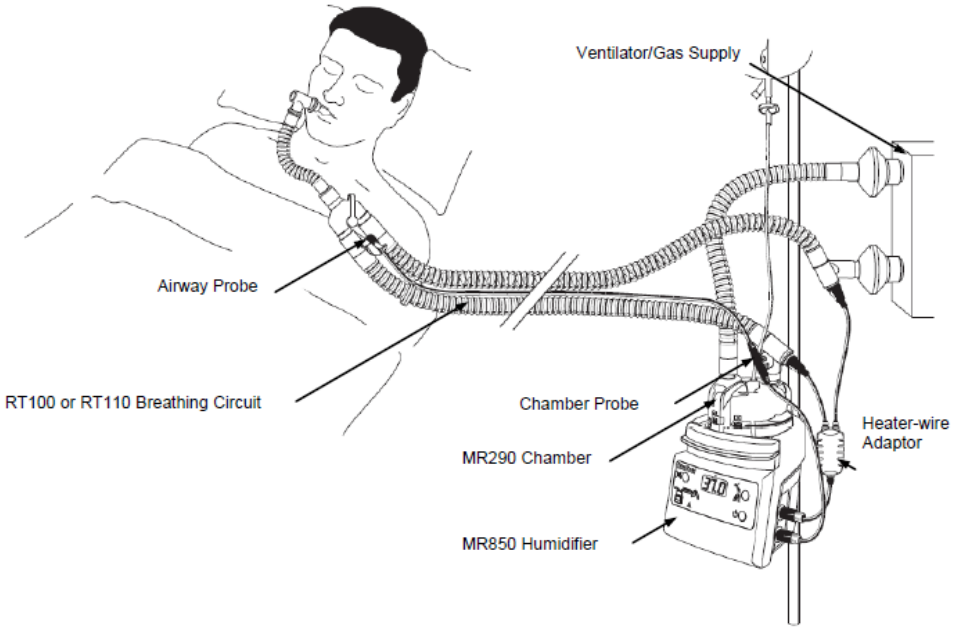

Figure 5 Heater wire humidifier set-up [16]

The temperature along the inspiratory limb is monitored at the airway probe. With this system, the gas is heated to 34 °C in the non-invasive mode and 40 °C in the invasive mode. [16.]

5.1.3 Non-heater-wire Operation

When used in this application, the temperature is maintained at the set-point (31 °C for non-invasive and 37 °C for invasive mode) by heating the humidification chamber through the heater plate. Non-heater-wire set-up is shown in Figure 6.

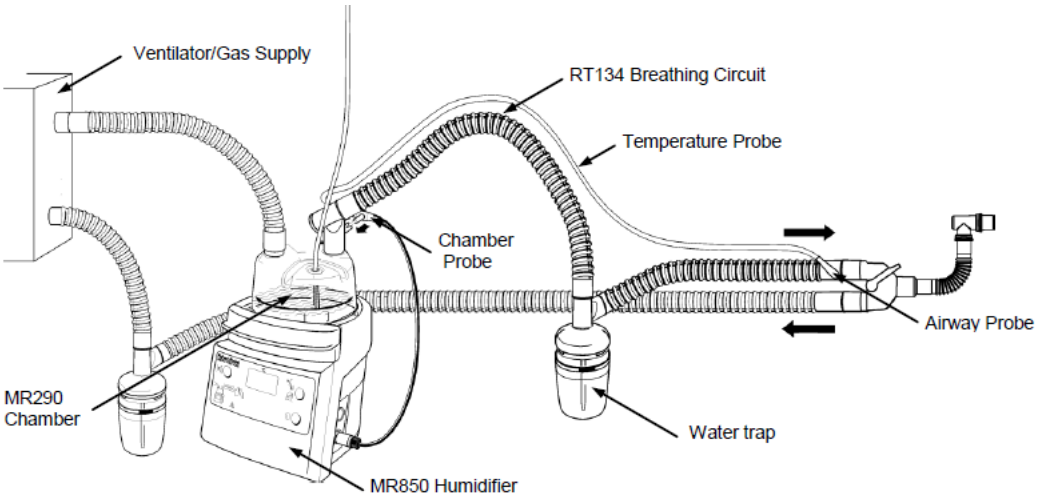

Figure 6 Typical Non-heater-wire set up [16]

Water trap circuit must be used in order to collect the condensate resulting from the cooling of the gas down in the unheated circuit. [16.]

5.2 MR850 from the User Perspective

To learn more about the actual use of the humidifier, a short questionnaire was sent to the neonatal intensive care unit (NICU) of HUS. NICU was selected as it is a unit with the largest amount of MR850 humidifiers. Out of 347 devices, 48 are currently in NICU service. The questionnaire is anonymous and was written in Finnish. The question part of the questionnaire is included as appendix 1.

Humidifiers are in daily use attached to a patient by either nasal continuous positive airway pressure (NCPAP) device, Optiflow – nasal high flow oxygen therapy, or to the respirator. Patients in NICU are new-borns, ranging between 500 g to 5.5 kg of weight, in need of respiratory support. Regardless of patients' breathing aid device, MR850 is always used in invasive setting. The ratio of respiratory therapy (invasive) to non-invasive therapy is roughly 25-30% (invasive) and 70-75% (non-invasive).

Possible set up used with Fisher & Paykel Optiflow Junior Nasal Cannula is shown in figure 6.

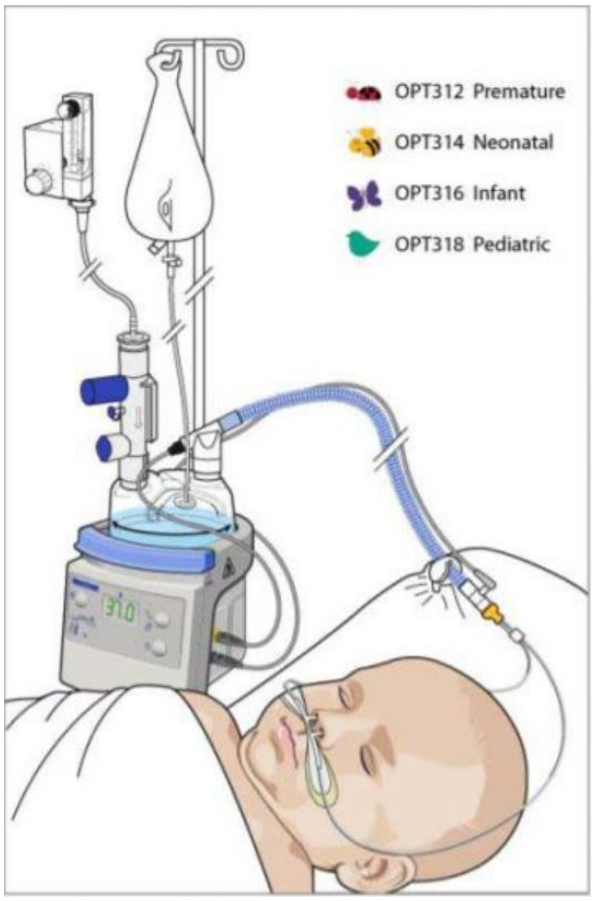

Figure 7 MR850 setup with OPT314 Neonatal Cannula [17]

As for the reliability of the device, fault situations were identified as relatively rare. The issue that occurs most often is either too low or too high temperature. Other than that, the device proves to be easy to use and reliable.

6 Annual Maintenance of MR850

Annual maintenance is the key element in ensuring patients' safety, preventing faults, and prolonging the service life of a device. It is not intended to always repair an issue, but to make sure that a device is operating within the limits described in the service manual.

The objective of this thesis work is to create a comprehensive maintenance template with step-by-step instructions on the procedures. This will serve as a digital history record

of results acquired during testing. Also, it will be helpful during repairs as it can provide insight on what might be the cause of an issue.

The service manual provided by the manufacturer contains procedures, which are recommended to be performed during annual maintenance. Service report template uses the same procedures, with detailed instructions, eliminating the need to search for needed information from within the manufacturer's manual, thus speeding up the process.

6.1 Maintenance Steps

This subsection contains a description of each step included in annual maintenance.

Visual/power-up Check

During this step, humidifier and probes are checked for damages such as scratches on heater plate, unfastened or missing screws or any damages to temperature probes or mains cable. Cleanliness of device is also important to ensure correct functionality and to avoid any possible contamination. May the need to clean the heaterbase or heater-wire adaptor arise, isopropyl alcohol or normal dishwashing detergent are recommended to avoid damages to the outer metal and plastic components of the humidifier. [15.]

Power-up check ensures that the device turns on and that it operates quietly. If there is any noise present, the cause of it must be found and resolved before continuing with the maintenance.

To proceed further, the humidifier needs to be placed in service mode. The order of the service steps is as such to eliminate the need to repeatedly enter or exit the service mode. Error code and electrical safety checks are the two steps not requiring the device to be placed in service mode.

Calibration Check

In calibration check, the accuracy of the temperature and flow measurement electronics is tested with the 900MR870 calibration probe. This probe is two sided – grey and blue. Table 1 shows values that are to be reached by the grey collet of the calibration probe.

Table 1 Pass/Fail values for the grey collet of the calibration probe [16]

TEST	PASS	FAIL (LOW)	FAIL (HIGH)
Airway temperature	100	101	102
Chamber temperature	100	104	108
Flow temperature	100	110	120
Calibration resistor	100	140	180
Overheat	Heater-wire LED OFF	Heater-wire LED ON	Heater-wire LED ON

Nominal resistance values of the grey plug of the probe are 55.2 °C for chamber temperature and 40.5 °C for airway temperature. As a result, the pass value ‘100’ should appear on the humidifier display. If any other value, higher or lower, is reached or the heater-wire LED is on, the calibration check has failed. In table 2, values for the blue collet of the probe are shown. [15.]

Table 2 Pass/Fail values for the blue collet of the calibration probe [15]

TEST	PASS	FAIL (LOW)	FAIL (HIGH)
Airway temperature	200	201	202
Chamber temperature	200	204	208
Flow temperature	200	210	220
Calibration resistor	200	240	280
Overheat	Heater-wire LED OFF	Heater-wire LED ON	Heater-wire LED ON

In the case of the blue plug, the nominal resistance value for chamber temperature is 75.0 °C and 42.8 °C for airway temperature. Pass value to be reached after inserting the

blue collet into the temperature/flow probe socket of the humidifier and letting the display to stabilize, is ‘200’. Failing to reach the pass values in each side of the probe indicates that the PCBs of the humidifier are faulty and need to be either serviced or replaced. [16.]

Screen Test

This test is to confirm functionality of indicator LEDs and all segments in the display. Display is three digits, 14 mm, 7 segment LED display.

Probe Accuracy Check

Both airway and chamber probes are submerged in the container of water at approximately 40 °C along with the thermometer of ± 0.5 degrees accuracy. Temperature difference between the humidifier and thermometer is not to exceed 1.5 degrees. By this, it is ensured that the gas flowing to a patient will be of a safe temperature.

Probe Flow Accuracy Check

The flow accuracy of temperature/flow probes is tested. As shown in Figure 7, a fully set up humidifier with the constant gas flow of 10 ± 1 SLPM (Standard Litres Per Minute) is required. This is to guarantee safe flow speed of gas administered to a patient.

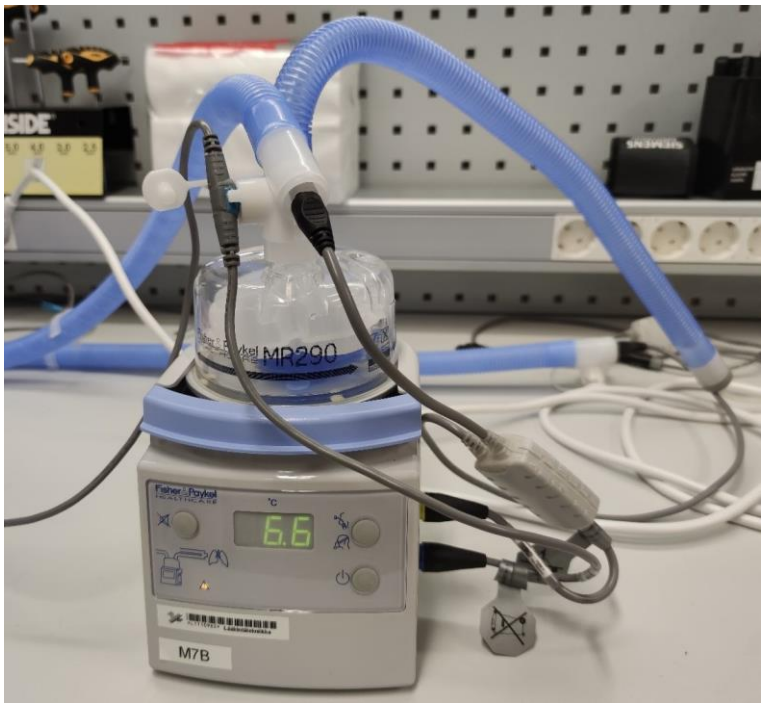

Figure 8 Humidifier set up for Probe flow accuracy check

Error Codes

This step is not included in the manufacturer's manual. Humidity compensation algorithm and last fault state values are to be 0 and E00 respectively. Any other value will point to a possible issue that was not revealed during previous steps. For this reason, it was added to the report template. Error code list was made part of the template as a way to make identifying issues faster.

Electrical Safety

By IEC 60601-1 classification, MR850 is a Class I device which means that has two levels of protection – basic insulation and an earth connection. As Figure 11 shows, the correct ground test point location on the heater plate is the front underside edge where the insulating anodizing layer has been removed. [16]

Figure 9 Correct ground test point location.

Electrical safety test is done with the use of ESA620 electrical safety analyzer by Fluke Biomedical, which is shown in Figure 12. Acquired results are automatically saved to Mequsoft under the tested device`s identification number.

Figure 10 ESA620 Electrical Safety Analyzer

7 Service Pricing

Service price for annual maintenance should be the same each time regardless of who performs the procedures or the workstation at which the maintenance is carried out. As the price is dependent on the amount of time needed to perform the maintenance, several timed tests were carried out. At the same time, the maintenance template was tested.

7.1 First Test

By timing each step of the maintenance from start to finish, a timeline showing the final duration was created. Figure 13 shows the timeline of the first test. It includes the name of each stage, its starting time and visual representation of the duration. Each blue block on the timeline corresponds to one minute of time spent.

Työvaihe n	Työvaiheen kuvaus	Aloitusaika	Aikajana (1 ruutu on 1 minuutti)
1.	Huoltotarvikeet työpisteelle	11:35	
2.	Visuaalinen tarkastus	11:46	
3.	Kalibroinnin tarkastus	11:50	
4.	Näytön testaus	11:53	
5.	Lämpötila-anturi tarkistus	11:54	
6.	Virtauksen tarkistus	12:02	
7.	Vikakoodin tarkistus	12:10	
8.	Sähköturvallisuusmittaus+MAH tar	12:12	
9.	Kirjaaminen	12:14	
10.	lopetus	12:20	

Figure 11 Timeline of the first test

First step of the maintenance is collecting all the necessary equipment to the workstation (Huoltotarvikeet työpisteelle). Even though a box dedicated specifically to MR850 maintenance equipment exists, it did not contain all the things needed to begin at the time of the test. As a result, unnecessary time was spent on this particular part of maintenance.

As the second step, visual check (Visuaalinen tarkastus), does not require any additional equipment it is done fairly quickly. Possible need of cleaning will add extra time to this step.

Calibration check (Kalibroinnin tarkastus) requires the use of a 900MR870 calibration probe, which was found ready in the box, resulting in a delay free test. Screen test (Näytön tarkastus) is another step not requiring any additional tools, as mode switching needed for this test is done by the device´s own button.

Probe accuracy check (Lämpötila-anturi tarkistus) has the need for a container filled with water of temperature around 40 °C. This container was not found in the equipment box which led to another delay. Sometimes, the devices arrive for maintenance without their own temperature probes. Still the accuracy of the device needs to be tested. For this purpose, a set of temperature probes is included in the box. In this case, the device arrived for service with its own temperature probes.

Flow accuracy check (Virtauksen tarkistus) is a step requiring a fully set up humidifier as seen in Figure 9. The MR290 chamber needs to be filled with water reaching no higher than the arrow mark. On the first attempt, the water was forgotten. Repeating the test with proper setup took additional time.

Seventh step, error codes check (Vikakoodin tarkistus), is an easy step allowing for quick move towards the final part of testing – the electrical safety test.
Electrical safety test (Sähköturvallisuusmittaus+MAH tarra) is done with the use of ESA620 testing device shown in figure 12. In this case, the device passed the tests without any issues, which meant a shorter time needed for this step. Sticker marking the next maintenance date was added.

Final step (Kirjaaminen) is uploading the maintenance report and writing the short description of the maintenance into the Mequsoft registry. However, during this test, the device belonged to the Effector system and as such the maintenance report was included there.

7.1.1 Results of the First Test

Multiple issues arose during the first test. Firstly, the maintenance box did not contain necessary equipment. That resulted in eleven minutes spent only on collecting the equipment from all around the place. Secondly, some parts of equipment were forgotten all together which meant another delay on steps five and six. All these issues accumulated to a maintenance time of 45 minutes.

To fix the first issue, missing equipment, such as the MR290 chamber and long enough tubing, was added to the box.

To ensure that all equipment is set up properly from the beginning, an extra sheet was added to the Excel template. It includes pictures and description of needed equipment, instructions on how to fill up the MR290 and correct water temperature needed for the probe accuracy test.

7.2 Second Test

Second test was carried out with an updated version of the maintenance template and the maintenance box. Figure 14 shows the timeline of this test. Comparably to the previous timeline, each green block represents one minute of time spent on each maintenance step.

Työvaihe nro	Työvaiheen kuvaus	Aloitusaika	Aikajana (1 ruutu on 1 minuutti)
1.	Varusteiden haku ja laitteen haku	13:38	
2.	Visuaalinen tarkastus	13:40	
3.	Kalibroinnin tarkastus	13:42	
4.	Näytön testaus	13:43	
5.	Lämpötila-anturin tarkistus	13:44	
6.	Virtauksen tarkistus	13:47	
7.	Vikakoodien tarkistus	13:51	
8.	Sähköturvallisuusmittaus, Seuraavahuoltotar	13:53	
10.	Lopetusaika	14:05	

Figure 12 Timeline of second test

Having the maintenance box including all the needed equipment resulted in significantly shorter time needed for the first step. By comparing the two timelines it can be seen that the time needed dropped from eleven to two minutes. Apart from the electrical safety test, all the steps of the maintenance required less or the same amount of time to complete. Electrical safety test of the device in questions took longer due to technical issues at the testing place.

7.3 Conclusion of the Tests

In addition to the two tests mentioned above, multiple others were conducted. The maintenance box is intended to be used by whoever performs the maintenance. For that reason, equipment such as the humidification chamber or extra tubing were added to it. Additional Excel sheet listing all the necessary equipment was included in the template to ensure full preparedness of the workstation straight from the beginning.

Noise during or after the power-up of the humidifier usually requires the device to be opened in order to resolve the issue and it must be done before continuing with the maintenance. This appears to be quite a rare issue as it appeared only once during the whole thesis work process. Many devices come with their own temperature probes which eliminates the need to use the service ones. The most common issue that prolongs the maintenance was found to be the electrical safety check. In some cases, the test had to be repeated multiple times which resulted in time added to the final duration. Example of such an issue is faulty mains cable or probe connector slipping off of the heater plate during the test. Additional charge for any type of delay is required. Minority of the humidifiers belong to the Effector system that requires a different approach in uploading the electrical safety test results. This does not result in any further charge.

Some humidifiers are fitted with a location tag with a battery that needs to be changed roughly every two years. Battery charge status ought to be checked during each maintenance and, in the case of the charge being too low, replaced. Be it the case, additional fifteen minutes are to be added to the final time count. Notion about these extra time charges was added as a comment in the report template.

To get an idea about the time charged for the maintenance in the past, entries in Mequsoft from previous year were compared. According to these entries, time spent on the maintenance varied from 20 minutes to 1 hour. However, as result of the test and adjustments made during them, it was found out that a glitch-free maintenance takes approximately thirty minutes to complete. The actual implementation of the set time charge will likely happen during summer 2022. After these tests a final version of the template was created. As the instructions are meant only for the use of the medical engineering department, the template in its entirety cannot be included in the thesis work. Nevertheless, to show the check list of the maintenance, the front page of the template is attached as appendix 2.

8 F&P 950 Respiratory Humidifier

F&P 950 respiratory humidifier shown below in Figure 15, is an updated version of MR850. Its intended purpose is to provide medical gases, delivered to patients who are in need of respiratory support, with heat and humidity. At the time of writing, there were only 47 devices in use throughout HUS with more to be added in near future. As F&P 950 is slowly replacing its predecessor, it was decided to create a maintenance template for this device as well.

Figure 13 F&P 950 Respiratory humidifier [18]

8.1 Comparison of F&P 950 to MR850

The number of required connections was reduced to minimum to allow faster assembly and decrease the possibility of triggering system alarm due to flawed setup. One such modification is the integration of temperature and flow sensors inside the tubing and sensor cartridge.

Unlike MR850 which is equipped with three digits, 14 mm, 7 segment LED display, F&P950 is fitted with an interactive touch screen which allows user to easily choose among different modes of use or, for example change the language settings. The screen also shows intuitive alarms containing text or animation that clearly show the issue and the action required to correct it. When powered on, the device automatically enters adult user interface that offers the selection of invasive, mask and Optiflow modes. In mask and Optiflow modes it is possible to adjust the temperature which can help to improve patients' comfort during the treatment.

In invasive mode, the goal is the optimal humidity of gases at 37°C and 44 mg/L. It is not possible to adjust the temperature while in this mode.

Optiflow mode aims for the same temperature and flow. However, some patients might find 37°C to be too warm. In this case, the temperature can be lowered to 35°C or 33°C for a period of time. When the patient is accustomed to the treatment, the temperature will be set back to 37°C. Maximum flow that can be reached while using Optiflow is 70 L/min.

Unlike the two previous modes, mask mode temperature is lower. It is set to 31°C and 32 mg/L, with the possibility of lowering the temperature to 29°C or 27°C.
F&P 950 also has neonatal mode. This mode is not included in the main selection, but it is automatically selected when a neonatal breathing circuit is connected. [17.]

Sensor cartridge seen in Figure 16 is another feature different from the MR850. It is a fixture used together with the heaterbase to measure flow rate of the gas and its temperature. Expiratory heater wire adapter socket, electrical connector terminal for breathing tube and sensor probes are embedded in the cartridge. Temperature and flow probes have silicone covers that provide a protective barrier between the probes and the gases while still allowing accurate measurements. Typical service life of the sensor cartridge is 7 years from the date of manufacturing or 15,000 hours of use, whichever is reached earlier. The cartridge has an internal counter which will notify the user 30 days prior to expiry. [19.]

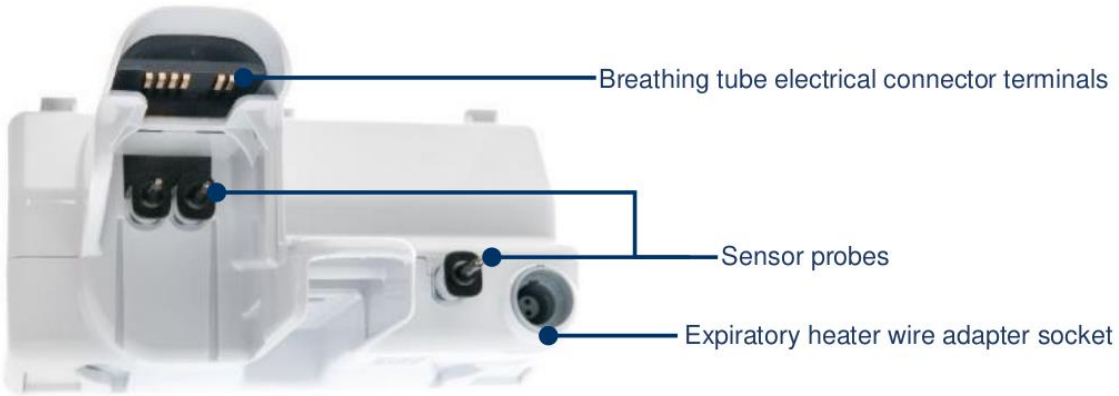

Figure 14 Sensor cartridge for F&P 950 [18]

IEC 60529 standard classifies and rates the grade of protection provided by mechanical casings and electrical enclosures against intrusion, dust, accidental contact, and water. According to this standard, F&P 950 ingress protection (IP) code is IP21. First numeral refers to solid particle protection, meaning the level of protection provided against e.g., electrical conductors or moving parts and the entry of foreign objects. Number 2 marks the protection against objects over 12.5 mm of size. Second number indicates liquid ingress protection. Level number 1 is effective against dripping water. At this level, the device must withstand a water amount equivalent to 1 mm of rainfall per minute during a ten-minute test. [20.]

Table 3 shows comparison of some mechanical and electrical specifications of both types of humidifiers. Supply voltages and supply currents are dependent on the exact model (marked A, J or G) of the humidifier. Supply voltage range is from 100 V to 230 V for both, while the range of supply current is 1.0 A - 2.4 A for MR850 and 1.5 A - 3.5 A for F&P 950.

Table 3 Comparison of MR850 and F&P 950 specifications, data taken from MR850 and F&P 950 service manuals [16;19]

	MR850	F&P 950
Dimensions (without chamber, in mm)	140 x 173 x 135	240 x 154 x 253
Weight (without chamber)	2.8 kg	3.45 kg (heater base + cord) 0.2 kg (sensor cartridge)
Power input	220 VA	350 VA
Supply frequency	50/60 Hz, sinusoidal wave	50/60 Hz, sinusoidal wave
Heater plate capacity (at nominal mains voltage)	150 W	200 W
Heater plate thermal cutout	118 ± 6 °C	155 °C
Heater wire supply	22 ± 5 V~, 2.73 A Max, 50 /60 Hz	22 ± 5 V~, 3.7 A Max, 50/60 Hz
Sound pressure level at 1 m	Exceeds 50 dBA	Exceeds 45 dBA
IP code	IP X1	IP 21
IEC 60601-1 classification	Class I	Class II

Both humidifiers also belong to applied parts classification BF (body floating). Applied part refers to such part of medical device equipment that necessarily comes to physical contact with the patient. Body floating type classification is commonly used for applied parts that are in conductive contact or have prolonged contact with the patient. [9.] Ultrasound devices and incubators are examples of this equipment type.

8.2 Annual Maintenance of F&P 950

Maintenance template for F&P 950 was done in the same style as the previous one. However, due to the current amount and age of the devices in use, only a preliminary template was created. Maintenance period for the humidifier is 2 years. This meant that

it was the first maintenance session for all available devices of this type. Also, the warranty on these devices is currently valid. Devices with warranty are sent to the manufacturer in case of any issues not caused by mishandling of the device. As a result, there was virtually no need for repairs to be done by the medical engineering department. While creating the template, it was found that the humidifier was registered in Mequsoft by the wrong product name. The issue was forwarded to the Mequsoft administrator who then corrected the matter by following the manufacturer's manual and changing the product name to F&P 950.

8.2.1 Maintenance Steps

Visual Check

As the humidifier consists of two parts, which are the F&P 950 itself and the sensor cartridge, visual check must be performed on both. To perform the check of the sensor cartridge, it must be disconnected from the humidifier. This allows for connector and probes check-up. If the cartridge service life is near the end, it is to be replaced.

Alarms

When the breathing tube is disconnected from its connector, the device will give an audible alarm. Also, animation will appear on the screen. Both the alarm and the animation stop when the tube is reconnected. In addition to alarm check this step helps to ensure that the screen is working properly.

Electrical Safety

By IEC 60601-1 classification, the heaterbase is Class II medical device and as such does not require a ground connection test. Enclosure leakage or touch current check of externally accessible metal contacts of the heaterbase must be performed if the heaterbase has been disassembled since the last electrical safety check. The maximum allowed touch current is 100 µA. [16.]

Software Update

This section contains step by step instructions on how to update the software version of the device. It is to be done only when a new version is provided by the manufacturer and as such is marked IF NECESSARY in the template. Software update is to be done by using the neonatal tubing attachment to ensure that all modes are updated properly.

In addition to these steps, an error code list was made part of the template to speed up the error identification process as it eliminates the need of searching through the service manual.

By comparing the templates for both humidifiers it is seen that the annual maintenance of F&P 950 is much simpler. This is mainly due to the newness of the device in HUS departments. As for now it contains only the procedures that can be done during this stage of F&P 950 service life. Later, maintenance stages can be added to the template as needed.

8.3 Maintenance Pricing

Although multiple annual maintenance procedures were performed in order to create the template, actual trial of said template was not possible. However, the template was checked and approved by an engineer responsible for their maintenance. Appendix 3 shows the main page of this template.

Main reasons why the trial did not happen was the F&P 950 humidifiers accessibility for the tests and time availability of personnel. As a result, the template for F&P 950 was left untested and the unified price for the service was not set.

9 Conclusion

The purpose of the thesis work was to construct report templates for annual maintenance of Fisher & Paykel respiratory humidifiers MR850 and F&P 950, and at the same time unify the cost of the service charger upon its completion.

Maintenance performed on the devices must be (in accordance with law and regulations) done by manufacturer's instructions. For this reason, the main sources of information were service manuals of both humidifiers together with the information and training received from experienced personnel.

For the MR850 humidifier, Excel-based report template consisting of a main check-list page and eight sheets dedicated to the description of maintenance procedures, error codes and needed equipment was created. Each sheet was focused on different step of the maintenance. The template was tested multiple times in order to eliminate possible issues and to improve its content. By timing these tests, it was found that the average duration of issue-free maintenance is half an hour and as such this shall be the common time used to determine the cost of the service. Subsequently, an improved service-kit box was created which means that all required equipment is found within the box.

The F&P 950 proved to be a more challenging case. As this humidifier is still very new in HUS services (only 47 devices at the time of writing), and all of these devices are still under warranty, no proper annual maintenance has been done. As a result of this, an Excel report template was created for the steps that are currently done. As such, it comprises of a check-list page and five sheets with detailed instructions on the maintenance. Due to the availability of the devices, the report template could not be tested, nor the service cost created. Additional steps and instruction sheets can be added to the template in the future when the device becomes more common.

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MR850 Question part of the questionnaire

1 (1)

Kysely Lämpökostutin MR850 käyttäjille

1) Kuinka usein käytätte lämpökostutinta ja minkälaisten sairastapausten/potilaiden yhteydessä?
2) Miten käyttö jakautuu invasiivisen ja noninvasiivisen välillä (karkeasti -%)?
3) Mitkä ovat yleisempiä laiteeseen liittyviä vikatilanteita?
4) Mikä olisi teille paras laitteen määräaikaishuollon ajankohta työkuormituksenne kannalta?
5) Kuljetatteko laitetta käsin vai telakoituna/toiseen laitteen kanssa?
    i. Jos kuljetatte käsin, haluaisitteko sille erillisen pyörillä varustetun tason?
    ii. Jos kuljetatte tasolla/telakoituna onko sen toiminallisuudessa jotain parannettavaa?
6) Haluatteko että Lääkintätekniikka seuraa huoltotilannetta suoraan vai haluatteko itse seurata ja ilmoittaa määräaikaishuollon tarpeesta?
7) Onko teillä muita laitteen toimivuuteen tai määräaikaishuoltoihin liittyviä asioita, joihin haluaisitte Lääkintätekniikkan kiinnittävän huomioita?

Kysely on osa opinnäytetyötä HUS Lääkintätekniikkalle, laatija Radka Sádlíková.

Toimitattehan vastaukset osoitteeseen [redacted] 17.11.2021 mennessä.

Kiitoksia vastauksista!

MR850 Template, main page

HUS

11.1.2022 13:57

MR850 MÄÄRÄAIKAISHUOLTO

LAITETUNNUS L

Tarvittavat varusteet
Pääsy huoltotilaan

☐ VISUAALINEN TARKISTUS	Ohje	Tarkista laitteen puhtaus, lämpölevyn ja sormisuojan kunto, virtajohdon kunto,vauriot, tarrojen luettavuus, / vaihto tarvittaessa Tarkista lämmitysvastuksen sovitin (jos mukana)
☐ KALIBROINNIN TARKISTUS	Ohje	☐ Kalibrointikaapelin HARMAA holkki *(Lukeman oltava 100)* Valitse huoltotilasta kohta 1 painamalla MUTE painikketta. Harmaa holki lämpötilaliittimeen. Anna näytön tasaantua ☐ Kalibrointikaapelin SININEN holkki *(Lukeman oltava 200)* Paina käynnistyspainiketta ja liitä sininen holkki. Anna näytön tasaantua
☐ NÄYTÖN TESTAUS	Ohje	Valitse huoltotilasta kohta 6, tarkasta että kaikki LEDit syttyvät
☐ LÄMPÖTILA-ANTURI TARKISTUS	Ohje	Valitse huoltotilasta kohta 4. Laita ilmatieanturi ja kammioanturi vesisäiliöön (n.40°C) yhdessä lämpömittarin kanssa Odota noin 30 sekuntia. Antureiden ja lämpömittarin lämpötilan ero oltava alle 1,5°C. MODE-painike vaihtaa ilmä- ja kammion anturin välillä Ilmatieanturin lämpötila = Lämpömittari = ERO (max ±1.5°C)= 0 °C Kammioanturin lämpötila = Lämpömittari = ERO (max±1.5°C)= 0 °C
☐ VIRTAUKSEN TARKISTUS	Ohje	Aseta vedellä täytetty kostutussäiliö paikalle, valitse huoltotilasta kohta 5. Kytke kostuttimen kammion sisääntulo kaasulähteeseen (jatkuva 10±1 SLPM) Kostuttimen näytöllä näkyy '---' kunnes virtausmittausarvo on saavutettu. Virtausmittaus (oltava 5-15 SLPM)=
☐ VIKAKOODIEN TARKISTUS	Ohje	Poistu huoltotilasta. Paina MUTE+MODE samanaikaisesti n.1s. Näytöllä näkyy '==', vapauta molemmat painikkeet. Laite selaa vikakoodit läpi. MUTE-painikkeen painaminen näyttää toiminnon takana olevan arvon niin kauan kuin MUTE-painiketta pidetään painettuna. ☐ HC = 0 (Humidity Compensation) ☐ LFS = E00 (Last Fault State)
☐ SÄHKÖTURVALLISUUSMITTAUS	Ohje	☐ HYVÄKSYTTY ☐ HYLÄTTY
☐ LIIMAA 'SEUVAAVA HUOLTO' TARRA		Huoltoväli 12KK

HUOMIOITAVAA:

HUOLLON SUORITTI HUS LÄÄKINTÄTEKNIIKKA,

F&P 950 Template, main page

27.1.2022 7:26

F&P 950 MÄÄRÄAIKAISHUOLTO

LAITETUNNUS L

☐ VISUAALINEN TARKISTUS Ohje ☐ LAITE
Tarkista laitteen puhtaus, näytön, lämpölevyn ja sormisuojan kunto, virtajohdon kunto,vauriot, tarrojen luettavuus

Ohje ☐ ANTURIKASETTI
Tarkista antureiden kunto, hengitysletkun liitimen kunto, lämmittimen johdon sovitin

☐ ANTURIKASETTI OK ☐ ANTURIKASETTI VAIHDETTU
Vaihda anturikasetti 7 vuoden välein (tai 15000 käyttötuntia)

☐ HÄLYTYKSET Ohje Irrota hengitysletku. Laite hälyttää.

☐ SÄHKÖTURVALLISUUSMITTAUS HENGITYSKOSTUTIN ON LUOKAN II SÄHKÖLAITTEISTO!
-Maadotustarkistusta **EI** tarvitse tehdä

☐ OHJELMISTON PÄIVITYS TARVITTAESSA! Ohje

☐ LIIMAA "SEURAAVA HUOLTO" TARRA

HUOMIOITAVAA:

HUOLLON SUORITTI HUS LÄÄKINTÄTEKNIIKKA,