**Emergency Ventilator**

Production and test specification

Issue/change record

|  |  |  |  |
| --- | --- | --- | --- |
| Issue | Date | Author | Reason of issue/summary |
| 0.A | 10/04/2020 |  | DRAFT, released for ongoing development |
| 0.B | 15/04/2020 |  | Added precaution in pneumatic assemble section to assure gas pathway is clean. |
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# Introduction

This document contains the quality assurance plan for producing the Emergency Ventilator design.

# General quality assurance requirements

Council Directive 93/42/EEC, which remains current (while the MDR is under consideration for postponement), Annex V on production quality assurance requires:

The manufacturer, who is the entity who places their brand name on the ventilator, must ensure the following:

* The product is made in ways that it conforms to the approved design.
* The manufacturer’s quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures that are not open to misinterpretations. It must include in particular an adequate description of:

1. The manufacturer's quality objectives;
2. The manufacturer’s:

* Organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned.
* Methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform.
* Methods of monitoring the efficient operation of sub-contractors and in particular the type and extent of quality system controls applied to the third party.

1. Inspection and quality assurance techniques at the manufacturing stage and in particular:

* Processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents.
* Product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.

1. Appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

* Keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action.
* Notify the national ‘Competent Authorities’ of the following incidents immediately on learning of them:

1. Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
2. Any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.

In usual times, for products marketed within the EU/EEA, the manufacturer must submit the quality systems and design dossier to assessment and periodic surveillance by a Notified Body. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. This requirement may be deferred in time of a pandemic emergency (check your national regulatory authority’s position).

# Components procurement

## Specifying and purchasing components and services

Ensure that goods or service requirements, are fully and unambiguously specified – to reduce the risk of inadvertently receiving the wrong or sub-standard parts.

Ensure the supplier receives the latest drawings of fabricated parts. Where a document has been revised, ask the supplier to confirm that they have disposed of the outdated revision.

Where available, request a certificate of conformity.

Where deliveries were incomplete or had a discrepancy against what was orders, the issue will be resolved with the supplier, prior to putting the components into use.

Recorded evidence of receipt and status (inspection result, accepted or rejected) of ordered goods or services. On occasions, a discrepancy or other issue may not become apparent until the product is put into use. It is important to be able to obtain the suppliers commitment to correct the issue at the soonest possible.

## Traceability

Maintain traceability records of critical components – from purchasing orders, through warehousing, to production and product delivery – to enable locating and recalling any components that are subsequently to have a quality problem. Remember, the product is a life-support ventilator.

It cannot be tolerated that a ventilator operates with the risk of a known defect being realised. Even if it is not possible to replace a degraded component immediately, it must be possible to at least notify the user that a risk exists – to enable them prepare a backup response to the possible failure.

See the record sheet Appendix.

## Stocking parts

Maintain storage conditions in accordance to the manufactures’ recommendations.

Generally, use a first-in-first-out (FIFO) picking method, to ensure stock turn over and best manage any shelf-life implications.

# Assembly

## Electronic sub-assembly

To be determined and described in outline terms. Add pictures illustrating important details.

It may be appropriately to produce a test jig at this stage – in particular if the sub-assembly is made by a sub-contractor.

## Pneumatic sub-assembly

To be determined and described in outline terms. Add pictures illustrating important details.

The patient gas pathway must not include any adhesives, Polyvinyl chloride (PVC) and care is given to ensure that they are free of foreign material (e.g. oil, particles, volatile organic compounds, mould release agents) or toxic compounds (e.g., formaldehyde), and do not release noxious gases (e.g., ozone, carbon monoxide) and fumes.

Record serial and batch number information in the inspection, testing and release record (see Appendix).

It may be appropriately to produce a test jig at this stage – in particular if the sub-assembly is made by a sub-contractor.

## General assembly

To be determined and described in outline terms. Add pictures illustrating important details.

Pneumatic tubes and electric wires are routed orderly and securely. Tie or fasten at appropriate points, to ensure no item is snagged or could move to become snagged or rubbed. [add picture]

Leave the ventilator in default calibration settings.

## Burn-in

Operate the ventilator on air for 24 hours non-stop and maximum parameter settings. Remove the top cover during the burn-in, to be able to observe and measure any concerns.

There is no need to accurately calibrate the ventilator, prior to the burn-in. Some brand-new components, including pressure regulators and solenoid valves, will ever so slightly drift in their first 24 hours of operation – e.g. solenoid valve response time tends to improve very slightly.

Between 8 and 12 hours of burn-in, remove the power cord and let the ventilator run down its battery. Verify the battery delivers at least 45 minutes of operation. Measure and record the battery voltage after 45 minutes.

# Inspection and calibration

## Inspection

Visually verify that all pneumatic tubes and electric wires are routed orderly and securely. No item is snagged or could move to become snagged and wear.

Visually verify that all fasteners (screws, clips, ties) are correctly placed and securely made.

Visually check that when observed at 30cm distance, using a normal uncorrected or corrected vision, that the ventilator is free from detracting marks.

Visually verify that the ventilator has all the correct labels and that they are securely attached.

## Calibration

To be determined and described.

## Final testing

To be determined and described.

Using testing tools, verify each alarm function in turn.

If, as result of failing the first testing, the ventilator is reworked, then the final testing must be repeated in full.

# Release approval

The person who the manufacturer has designated authority to release the products, must verify that the Inspection, Testing and Release Record (see Appendix) for:

1. Ventilator identification is correctly recorded.
2. All traceability details are properly recorded.
3. Appropriateness of any concession items.
4. Test records demonstrate that the ventilator conforms to the test specification.
5. That any rework information is recorded and has resulted a final testing in full.

The authorised person signs the correctly completed document, to approve the ventilator’s release into the market.

# Appendix – Inspection, testing and release record

|  |  |
| --- | --- |
| Emergency Ventilator 2020 | |
| Ventilator serial number: |  |
| Hardware revision number: |  |
| Software revision number: |  |
| Inspector’s initials: |  |

|  |  |  |
| --- | --- | --- |
| Part ID | Description | Batch/serial number |
| PCB | Pre-assembled, pre-tested PCB with pressure transducers |  |
| PR | Pressure regulator <model number> |  |
| SV1 | Solenoid valve <model number> |  |
| SV2 |  |  |
| SV3 |  |  |
| PTR1 |  |  |
| PTR2 |  |  |
|  |  |  |
| PSU |  |  |
| Battery |  |  |
|  |  |  |
| Concession items | | |
|  | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test and measurement equipment | ID | | Calibration date | | |
| Flow meter |  | |  | | |
| Pressure sensor |  | |  | | |
| Voltage meter |  | |  | | |
| Test parameter | | Target | | Measured | |
| Battery operation time | | Minimum 45 min | |  | |
| Total power fail alarm voltage | | 11.5v | |  | |
| Battery charging voltage after 6 hours | |  | |  | |
|  | |  | |  | |
| Test point 1 voltage | | 5V (+/- 0.15) | |  | |
|  | |  | |  | |
| Inspiration flow rate from ‘Gas Output’ port | | 60L/min (+/-2) | |  | |
| Volume calculation, when delivering 450ml (+/-25) | | Max error 15ml | |  | |
| Pressure accuracy | |  | |  | |
|  | |  | |  | |
| Test each alarm trigger and message | | Target | | | Met/Not met |
| ‘Circuit Failure’ – disconnect test lung | |  | | |  |
| ‘EP Below Set’ – pinche/clamp pressure sense tube | |  | | |  |
| ‘EP Above Set’ – clamp pressure tube and compress | |  | | |  |
| ‘IP Below Set’ – pinche/clamp pressure sense tube | |  | | |  |
| ‘IP Above Set’ – clamp pressure tube and compress | |  | | |  |
| ‘Tdi Too Long’ | |  | | |  |
| ‘Tde Too Long’ | |  | | |  |
| ‘High pressure’ | |  | | |  |
| ‘Gas Failure’ | |  | | |  |
| ‘No Power Supply’ – unplug power supply | |  | | |  |
| ‘Battery Low’ – reduce voltage by variometer. Cancel alarm when sounding. | | MP alarm at 11.7v (+/- 0.1). No alarm repeat. | | |  |
| Total power fail – reduce voltage by variometer | | HP alarm at 11.3v (+/- 0.1v). Auto shut down after 3 min. | | |  |
| ‘Monitor Fail’ – short circuit monitor MPU crystal. | |  | | |  |
| ‘Control Fail’ – short circuit monitor MPU crystal. | |  | | |  |
| Visuals | | Target | | | Met/Not met |
| Labels and markings | | As per drawing | | |  |
| Free from marks and blemishes | | None, viewed at 30 cm | | |  |

|  |
| --- |
| Details of any rework and re-inspection |
|  |

|  |  |
| --- | --- |
| Release approval | |
| Approver initial |  |
| Approver signature |  |
| Date |  |