INTRODUCTION

This document provides a summary of the design verification activities and results for the AIRone emergency ventilator. This includes verifiation of design specifications, safety tests, and usability tests.
The design specifications are described in detail in the Design Specifications Document. For each specification, the applicable test reports are summarized in this document.
Usability tests and safety tests are also summarized in this document.

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CONCLUSION

The AIRone is currently undergoing the final stages of design verification. Almost all design specifications have been verified. Usability testing has yielded some improvements to the design, which have all been implemented and verified as well. Electrical safety has been verified. Although full compliance with the standards regarding Electromagnetic compatibility has not been acquired, we believe that the AIRone is ready for clinical testing when needed in emergency situations where no conventional ventilation equipment is available.

USABILITY TESTS

Two formative usability test sessions were held with several intensive care physicians and ventilation specialists. Special focus was paid to ease of use, safety, and applicability for COVID-19 patients on intensive care units in The Netherlands.

03-04-2020

Participants:

[redacted], Intensivist; [redacted], Intensivist; [redacted], Technical Physician; [redacted], Technical Physician

Conclusion:

The device is intuitive to use. The current alarms are sufficient, but the default alarm limits should be smaller. COVID-19 patients generally require complex ventilation strategies, so the device must be able to handle high breathing rates up to 40/min with large minute volumes. Additionally, the possibility to perform expiratory holds is a must. Also a way to detect AutoPEEP should be added.

10-04-2020

Participants:

[redacted], Intensivist; [redacted], Technical Physician; [redacted], Ventilation Practicioner

Conclusion:

The user interface works as it should, comparable to standard ventilators. Starting ventilation is easy. The device is able to provide the ventilation performance that is required. Peak pressure is generally set as relative pressure above PEEP instead of relative to ambient pressure. Pressure settings and especially PEEP should be adjustable in small intervals of 1 or 2 cmH2O. The time-axis of the flow and pressure curves should be smaller, generally 4 to 5 breaths should be displayed.

SAFETY TESTS

ELECTRICAL SAFETY

Leakage current testing was performed using the acceptance criteria for leakage current as defined in IEC 60601-1:2006. Measured leakage current was within acceptable limits for all tests.

ELECTROMAGNETIC COMPATIBILITY

Explorative tests were performed for radiated immunity, radiated emission, and electrostatic discharge. Tests and acceptance criteria were based on IEC 60601-1-2:2015.

Radiated immunity testing indicated that some components were sensitive for certain irradiated freqencies. The speaker emitted noise when irradiated at 54, 117 and 124 MHz. The UPS module started vibrating when

irradiated with frequencies around 270 MHz. And the screen malfunctioned when irradiated in the 200 - 235 MHz range. The following design changes were made to eliminate these sensitivities:

- The speaker cable was placed directly on the protective earthing and capacitively coupled using conductive material
- Ferrite filters were placed on the cables to and from the UPS module
- The cable to the screen was shielded using conductive material and this shielding was connected to the protective earthing
- The screen was directly connected to the protective earthing

Radiated emission between 30 MHz and 1 GHz was measured in an anechoic chamber. Quasi-Peak emission limits were exceeded in two frequency bands: 42.7 dBµV/m around 40 MHz, and 51.9 dBµV/m at 219 MHz. Although these results technically constitute a failure, we consider the device acceptable for emergency use. Continued development is required.

Testing for bursts of electrostatic discharges at 8 kV showed that the flowsensor was susceptible. Discharges to the screws on the front of the device, close to the location of the flowsensor, could disrupt the sensordata communication. For this reason, the screws close to the flowsensor that were accessible from the exterior were replaced with non-conductive screws.

DESIGN SPECIFICATIONS

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-31 Ventilation mode	**XTC-30 Error margins: Pressure loss (TC-76)**	2020/04/02	2020/04/02 08:21:46	passed
	XTC-49 Pressure Rise Time (TC-120)	2020/04/05	2020/04/05 13:14:49	failed
	XTC-38 Peak-plateau difference (TC-121)	2020/04/02	2020/04/02 16:57:29	passed
SPEC-46 Usability user-interface	**XTC-110 Usability test (TC-65)**	2020/04/10	2020/04/24 09:47:51	documentation
SPEC-34 Visualized measurements	**XTC-2 Visualized measurements (TC-31)**	2020/03/27	2020/03/27 17:41:48	passed
SPEC-150 Instructions For Use	**XTC-127 IFU packed with device (TC-162)**	2020/04/24	2020/04/24 10:41:32	passed
SPEC-42 Compatibility with standard hospital equipment	**XTC-77 Compatibility with standard hospital equipment (TC-39)**	2020/04/06	2020/04/06 18:59:48	passed
SPEC-141 Inspiratory hold	**XTC-65 Inspiratory Hold (TC-156)**	2020/04/10	2020/04/10 07:45:23	passed with deviation

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-156 Expiratory Hold	XTC-111 Expiratory Hold (TC-170)	2020/04/24	2020/04/24 08:03:36	passed
SPEC-73 Interruption of power supply	XTC-82 Back up battery (TC-10)	2020/04/07	2020/04/10 08:03:11	passed
SPEC-60 Breaks	XTC-66 IFU: Use breaks when needed (TC-104)	2020/04/06	2020/04/06 10:01:15	passed
	XTC-51 Breaks (TC-103)	2020/04/05	2020/04/06 17:17:52	passed
SPEC-27 Flow Sensor	XTC-56 Flow sensor (TC-24)	2020/04/05	2020/04/05 11:57:41	passed
SPEC-153 HEPA filter	XTC-112 HEPA filter (TC-171)	2020/04/24	2020/04/24 08:11:37	passed
SPEC-25 HME-filter	XTC-14 HME filter (TC-70)	2020/03/31	2020/03/31 17:15:06	passed
SPEC-166 Ventilator	XTC-123 Ventilator (TC-172)	2020/04/24	2020/04/24 10:00:19	passed
SPEC-155 Ppeak setting	XTC-109 Pressure setting (TC-168)	2020/04/23	2020/04/23 09:42:42	passed
SPEC-35 PEEP setting	XTC-43 PEEP value (TC-30)	2020/04/06	2020/04/06 13:40:19	passed
	XTC-46 PEEP stability (TC-133)	2020/04/06	2020/04/06 14:09:20	passed
	XTC-60 PEEP settings (TC-32)	2020/04/05	2020/04/05 13:18:51	passed
SPEC-20 Breathing rate setting	XTC-25 Error margins: Breating rate (TC-78)	2020/04/06	2020/04/06 13:25:22	passed
SPEC-38 I:E ratio setting	XTC-27 Error Margins: I:E ratio (TC-80)	2020/04/02	2020/04/24 08:22:50	failed
	XTC-69 I:E ratio (TC-148)	2020/04/24	2020/04/24 08:13:07	passed
SPEC-37 FiO2 setting	XTC-57 Fi02 setting (TC-34)	2020/04/05	2020/04/05 12:01:25	passed
SPEC-6 Alarm for Inspiratory O2 concentration (FiO2)	XTC-86 Oxygen alarm (TC-9)	2020/04/07	2020/04/07 09:09:38	passed
	XTC-87 Air pressure drop alarm (TC-155)	2020/04/07	2020/04/07 09:19:03	passed

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-9 Alarm for positive end-expiratory pressure (PEEP)	XTC-101 PEEP alarm (TC-8)	2020/04/13	2020/04/13 09:12:01	passed
SPEC-8 Alarm for Tidal volume (Tv)	XTC-124 Tidal volume alarm I (TC-7)	2020/04/24	2020/04/24 10:18:02	passed
	XTC-125 Tidal volume alarm II (TC-68)	2020/04/24	2020/04/24 10:19:26	passed
SPEC-89 Alarm for Peak Pressure (Ppeak)	XTC-102 Plateau pressure alarm II (TC-83)	2020/04/13	2020/04/13 09:19:16	passed
SPEC-87 Alarm for Apnea or disconnect	XTC-103 Apnea/Disconnect alarm (TC-101)	2020/04/13	2020/04/13 09:33:34	passed
SPEC-84 Alarm for empty battery	XTC-128 Back-up battery empty alarm (TC-84)	2020/04/24	2020/04/24 10:57:08	failed
SPEC-19 Clear explanation per alarm on GUI	XTC-113 Clear explanation per alarm (TC-17)	2020/04/24	2020/04/24 08:59:03	passed
SPEC-95 Error margins: Tidal Volume	XTC-28 Error margins: Tidal Volume (TC-81)	2020/04/02	2020/04/06 20:13:57	passed with deviation
SPEC-94 Error margins: I:E ratio	XTC-27 Error Margins: I:E ratio (TC-80)	2020/04/02	2020/04/24 08:22:50	failed
SPEC-93 Error margins: FiO2	XTC-26 Error margins: FiO2 (TC-79)	2020/04/02	2020/04/02 09:32:59	passed
SPEC-92 Error margins: breating rate	XTC-25 Error margins: Breating rate (TC-78)	2020/04/06	2020/04/06 13:25:22	passed
SPEC-90 Error margins: Lung/airway pressure	XTC-30 Error margins: Pressure loss (TC-76)	2020/04/02	2020/04/02 08:21:46	passed
SPEC-36 FiO2 range	XTC-26 Error margins: FiO2 (TC-79)	2020/04/02	2020/04/02 09:32:59	passed
SPEC-26 Tidal Volume	XTC-34 Tidal volume range (TC-23)	2020/04/02	2020/04/02 09:19:27	passed
SPEC-40 Inspiratory Flow	XTC-70 Inspiratory flow (TC-37)	2020/04/06	2020/04/07 11:44:59	passed
SPEC-118 Reliability	XTC-130 Measurement Reliability (TC-106)	2020/04/24	2020/04/24 11:09:06	passed
SPEC-128 14 day reliability	XTC-79 Long-term reliabillity (TC-38)	2020/04/06	2020/04/08 11:01:57	passed
	XTC-81 Specification of expected durability (TC-130)	2020/04/07	2020/04/07 08:07:49	passed with deviation

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-29 **Peak pressure**	XTC-106 **Fail-safe valve (TC-67)**	2020/04/10	2020/04/15 11:22:04	passed
SPEC-146 **Flow sensor shielding**	XTC-131 **Flow Sensor (TC-169)**	2020/04/24	2020/04/24 11:10:20	passed
SPEC-144 **Airflow materials**	XTC-114 **Airflow materials (TC-159)**	2020/04/24	2020/04/24 09:01:40	passed
SPEC-129 **Robustness**	XTC-91 **Push test (TC-61)**	2020/04/08	2020/04/08 09:38:51	passed
	XTC-92 **Impact test (TC-62)**	2020/04/08	2020/04/08 09:39:39	passed
	XTC-120 **Internal components tightly attached (TC-4)**	2020/04/24	2020/04/24 09:46:59	passed with deviation
	XTC-68 **Tipping test (TC-109)**	2020/04/06	2020/04/06 11:15:24	passed
	XTC-118 **Tipping test II (TC-110)**	2020/04/24	2020/04/24 09:38:40	passed with deviation
	XTC-11 **Do not push warning (TC-129)**	2020/03/31	2020/03/31 15:58:06	passed
SPEC-126 **Cleaning and disinfection**	XTC-115 **Cleaning and disinfection (TC-127)**	2020/04/24	2020/04/24 11:12:51	passed
SPEC-120 **Alarms are easy to understand and intuitive**	XTC-97 **Alarms easy to understand (TC-119)**	2020/04/08	2020/04/08 11:56:22	passed
SPEC-113 **Impairment of cooling**	XTC-94 **Impariment of cooling (TC-99)**	2020/04/06	2020/04/08 11:18:41	passed
SPEC-103 **No air leakage**	XTC-116 **Pressure Hold (TC-91)**	2020/04/24	2020/04/24 09:20:20	failed
SPEC-100 **External exhaust outlets**	XTC-58 **External exhaust outlet oxygen rich environment (TC-86)**	2020/04/05	2020/04/05 12:13:52	passed
SPEC-99 **Temperature of inspirated air**	XTC-93 **Temperature of applied parts (TC-85)**	2020/04/08	2020/04/08 11:05:25	passed
SPEC-85 **High Voltage circuit outside casing**	XTC-9 **230 V circuit outside casing (TC-112)**	2020/03/30	2020/03/30 11:14:35	passed
SPEC-83 **Testing of the fail-safe valve during production**	XTC-134 **Fail safe valve test during production (TC-111)**	2020/04/28	2020/04/29 07:11:46	passed

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-80 Housing impact test	**XTC-92 Impact test (TC-62)**	2020/04/08	2020/04/08 09:39:39	passed
SPEC-79 Housing mechanical resistance	**XTC-91 Push test (TC-61)**	2020/04/08	2020/04/08 09:38:51	passed
SPEC-72 Leakage current testing	**XTC-63 Leakage current testing (TC-54)**	2020/04/10	2020/04/10 08:02:28	passed
SPEC-71 Patient leakage current	**XTC-63 Leakage current testing (TC-54)**	2020/04/10	2020/04/10 08:02:28	passed
SPEC-70 Touch current	**XTC-63 Leakage current testing (TC-54)**	2020/04/10	2020/04/10 08:02:28	passed
SPEC-67 Acoustic Energy	**XTC-19 Sound test (TC-49)**	2020/04/06	2020/04/06 20:18:18	passed
SPEC-65 Sharp edges	**XTC-117 Sharp edges (TC-48)**	2020/04/24	2020/04/24 09:36:21	passed
SPEC-63 Instability unintended force	**XTC-118 Tipping test II (TC-110)**	2020/04/24	2020/04/24 09:38:40	passed with deviation
SPEC-62 Instability incline surface	**XTC-68 Tipping test (TC-109)**	2020/04/06	2020/04/06 11:15:24	passed
SPEC-143 Visibility User Interface	**XTC-119 Usability with protective equipment (TC-41)**	2020/04/24	2020/04/24 09:40:03	passed
SPEC-145 Watchdog program	not covered by selected test run(s)			
SPEC-53 Power Supply	**XTC-74 Power supply (TC-47)**	2020/04/06	2020/04/06 17:30:32	passed
SPEC-32 Expirated air	**XTC-50 Expirated air (TC-29)**	2020/04/05	2020/04/05 07:26:32	passed
SPEC-44 Non-conductive exterior casing	**XTC-52 Non-conductive exterior casing (TC-74)**	2020/04/05	2020/04/05 08:05:32	passed
SPEC-45 Protective equipment	**XTC-119 Usability with protective equipment (TC-41)**	2020/04/24	2020/04/24 09:40:03	passed
SPEC-23 Protected off switch	**XTC-99 Off switch protection (TC-21)**	2020/04/09	2020/04/09 18:08:37	passed
SPEC-22 The O2 and air input connectors	**XTC-85 O2 and air input connectors (TC-20)**	2020/04/07	2020/04/07 09:05:22	passed
SPEC-18 Battery use warning	**XTC-129 Back up battery warning (TC-69)**	2020/04/24	2020/04/24 11:07:59	failed

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-5 Pressure relief valve	**XTC-106 Fail-safe valve (TC-67)**	2020/04/10	2020/04/15 11:22:04	passed
SPEC-4 Calibrate sensors during assembly	**XTC-18 Calibrate sensors during assembly (TC-66)**	2020/04/01	2020/04/01 14:20:00	passed with deviation
SPEC-2 Robustness internal components	**XTC-120 Internal components tightly attached (TC-4)**	2020/04/24	2020/04/24 09:46:59	passed with deviation
SPEC-1 Ingress of water	**XTC-98 Splash proof (TC-3)**	2020/04/09	2020/04/09 18:06:49	passed
SPEC-162 Installation Verification	**XTC-132 Installation Verification (TC-174)**	2020/04/24	2020/04/25 10:37:38	passed
SPEC-152 IFU: regulatory requirements	**XTC-135 IFU: regulatory requirements (TC-165)**	2020/04/29	2020/04/29 09:45:44	passed with deviation
SPEC-47 IFU: intended use	**XTC-35 Clear explanation for intended use in IFU (TC-134)**	2020/04/02	2020/04/02 09:17:10	passed
SPEC-13 IFU: Device not for use during transport	**XTC-32 IFU: Not for use during transport (TC-12)**	2020/04/02	2020/04/02 08:58:38	passed
SPEC-14 IFU: Check device before use	**XTC-33 IFU: Check device before use (TC-13)**	2020/04/02	2020/04/02 09:03:16	passed
SPEC-98 IFU: Do not use when damaged	**XTC-31 IFU: Unplug device when damaged (TC-114)**	2020/04/02	2020/04/02 09:00:06	passed
SPEC-117 IFU: turn off device before unplugging	**XTC-36 IFU: Device turned off (TC-117)**	2020/04/02	2020/04/02 09:18:56	passed
SPEC-134 IFU: ventilator settings	**XTC-39 IFU: Upper en lower limit of the ventilator settings (TC-135)**	2020/04/02	2020/04/02 09:24:30	passed
SPEC-135 IFU: Explanation of the alarms	**XTC-41 IFU: explanation of the alarms (TC-136)**	2020/04/02	2020/04/02 09:29:07	passed
SPEC-137 IFU: HEPA filter	**XTC-44 IFU: Instructions about the use of the HEPA-filter (TC-137)**	2020/04/02	2020/04/02 09:37:05	passed
SPEC-51 IFU: Instructions for correct and safe maintanance	**XTC-80 IFU: Maintanance (TC-44)**	2020/04/07	2020/04/07 08:02:10	passed

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-138 IFU: alarm boundaries	XTC-45 IFU: How to set the upper and lower boundaries of the alarms (TC-138)	2020/04/02	2020/04/02 09:40:54	passed with deviation
SPEC-17 Training and clear IFU for the users	XTC-67 IFU: trained user (TC-75)	2020/04/06	2020/04/06 10:01:52	passed
	XTC-110 Usability test (TC-65)	2020/04/10	2020/04/24 09:47:51	documentation
SPEC-49 IFU: checked by experts	XTC-136 IFU Review (TC-43)	2020/04/29	2020/04/29 09:52:20	passed
SPEC-151 Label: regulatory requirements	XTC-137 Label: regulatory requirements (TC-164)	2020/04/28	2020/04/29 09:54:13	passed
SPEC-64 Emergency use sticker	XTC-13 Labeling: Warning Sticker (TC-105)	2020/03/31	2020/03/31 16:01:10	passed
SPEC-115 Emergency number on label	XTC-12 Sticker with emergency number on device (TC-113)	2020/03/31	2020/03/31 15:58:50	passed
SPEC-133 HEPA filter warning sticker	XTC-126 HEPA filter warning sticker (TC-173)	2020/04/24	2020/04/24 10:34:53	passed
SPEC-61 Do not push warning	XTC-11 Do not push warning (TC-129)	2020/03/31	2020/03/31 15:58:06	passed
SPEC-154 Fire warning sticker	XTC-108 INSPECT: Information about fire hazard on the label (TC-166)	2020/04/20	2020/04/20 10:42:28	passed
SPEC-148 Device label	XTC-121 Visiblility of label (TC-160)	2020/04/24	2020/04/24 09:49:13	passed
SPEC-130 Intuitive for use - training	XTC-78 Intuitive for use - training (TC-131)	2020/04/06	2020/04/06 19:01:40	passed
SPEC-48 Vocabulary and Semantics	XTC-138 Vocabulary and Semantics (TC-71)	2020/04/29	2020/04/29 09:55:30	passed
SPEC-167 Open Source	XTC-133 Open Source (TC-175)	2020/04/24	2020/04/24 14:05:27	passed
SPEC-124 Pre-Set Controls	XTC-83 Pre-Set Controls (TC-125)	2020/04/07	2020/04/07 09:00:46	passed
SPEC-121 Battery Housing	XTC-104 Battery Housing (TC-122)	2020/04/13	2020/04/13 12:21:08	passed
SPEC-112 Incorrect output	XTC-84 Incorrect output (TC-98)	2020/04/07	2020/04/07 09:02:13	passed
SPEC-111 Indication of parameters relevant to safety	XTC-88 Indication of parameters relevant to safety (TC-97)	2020/04/07	2020/04/07 09:22:04	passed

Item	Tested By	Execution Date	Last Modification	Test Result
SPEC-110 Intentional exceeding of safety limits	**XTC-100 Intentional exceeding of safety limits (TC-96)**	2020/04/10	2020/04/10 08:07:54	passed
SPEC-109 Alarm systems	**XTC-24 Alarmsystems (TC-95)**	2020/04/01	2020/04/01 15:26:10	passed
SPEC-108 Usability	**XTC-89 Usability (TC-94)**	2020/04/07	2020/04/07 09:28:25	passed with deviation
SPEC-107 Accuracy of controls and instruments	**XTC-90 Accuracy of controls and instruments (TC-93)**	2020/04/07	2020/04/07 11:21:34	passed
SPEC-105 Compatibility with substances	**XTC-8 Compatibility with substances (TC-90)**	2020/03/30	2020/03/30 08:22:16	passed
SPEC-102 Flammable agent	**XTC-7 ME intended for use in conjunction with flammable agent (TC-88)**	2020/03/30	2020/03/30 08:21:17	passed
SPEC-77 Arangements of controls and indicators	**XTC-105 Arrangements of controls and indicators (TC-59)**	2020/04/13	2020/04/13 12:24:03	passed
SPEC-76 Electromagnetic compatibility	**XTC-122 Electromagnetic compatibility (TC-58)**	2020/04/24	2020/04/24 09:50:16	passed

TEST REPORTS

XTC-32 IFU: Not for use during transport (TC-12)
INSPECTION Warning in IFU that device is not to be used during transport
1
Version 1.0 of the IFU.
Legal OperationAIR
2020/04/02
passed
Page 19 under section 10.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect Instructions For Use	Contains a warning that device is not to be used during transport	passed	

XTC-33 IFU: Check device before use (TC-13)

INSPECTION

IFU contains information on what inspection must be done before use

1

Version 1.0 of the IFU

Legal OperationAIR

2020/04/02

passed

Page 13 under section 5 subsection 1.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect instructions for use	contains information on inspections to be done before using the device	passed	

XTC-34 Tidal volume range (TC-23)

TEST

Confirm that the device is able to provide tidal volumes between 300 and 700 mL

1

2020/04/02

passed

1. tV: >> 700mL (888mL)
2. tV: << 300 mL (15mL)

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Set lung compliance to 0.1 L/cmH2O			Compliance = 0.4 L/cmH2O
3	Ventilate with PPLAT 50 cm H2O, PEEP 5 cm H2O, freq 10/min			
4	Read out tidal volume on MI lung	tidal volume >= 700 mL		
5	Set lung compliance to 0.01 L/cmH2O			Compliance = 0.4 L/cmH2O
6	Ventilate with PPLAT 10 cm H2O, PEEP 5 cm H2O, freq 10/min			
7	Read out tidal volume on MI lung	tidal volume <= 300 mL		

XTC-43 PEEP value (TC-30)

TEST

Confirm that device is able to provide PEEP of at least 15 cm H2O

1

Prototype

Quality Control OperationAIR

2020/04/06

passed

PEEPlung 19.51 cm H2O

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PEEP 20 cm H2O			
3	Read out PEEP in MI test lung	PEEP > 15 cm H2O	passed	

XTC-2 Visualized measurements (TC-31)

INSPECTION

Flow, Pressure and Volume are visualized on the touchscreen

1.0
Prototype 1.0
Quality Control OperationAIR
2020/03/27
passed
Pass

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect user interface	Graphs and numbers showing values for Flow, Volume and Pressure are depicted	passed	

XTC-3 Touchscreen gloves (TC-41)

DEMONSTRATION
Confirm that the user interface touch screen works when the user wears gloves

1.0
Isolated component
Quality Control OperationAIR
2020/03/26
passed
Works perfect with a single glove. There may be an almost imperceivable latency when wearing two gloves

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put on two layers of protective gloves			
2	Adjust some settings on the user interface	Touchscreen responds to touching	passed	

XTC-19 Sound test (TC-49)

The sound emitted by the device can not exceed 80 dBA. Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2. The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the device is not less than 3 m.

1

Prototype

QA OperationAIR

2020/04/06

passed

sound level peaks at 56 dBA

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Place device in room with hard reflecting floor, at least 3 m distance to every wall			
2	Turn device on maximum pressure and flow (to find the worst-case scenario)			
3	Measure dBA at 50 cm from the device	does not exceed 80 dBA	passed	

XTC-18 Calibrate sensors during assembly (TC-66)

Inspection

1

Documentation

Quality Control OperationAIR

2020/04/01

passed with deviation

Installation verification protocol contains a check if calibration certificates are available for the relevant sensors (pressure and flow)

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect Installation Verification protocol	Sensor calibration is mentioned	passed	

XTC-14 HME filter (TC-70)

INSPECTION
Show that the device can be equipped with an ISO 9360-1:2000 certified HME filter

1

Prototype

Quality Control OperationAIR

2020/03/31

passed

HME filter is placed at patient airway side. The standard hospital equipment is compatible with standard HME filters and this device

Step	Action Result	Expected Result	Passed/Failed	Comment
1	inspection		passed	Included documentation in inspection

XTC-30 Error margins: Pressure loss (TC-76)

ANALYSIS
Maximum loss of pressure between device and patient lungs is 10 cm H2O

2

2020/04/02

passed

1. PIP: 11.7 cmH2O, Difference: -3.3
    - PEEP: 4.1 cmH2O, Difference: -0.9

2. PIP: 26.6 cmH2O, Difference: -3.4
    - PEEP: 19.3 cmH2O, Difference -0.7
3. PIP: 41.7 cmH2O, Difference: -3.3
    - PEEP: 34.5 cmH2O, Difference -0.5
4. PIP: 56.6 cmH2O, Difference: -3.4
    - PEEP: 49.2 cmH2O, Difference: -0.8

Kalibreren!!!

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PPLAT 15, PEEP 5 cm H2O, I:E 0.5, Freq 15, FiO2 21%			
3	Read out Plateau pressure on MI test lung			
4	Increase PPLAT to 60 in 15 cm H2O interval and the peep to 50 in 15 cm H2O interval and read out Plateau pressure on MI lung each time			
5	Calculate deviation between set and measured values	Deviation < 10 cm H2O for each measurement		

XTC-25 Error margins: Breating rate (TC-78)

ANALYSIS
confirm that maximum error between measured and set breating rates is 1/min

2

Quality Control OperationAIR

2020/04/06

passed

pass

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PPLAT 25 cm H2O, PEEP 15 cm H2O, I:E 0.5, FiO2 21%			
3	Set Freq to 10/min			

4	Read out breathing rate on MI test lung			
5	Increase freq to 30/min in intervals of 10/min and read out breathing rate on MI test lung each time			
6	Calculate deviation between set and measured values	deviation < 1/min	passed	

XTC-26 Error margins: FiO2 (TC-79)

ANALYSIS
Confirm that maximum error margin between measured and set FiO2 is 5%

2

Prototype

Quality Control OperationAIR

2020/04/02

passed

FiO2 Setting | Measurement | Deviation
21% | 21% | 0%
40% | 41% | 1%
60% | 60% | 0%
80% | 79% | 1%
100% | 99% | 1%
Mean deviation: 1%
Mean settle time 3:30

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Connect external O2 sensor at test lung			
3	Ventilate with PPLAT 25 cm H2O, PEEP 15 cm H2O, I:E 0.5, Freq 15			
4	Set FiO2 to 21%			
5	Read out O2 on external sensor			Additionally measured time untill O2 sensor settles

6	Increase FiO2 to 100% in 20% intervals and read out O2 on external sensor each time			
7	Calculate deviation between set and measured values	Deviation < 5%	passed	Mean deviation 1%

XTC-27 Error Margins: I:E ratio (TC-80)

ANALYSIS
Confirm that maximum error between set and measured I:E ratio is 0.05

2

2020/04/02

failed

1. I:E = 2.35 , Difference: 0.35
2. I:E = 3.45 , Difference:0.45 (alternates between 3.32 en 3.48)
3. I:E = 4.75 , Difference:0.75 (alternates between 4.70 en 4.82)

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PPLAT 25 cmH2O, PEEP 15 cmH2O, Freq 15, FiO2 21%			
3	Set I:E to 0.5			
4	Read out I:E on MI test lung	deviation < 0.05		
5	Set I:E to 0.33			
6	Read out I:E on MI test lung	deviation < 0.05		
7	Set I:E to 0.25			
8	Read out I:E on MI test lung	deviation < 0.05		

XTC-28 Error margins: Tidal Volume (TC-81)

ANALYSIS
Confirm that maximum error margin between internally and externally measured tidal volume is 5%

2

Prototype

Quality Control OperationAIR

2020/04/02

passed with deviation

1. tV_testlung 77 mL: , tV_device: 82, deviation 6.0%
2. tV_testlung 364 , tV_device 339, deviation 7.3%
3. tV_testlung 811 , tV_device 821, deviation 1.2%
4. tV_testlung 885, tV_device 860, deviation 2.9%
5. tV_testlung : , tV_device Not measured because maximum volume of test lung was exceeded

Deviation seems to be a constant rather than percentual. Averages out < 5%

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PEEP 5cm H2O, I:E 0.5, FiO2 21%			
3	Set PPLAT to 10 cm H2O, freq 30/min, lung compliance 0.01 L/cmH2O			
4	Read out tidal volume on MI test lung AND on internal sensor			
5	Increase PPLAT to 50 in 10 cm H2O intervals; decrease freq to 5/min in 5/min intervals; increase lung compliance to 0.1 in 0.02 L/cmH2O intervals. Read out tidal volume for each measurement on MI test lung AND on internal sensor			
6	Calculate deviations between values	deviations < 5%	passed	Mean deviation < 5%

XTC-7 ME intended for use in conjunction with flammable agent (TC-88)

INSPECTION

Adress risk of fire in risk management file

1

RMF 30/03/2020

Quality Control OperationAIR
2020/03/30
passed
Risks of flammable agent (oxygen) adressed in RMF

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-8 Compatibility with substances (TC-90)

Adress risks associated with compatibility with substances used with the medical device (oxygen) in risk management file
1
RMF 30/03/2020
Quality Control OperationAIR
2020/03/30
passed
Risk of oxygen adressed in RMF

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-24 Alarmsystems (TC-95)

Address need for alarm systems by means of risk control and address the risks associated with the operation or failure of the alarm system in Risk management File.
1
documentation
Quality Control OperationAIR

2020/04/01
passed
Adressed in Risk management file

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-13 Labeling: Warning Sticker (TC-105)

INSPECTION
Show that the label on the device indicates that the device is only to be used in emergency situations on COVID-19 patients

1
isolated label design
Quality Control OperationAIR
2020/03/31
passed
Has text on label indicating the intended use for covid-19 patients

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect device	has warning sticker	passed	

XTC-9 230 V circuit outside casing (TC-112)

INSPECTION
Show that the 230 V adapter and circuitry are not in the same encasing as the airflow circuits

1
Prototype
Quality Control OperationAIR

2020/03/30
passed
PASS 230V adapter and battery are placed in a separate encasing at distance of the main encasing that contains the oxygen circuitry

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-12 Sticker with emergency number on device (TC-113)

INSPECTION Inspect Device for labelling. Should name the number to call in case of emergency.
1
isolated label design
Quality Control OperationAIR
2020/03/31
passed
Has telephone number on label

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect Labelling		passed	

XTC-31 IFU: Unplug device when damaged (TC-114)

INSPECTION Show that IFU mentions to unplug device when damaged
1
Version 1.0 of the IFU.

Legal OperationAIR
2020/04/02
passed
Page 19 under section 10.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	inspect IFU		passed	

XTC-36 IFU: Device turned off (TC-117)

INSPECT Warning in IFU that the device should be turned off
1
Version 1.0 of the IFU
Legal OperationAIR
2020/04/02
passed
Page 14 under section 6 subsection 2.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU		passed	

XTC-38 Peak-plateau difference (TC-121)

TEST Show that the difference between peak and plateau pressure is < 2 cm H2O at default ventilation settings
1
Prototype

Quality Control OperationAIR

2020/04/02

passed

PIP: 23.2
PEEP: 9.0
initial analysis PPLAT: 9.0
After final analysis: Peak-plateau difference mean 1.08 cm H2O over 1 minute

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Set compliance to 0.03 L/cmH2O			
3	Ventilate with PPLAT 25, PEEP 10, Freq 10, I:E 0.5, FiO2 21%			
4	Read out peak lung pressure and pplat on mi lung			
5	Calculate difference between measured PPLAT and PIP	difference < 2 cm H2O	passed	1.08

XTC-11 Do not push warning (TC-129)

DEMONSTRATION
Show that the device has a sticker that says to not push on the device

1

Isolated label design

Quality Control OperationAIR

2020/03/31

passed

Has iso 7010-P017 icon on label

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Demonstration		passed	

XTC-35 Clear explanation for intended use in IFU (TC-134)
INSPECT Check if the intended use is documented in the IFU
1
Version 1.0 of the IFU
Legal OperationAIR
2020/04/02
passed
Page 5 under section 1 subsection 1.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect the IFU	It is documented	passed	

XTC-46 PEEP stability (TC-133)
TEST Confirm that the set PEEP level is maintained at all times
1
Prototype
Quality Control OperationAIR
2020/04/06
passed
PEEP 13.93 SD 0.12 over 1 minute

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			

2	Ventilate with PPLAT 25, PEEP 15, Freq 15			
3	Ventilate for 1 minute			
4	Determine PEEP levels for each breath	deviation between PEEP levels < 1 cm H2O	passed	

XTC-39 IFU: Upper en lower limit of the ventilator settings (TC-135)

INSPECT
Check if the upper and lower limits of the ventilator are explained correctly. Check whether the IFU explains how to set your ventilator parameter.

1

Version 1.0 of the IFU

Legal OperationAIR

2020/04/02

passed

Page 12 under section 4.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	Correctly documented way to set your settings	passed	

XTC-41 IFU: explanation of the alarms (TC-136)

INSPECT
Check if the alarms, their causes and how to deal with them are clearly explained in the IFU.

1

Version 1.0 of the IFU

Legal OperationAIR

2020/04/02

passed

Page 15 under section 7 and pages 20 & 21 under section 11.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	Alarms are explained	passed	

XTC-44 IFU: Instructions about the use of the HEPA-filter (TC-137)

INSPECT Check whether correct usage of the HEPA-filter is explained in the IFU
1
Version 1.1 of the IFU
Legal OperationAIR
2020/04/02
passed
Page 13 under section 5.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	The instructions about the HEPA filter are correctly documented	passed	

XTC-45 IFU: How to set the upper and lower boundaries of the alarms (TC-138)

INSPECT Check whether instructions about how to set the alarm limit is documented
1
Version 1.0 of the IFU
Legal OperationAIR
2020/04/02

passed with deviation
Page 8 under section 3 subsection 2.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	Alarm instructions are well documented	passed	Still has to be supplemented after completion of the GUI. But basics are there. Screenshots have to be implemented.

XTC-47 Patient leakage current (TC-53)

The values for patient leakage must not exceed:

- Alternating current maximally 500 micro Ampere, direct current maximally 50 micro Ampere in normal condition
- Alternating current maximally 1000 micro Ampere, direct current maximally 100 micro Ampere in single fault condition

1

not started

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Measure leakage current at patient level	A current < 500 uA is measured		

XTC-48 Touch current (TC-52)

Touch current from or between parts of the medical device within the patient environment must not exceed 100 µA. Leakage current from accessible outer surfaces of the equipment is also considered to be touch current.

1

not started

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Measure touch current for the different parts and outer surface of the medical device	Touch current is maximally 100 µA.		

XTC-49 Pressure Rise Time (TC-120)

TEST
Show that pressure rise time to peak at default ventilation settings is lower than 200 ms

1

Prototype

Quality Control OperationAIR

2020/04/05

failed

10%-90% pressure rise time as measured at the input of the device was ca. 300 ms.
When measured at the output, the pressure rise time was ... ms.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Set lung compliance to 0.03 L/cmH2O			
3	Ventilate with PPLAT 25, PEEP 10, Freq 10, I:E 0.5			And resistance of 5
4	Read out pressure rise time	< 200 ms	failed	

XTC-50 Expirated air (TC-29)

DEMONSTRATION
Show that the device has a check valve to block expiratory air from entering the device

terugslagklep testen op 80

1

Prototype

Quality Control OperationAIR

2020/04/05

passed

Check valve is present

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Show check valve		passed	

XTC-51 Breaks (TC-103)

Inspection

Show that the device has breaks on its wheels

1

Prototype

Quality Control OperationAIR

2020/04/05

passed

Inspection of prototype and documentation. Device has 4 wheels with breaks for the two on the front side.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect wheels	wheels have breaks	passed	

XTC-52 Non-conductive exterior casing (TC-74)

DEMONSTRATION

Show that the external casing is made of a non-conductive material and that conductive parts are grounded

1

Prototype

Quality Control OperationAIR

2020/04/05

passed

Inspect prototype and documentation. Casing is made of Polyurethane which is an insulator. The stainless steel bottomplate is grounded

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect design schematic			
2	Inspect casing datasheet			

XTC-53 Protective earth connections (TC-56)

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part. Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.

1

All components are grounded via the bottomplate. Removal of one component will therefore not lead to interruption of protective earthing. Removal of the bottomplate could disrupt grounding, but this is impossible without completely dissembling the device, so this is considered acceptable.
The additional protective earth conductor can be easily removed

Quality Control OperationAIR

2020/04/05

failed

Failed. Additional protective earth is easily removed without a tool

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect design schematics			

XTC-56 Flow sensor (TC-24)

INSPECTION
Show that the device is equipped with a flow sensor

1

Design schematic

Quality Control OperationAIR
2020/04/05
passed
Device has two flow sensors, one expiratory and one inspiratory

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-57 Fi02 setting (TC-34)

DEMONSTRATION

Confirm that the FiO2 can be set between 21% and 100% in intervals of 5%

1
Prototype
Quality Control OperationAIR
2020/04/05
passed
User interface has option to set FiO2

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Demonstrate FiO2 setting		passed	
2				

XTC-58 External exhaust outlet oxygen rich environment (TC-86)

INSPECTION

External exhaust outlets must not be located so that risk of ignition occurs because of any electrical component mounted on the outside of the medical device.

1
design schematic and prototype

Quality Control OperationAIR
2020/04/05
passed
All exhausts are placed at the bottom of the device, where no electrical equipment is placed

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-60 PEEP settings (TC-32)

DEMONSTRATION

Confirm that the PEEP can be set between 5 and 70 cm H20 and is adjustable per 5 cm H2O

1

2020/04/05

passed

PEEP can be set between 5 and 70 cmH2O and is adjustable per 5 cmH2O

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Demonstrate PEEP settings			
2				

XTC-61 Fail-safe valve (TC-67)

TEST

Confirm that the fail-safe valve opens and releases pressure when pressure exceeds 70 cm H2O

1

2020/04/05

passed

Pressure reaches 100 cmH2O at first, but drops to 70 as soon as pressure reaches Fail Safe Valve.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Attach pressure sensor to airflow output			
2	Open proportional valve to put 100 cm H2O on system			Via PC because settings on GUI are limited
3	Read out pressure sensor	Pressure has not exceeded 70 cm H2O (+- 1 cm H2O)		Expected result: When ventilation stops, pressure instantly drops to 70 cmH2O

XTC-63 Leakage current testing (TC-54)

INSPECTION

Factory acceptance test protocol states that each manufactured device is checked for leakage current and shall be < 500 uA.

2

IV protocol v 1.1

Quality Control OperationAIR

2020/04/10

passed

Stated leakage current testing in installation verification protocol

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect factory acceptance test protocol		passed	

XTC-64 Off switch protection (TC-21)

DEMONSTRATION

Show that the off switch is positioned so that it is protected from accidental switching

1

Prototype

Quality Control OperationAIR

2020/04/05

passed

Device has an off switch on the user interface. When pressed, the user is prompted to confirm switching off the device. The power adapter has a button to turn of charging the battery, but this is located relatively protected

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Find location of off switch, try to bump into it		passed	

XTC-65 Inspiratory Hold (TC-156)

Medical device must be equipped with a button that will stop respiration at the end of inspiration when pressed, while measuring the pressure in the system. When the user lets go of the button, respiration must instantly start again

1

2020/04/10

passed with deviation

Inspiratory hold is started by a button and stopped by another button, or when exceeding a set time limit

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Press inspiratory hold button	Respiration stops at end of inspiration, Pressure over the system is measured	passed	
2	Let go of button	Respiration is restored	passed	after 7 seconds

XTC-66 IFU: Use breaks when needed (TC-104)

INSPECTION
Confirm that the instructions mention that the breaks need to be used when the device is not being moved

1

Version 1.2 of the IFU
Legal OperationAIR
2020/04/06
passed
Page 16 under section 10.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	Mention to use breaks	passed	

XTC-67 IFU: trained user (TC-75)

Warning in IFU that the device may only be used by trained users
1
Version 1.2 of the IFU
Legal OperationAIR
2020/04/06
passed
Page 1 on title page

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU		passed	

XTC-68 Tipping test (TC-109)

TEST Confirm that the device does not overbalance when placed on a 10 degree incline surface
1

Prototype

Quality Control OperationAIR

2020/04/06

passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put device on hard, flat horizontal, movable surface			
2	Put device on breaks			
3	Tilt surface to 10 degree angle to horizontal	device does not fall over	passed	

XTC-69 I:E ratio (TC-148)

Inspection
The inspiratory:expiratory ratio is visible and adjustable on GUI.

1

Prototype

Quality Control OperationAIR

2020/04/24

passed

I:E can be set to:
1:0.5; 1:1; 1:1.5; 1:2; 1:2.5; 1:3

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-70 Inspiratory flow (TC-37)

TEST
Confirm that maximum inspiratory flow > 1.5 L/s

1
prototype
Quality Control OperationAIR
2020/04/06
passed
Flow = 105 L/min

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung with flow sensor			
2	Set MI lung compliance to 0.1 L/cmH2O			
3	Ventilate with PPLAT 50, PEEP 5, I:E 0.5, freq 10/min, FiO2 21%			
4	Read out peak inspiratory flow	> 90 L/min	passed	
5				

XTC-74 Power supply (TC-47)

DEMONSTRATION
Show that the device has a IEC 60601-1 certified mains supply adapter for connection to a 230V AC supply mains

1
2020/04/06
passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU	Supply mains connection to 230V AC mentioned		
2	Inspect datasheet of supply mains adapter	Has IEC 60601-1 certification		

XTC-75 Power Supply Connection (TC-123)

INSPECTION

Power supply cannot be incorrectly connected or replaced

1

2020/04/06

passed

Connections of Power outlet to battery and battery to device ar not interchangeable.

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-76 Protection of conductors (TC-57)

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.

1

Design schematics, prototype

Quality Control OperationAIR

2020/04/06

passed

All conductive parts are placed inside either one of the casings, or have a strain-relief

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect, try to damage mechanically	Conductor stays intact	passed	

XTC-77 Compatibility with standard hospital equipment (TC-39)

DEMONSTRATION

Show that connectors and components are compatible with standard equipment based on the relevant standards

1
Prototype
Quality Control OperationAIR
2020/04/06
passed
Airflow tubing connectors are compatible with the standard 22 mm tubing, as specified in EN-ISO-5361:2016 O2 and pressurized air input connectors are compatible with the standard male NIST connectors as specified in ISO 18082:2014

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect datasheets		passed	

XTC-78 Intuitive for use - training (TC-131)

Must not require more than 30minutes training for a doctor with some experience of ventilator use.
1
Documentation
Quality Control OperationAIR
2020/04/06
passed
Training materials indicate 20 minute training for users

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-79 Long-term reliabillity (TC-38)

TEST
Reliability test with 12 hours as initial investigation into the reliability of the device
Additionally:

- Measure temperature on several moments in time - Post-analysis: pplat and peep stay constant. moving average coefficient = 0
1
Prototype
Quality Control OperationAIR
2020/04/06
passed
Log 22:00 Start measurement 22:20 Temperature inside casing bottomplate 27.0, expiratory valve 50.1, Pi 47.2 22:59 stopped ventilation to add pulmotech pressure catheter to measurement setup 23:53 ambient: 28, Valve: 53, GUI/pie: 51 degrees Celsius 00:41 ambient 26.7, Valve 50.6, Pi 45,6 degrees. Ventilation parameters perfect 01:10 ambient: 29, Valve: 53, Pi: 51, variables are amazing 2:04 ambient 28, Valve 51, Pi 49 2:29 ambient 27.9, valve 51.4, Pi 47.5. Ventilation parameters ok, tidal volume deviation +- 50 ml 3:02 ambient 17.9 Valve 52.6 Pi 50.8 3:05 Deken er omheen (per ongeluk op stop knop gedrukt!!!!!! --> Moet eigenlijk niet kunnen natuurlijk) 3:16 Deken eraf Ambient 30, Valve 52, GUI 51 4:17 Ambient 28, Valve 53, GUI 52 5:00 Ambient 28, Valve 53, GUI 51 Vt deviation c. 50 cmH2O 5:36 Ambient 26.9, valve 50.2, Gui 49.3 6:32 Ambient 26.9, valve 50.2, Gui 48.9 8:21 Ambient 27.6, valve 49.3, gui 44.9 8:57 Ambient 28.0, valve 50.0, gui 49,6 9:42 Ambient 26.7, valve 49.6, gui 47.5 10:00 Stopped measurement **Data analysis** Two points where device stops ventilating, explained by manual stopping, see log. Trend in Peak pressure and PEEP over time is stable (directional coeficcient 1.00, R^2<1*10^-10 **Conclusion** Device functions as expected, no unexplained interruptions. Temperature of components did not exceed 53 degrees celsius.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Ventilate with PPLAT 35 cm H2O, PEEP 10 cm H2O, Freq 25/min, FiO2 21%, I:E 0.5			
3	Keep ventilating for at least 12 hours	Device stays active throughout the whole time	passed	
4	Measure internal temperature at 4 points in time			
5	Analyse temperature	Temperature inside casing does not exceed 60 degrees celsius	passed	

XTC-80 IFU: Maintanance (TC-44)

DEMONSTRATION
Show that the IFU states maintenance instructions

1

Version 1.3 of the IFU

Legal OperationAIR

2020/04/07

passed

Page 15 and 16 under section 8.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU		passed	

XTC-81 Specification of expected durability (TC-130)

Specify expected durability in documentation.

1

All documentations are tested (IFU, Technical manual), Onderzoeksprotocol, IMDD, RMF.

Legal OperationAIR

2020/04/07
passed with deviation
All documentation mention the intended use of a minimum of four weeks. All parts are more durable given correct usage. Because we cannot test durability, this is the most we can do.

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-82 Back up battery (TC-10)

TEST
Confirm that the UPS continues device functionality in case of power failure

1

Prototype

Quality Control OperationAIR

2020/04/07

passed

Device keeps functioning as expected without interruption when disconnected from mains power supply.
Ventilation parameters do not change.
Battery keeps device functional for 36 minutes 16 seconds

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI test lung			
2	Ventilate with PPLAT 35 cm H2O, PEEP 5 cm H2O, freq 30/min			
3	Read out Tidal volume and plateau pressure on test lung			
4	Cut off the main power supply	Device keeps ventilating	passed	
5	Read out tidal volume and plateau pressure on test lung	Values should stay within 1% deviation from values read out at step 3	passed	

6	Time untill battery fails	> 30 minutes	passed	

XTC-83 Pre-Set Controls (TC-125)

Risks associated with pre-set controls must be addressed in RIsk Management File

1

RMF of today (see date).

Legal OperationAIR

2020/04/07

passed

Documented in risk 39 and 40

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-84 Incorrect output (TC-98)

Risks associated with incorrect output must be addressed in risk management file.

1

RMF of today

Legal OperationAIR

2020/04/07

passed

Risks under folder H02

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-85 O2 and air input connectors (TC-20)

DEMONSTRATION

show the different inlets and show that the O2 cannot be connected to the air inlet and that air cannot be connected to the O2 inlet
1
Prototype
Quality Control OperationAIR
2020/04/07
passed
Connectors cannot be interchanged

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Attempt to connect O2 to air inlet	Will not connect	passed	
2	Attempt to connect air to the O2 inlet	will not connect	passed	

XTC-86 Oxygen alarm (TC-9)

TEST Confirm that an alarm is issued when oxygen levels are outside the acceptable range
1
Prototype
Quality Control OperationAIR
2020/04/07
passed
O2 alarm is issued as expected

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Connect 100% oxygen and air to device input			

3	Set minimum oxygen level to 60%			
4	Ventilate at PPLAT 35 cm H2O, PEEP 5 cm H2O, FiO2 80%			
5	Cut off oxygen input	Oxygen alarm is issued	passed	

XTC-87 Air pressure drop alarm (TC-155)

TEST
Show that an alarm is issued when input air pressure is insufficient

1

Prototype

Quality Control OperationAIR

2020/04/07

passed

Oxygen too high alarm is issued

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Ventilate with PPLAT 25, PEEP 10, Freq 15, FiO2 40%			
3	Set maximum oxygen to 50%			
4	Disconnect input air			
5	wait 20 seconds	An alarm is issued	passed	

XTC-88 Indication of parameters relevant to safety (TC-97)

Address the need for the indication of parameters that are associated with hazardous output in Risk Management Process (i.e. you want to know the air pressure, volume of air, oxygen content that is delivered to the patient)

1

Current RMF

Legal OperationAIR

2020/04/07
passed
Under folder H02

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-89 Usability (TC-94)
Risks of poor usability, including those associated with identification, marking and documents must be addressed in Usability engineering process results
1
Current RMC
Legal OperationAIR
2020/04/07
passed with deviation
This is elaborately tested over the entirety of the RMF. Still some changes can occur.

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-90 Accuracy of controls and instruments (TC-93)
Risks associated with accuracy of controls and instruments must be addressed in Risk management file
1
Current RMF
Legal OperationAIR
2020/04/07

passed
Described in folder H03

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-91 Push test (TC-61)

External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE.
After the test, any damage sustained that results in an unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE, constitutes a failure.

1

First prototype moulded encasing

Quality Control OperationAIR

2020/04/08

passed

Material is strong enough, no damage

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Apply force of 250 N ± 10 N for a period of 5 s, over a circular plane surface 30 mm in diameter on the enclosure (not to the bottom)	No damage seen at inspection after push test	passed	

XTC-92 Impact test (TC-62)

The medical device must withstand an impact of a solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, falling freely from 1,3 m height once onto each relevant part of the test sample or swinging like a pendulum, that drops through a vertical distance of 1,3 m, against vertical surfaces. The test is not applied to flat panel displays.

1

First prototype moulded encasing
Quality Control OperationAIR
2020/04/08
passed
No damage

Step	Action Result	Expected Result	Passed/Failed	Comment
1	a solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, falling freely from 1,3 m height once onto each relevant part of the test sample or swinging like a pendulum, that drops through a vertical distance of 1,3 m, against vertical surfaces. The test is not applied to flat panel displays.	No damage is sustained that results in uncceptable risk	passed	

XTC-93 Temperature of applied parts (TC-85)

Temperature of tube must be disclosed in Risk Management File when it exceeds 41 degrees Celsius or is below ambient temperature
1
Prototype
Quality Control OperationAIR
2020/04/08
passed
Temperature of air tube at patient side is 23.4 degrees celsius Ambient temperature 21.7 degrees celsius

Step	Action Result	Expected Result	Passed/Failed	Comment

1	Connect device to test lung			
2	Ventilate with PPLAT 10, PEEP 5, Freq 10			
3	Measure temperature of intubation tube using infrared thermometer	temperature is ambient temperature +- 2 degrees celcius	passed	
4				

XTC-94 Impariment of cooling (TC-99)

TEST
The medical device must remain safe during the failure of cooling systems, f.e. when ventilation openings are covered.

1

Prototype

Quality Control OperationAIR

2020/04/06

passed

Covered ventilation holes for 10 minutes.
Temperatures in housing: ambient 30, Valve 52, GUI 51

Step	Action Result	Expected Result	Passed/Failed	Comment
1	connect device to test lung			
2	Ventilate with PPLAT 25, PEEP 10, Freq 30			
3	Cover ventilation holes and wait 10 minutes			
4	Measure temperature inside casing	does not exceed 60 degrees celcius	passed	

XTC-96 Alarm settings (TC-157)

INSPECTION
Show that the alarm minimum and maximum settings can be set by the users

1

Prototype
Quality Control OperationAIR
2020/04/08
passed
Can be set by user

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-97 Alarms easy to understand (TC-119)

INSPECT

Making sure the alarms are made according to ISO 60601-1-8

1
Prototype
Quality Control OperationAIR
2020/04/08
passed
Passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect alarms with documentation	Alarms are according to 60601-1-8	passed	
2				
3				
4				

XTC-98 Splash proof (TC-3)

TEST

Confirm that the housing is able to protect the internal components from ingress of water

1
ABS housing prototype
Quality Control OperationAIR
2020/04/09
passed
Passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Setup device with test lung and default ventilation settings			
2	Drip water with 3 mm/min on device placed at 15 degree	Device stays fully functional	passed	
3	Repeat for angles at 4 directions	Device stays fully functional	passed	
4	Check if any water has breached the external casing	No water is inside the casing	passed	

XTC-99 Off switch protection (TC-21)
DEMONSTRATION Show that the off switch is positioned so that it is protected from accidental switching
1
Prototype
Quality Control OperationAIR
2020/04/09
passed
Off switch is located at power adapter box, relatively protected

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Find location of off switch, try to bump into it		passed	

XTC-100 Intentional exceeding of safety limits (TC-96)

Risks associated with hazardous output arising from the intentional exceeding of safety limits must be addressed in risk management file

1

Current RMF

Legal OperationAIR

2020/04/10

passed

Documented in Risk 75 H10.4

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-101 PEEP alarm (TC-8)

TEST
Confirm that an alarm is issued when the PEEP decreases beneath the set value

1

Quality Control OperationAIR

2020/04/13

passed

React < 1 sec

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI lung simulator			

2	Set minimum PEEP to 15 cm H2O			
3	Ventilate with PPLAT 35 cm H2O, PEEP 10 cm H2O			
4	Wait 10 seconds	a PEEP alarm is issued	passed	

XTC-102 Plateau pressure alarm II (TC-83)

TEST
Confirm that an alarm is issued when the plateau pressure is outside the acceptable range set by the user.

1

Quality Control OperationAIR

2020/04/13

passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Set maximum plateau pressure to 30 cm H2O			
3	Ventilate with PPLAT 35, PEEP 5 cm H2O, Freq 15/min, FiO2 21%	An alarm is issued indicating PPLAT is too high	passed	

XTC-103 Apnea/Disconnect alarm (TC-101)

TEST
Confirm that an alarm is issued in case of apnea or disconnection of tubes

1

Quality Control OperationAIR

2020/04/13

passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			

2	Ventilate with PPLAT 25, PEEP 5 cm h2O, Freq 15/min, I:E 0.5			
3	Block expiration tube			
4	wait 10 seconds	an alarm is issued	passed	
5	Unblock expiration tube	Alarm stops	passed	
6	Block inspiration tube			
7	wait 10 seconds	An alarm is issued	passed	
8	disconnect inspiration tube			
9	wait 10 seconds	An alarm is issued	passed	
10	reconnect inspiration tube	alarm stops	passed	
11	disconnect expiration tube			
12	wait 10 seconds	An alarm is issued	passed	

XTC-104 Battery Housing (TC-122)

INSPECTION
Address that battery housing has no ventilation and that the battery is medically certified in Risk Management File

1

Current RMF

Legal OperationAIR

2020/04/13

passed

Documented in Risk-76, H01.4

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-105 Arrangements of controls and indicators (TC-59)

the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT.

1
Current RMF
Legal OperationAIR
2020/04/13
passed
Is documented in the Risks under folder H02,H03, H06 and H09

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect risk management file	is present	passed	

XTC-106 Fail-safe valve (TC-67)

TEST

Confirm that the fail-safe valve opens and releases pressure when pressure exceeds 70 cm H2O

2
Prototype, fail-safe placed at the expiratory module side
Quality Control OperationAIR
2020/04/10
passed
Pressure peaks at 96 cm H2O, and then decreases and settles at 70 after 2 seconds

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Attach test lung to device			
2	Attach pressure sensor to the system at the side of the test lung			
3	open expiratory valve			

4	Open inspiratory valve to put 600 mbar on system			
5	Read out pressure sensor	Does not exceed 100 mbar on peak pressure, and settles at 70 mbar	passed	

XTC-107 GUI is clearly visible with protective eyewear (TC-158)

To test whether the GUI is clearly visible, the subject has to change settings using protective eyewear, normally used on ICUs. These are usually made from PET.

1

AIRone Version1.1

QA OperationAIR

2020/04/17

passed

The GUI is clear to read with eyewear. There is no difficulty experienced in adjusting settings or interpreting measurements using eyewear or without.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put on protective eyewear		passed	
2	Turn on device		passed	
3	Adjust settings:		passed	
4	- PEEP		passed	
5	- Plateau Pressure		passed	
6	Interpret measurements	Everything is clear and easy to read	passed	

XTC-108 INSPECT: Information about fire hazard on the label (TC-166)

INSPECT:
Inspect the sticker

1

The first version of the sticker

Legal OperationAIR

2020/04/20
passed
Fire symbol is present

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect sticker for firesymbol	Fire is forbidden symbol is present	passed	

XTC-109 Pressure setting (TC-168)

DEMONSTRATION
Show that the pressure above PEEP can be set by the user between 5 and 40 in intervals of 1 cm H2O

1
Prototype
Quality Control OperationAIR
2020/04/23
passed
Pressure setting as relative pressure above PEEP, can be set between 5 and 40, interval is 1

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-110 Usability test (TC-65)

This Test Case is meant to test whether a potential user can easily comprehend the functionalities (GUI, inputs and outputs) of the device. The goal is to test if the device is intuitive and to see if untrained personnel can safely use the device.
This test uses the test protocol 'Protocol (pre-)klinische tests RMVS' developed by Peter Somhorst

1
Prototype

Quality Control OperationAIR

2020/04/10

documentation

See notes pre-clinical test 10-04-2020

Step	Action Result	Expected Result	Passed/Failed	Comment
1				

XTC-111 Expiratory Hold (TC-170)

DEMONSTRATION

Show that the device can perform an expiratory hold

1

prototype

Quality Control OperationAIR

2020/04/24

passed

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-112 HEPA filter (TC-171)

INSPECTION

Show that a HEPA filter can be equipped

1

Prototype

Quality Control OperationAIR

2020/04/24

passed

Expiratory module has a 22 mm connector which can be connected to a standard HEPA filter

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect design drawings			

XTC-113 Clear explanation per alarm (TC-17)

DEMONSTRATION

When an alarm is issued, the user interface indicates what alarm is issued

1

Prototype

Quality Control OperationAIR

2020/04/24

passed

When an alarm is issued, the parameter outside of its limits is shown in red. Additionally, all previous alarms are displayed in the alarm overview untill acknowledged by the user

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect user interface while device issues an alarm		passed	

XTC-114 Airflow materials (TC-159)

INSPECTION

Show that all parts which have inspiratory air flowing through them are biocompatible and oxygen compatible

1

Documentation

Quality Control OperationAIR

2020/04/24

passed
Inspected Technical Manual. Most materials are proven biocompatible, and when not proven a rationale is provided

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect Technical Manual	Each part which has inspiratory air flowing through it has a description of biocompatibility and oxygen compatibility	passed	

XTC-115 Cleaning and disinfection (TC-127)

TEST
Confirm that the device can withstand regular cleaning and disinfection with alcohol 70%

1

Final design casing and labeling

Quality Control OperationAIR

2020/04/24

passed

No deterioration seen in casing material or labeling

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Subject device to 14 cleaning cycles with alcohol 70%, wait until alcohol dries inbetween cycles. Make sure to clean the labels and touchscreen as well	Device is not affected by cleaning cycles. Labels do not degrade	passed	

XTC-116 Pressure Hold (TC-91)

TEST
Confirm that the device does not leak oxygen by keeping the airflow system pressurized for an extended period of time

2
Prototype
Quality Control OperationAIR
2020/04/24
failed
Pressure loss too large

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Block the expiration tube			
3	Pressurize the tubes to 70 cm H2O			
4	Hold pressure for 2 minutes and continuously read out the internal pressure sensor			
5	Analyse pressure loss over time	Pressure loss in 2 minutes is smaller than 10 cm H2O	failed	
6				

XTC-117 Sharp edges (TC-48)
TEST Confirm that the device has no sharp edges
1
Final housing
Quality Control OperationAIR
2020/04/24
passed
Passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put on protective glove on one hand			
2	Trace hand with glove along all edges of the device	Glove does not tear	passed	
3				

XTC-118 Tipping test II (TC-110)

TEST

Show that the device is able to withstand unintended forces without tipping over.

1

Prototype

Quality Control OperationAIR

2020/04/24

passed with deviation

Does not fall over. With force applied from some directions, the device does displace more than 50 mm, because it only has brakes on the two front wheels

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put device on horizontal plane			
2	Put device on brakes			
3	Apply a force of 25% of the weight of the device parallel to the horizontal at 1.5m height	Device does not fall over; Does not displace more than 50 mm	passed	

XTC-119 Usability with protective equipment (TC-41)

TEST

Confirm that the user interface touchscreen works when the user wears protective gloves and can easily be seen when wearing protective eyewear.

2

Prototype

Quality Control OperationAIR

2020/04/24
passed
Touchscreen works also when wearing gloves, and can be seen while wearing protective eyewear

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Put on two layers of protective gloves			
2	Put on protective glasses			
3	Adjust several settings on the user interface	Touchscreen responds to touching	passed	

XTC-120 Internal components tightly attached (TC-4)

TEST
Confirm the device can withstand basic movements expected during transport and all components stay attached

1

Prototype

Quality Control OperationAIR

2020/04/24

passed with deviation

Removed device from frame to make shaking easier

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Shake device manually for 1 minute			
2	Remove housing			
3	Look & Feel all internal components	Everything is attached/ doesn't move	passed	

XTC-121 Visiblility of label (TC-160)

DEMONSTRATION
Show that the label can be seen and read while standing next to the device at 1 m distance

1
Final housing and labeling
Quality Control OperationAIR
2020/04/24
passed
Label is placed at the back of the device. Can be seen when device is turned around

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-132 Installation Verification (TC-174)

INSPECTION
Inspect whether the necessary tests are incorporated in the Installation-Verification protocol of the AIRone.

1
Approved 1 of the IV-INT.AIRone
Legal OperationAIR
2020/04/24
passed
All tests are present.

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect the Installation-Verification protocol if the following tests are present:			
2	Serial numbers of components have to be registered	Is present	passed	IV-INT.AIRone4
3	The power supply has to be inspected	Is present	passed	IV-INT.AIRone5
4	The device has to be inspected visually	Is present	passed	IV-INT.AIRone6

5	Pressure sensors have to be inspected	Is present	passed	IV-INT.AIRone7
6	The device has to be turned on and off and power down has to be inspected	Is present	passed	IV-INT.AIRone8
7	Electrical safety has to be inspected	Is present	passed	IV-INT.AIRone9
8	Sensors, valves and output have to be tested	Is present	passed	IV-INT.AIRone10
9	Gas system integrity has to be tested.	Is present	passed	IV-INT.AIRone11

XTC-122 Electromagnetic compatibility (TC-58)

Risks associates with

- electromagnetic phenomena existing at the locations where the ME EQUIPMENT or ME SYSTEM is intended to be used
- the introduction by the ME EQUIPMENT or ME SYSTEM of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems

must be addressed in Risk Management Process

1

Documentation

Quality Control OperationAIR

2020/04/24

passed

Documented in risks 80 and 81

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect Risk Management file		passed	

XTC-123 Ventilator (TC-172)

INSPECTION

Show that the device has a ventilator that can displace potential leaking oxygen to outside the encasing

1

Prototype

Quality Control OperationAIR
2020/04/24
passed
Device has a ventilator in the bottomplate

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-124 Tidal volume alarm I (TC-7)

Confirm that an alarm is issued when tidal volume is outside acceptable range
1
Prototype
Quality Control OperationAIR
2020/04/24
passed
Tidal volume too low alarm is issued

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI lung simulator			
2	Set minimum tidal volume to 300 mL			
3	ventilate with Ppeak 15 cm H2O, PEEP 5 cm H2O			
4	Wait 10 seconds	A tidal volume alarm is provided	passed	

XTC-125 Tidal volume alarm II (TC-68)

Confirm that an alarm is given when tidal volume is outside acceptable range
1

Prototype
Quality Control OperationAIR
2020/04/24
passed
Tidal volume too high alarm is issued

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to MI lung simulator			
2	Set lung compliance to 0.03			
3	Set maximum tidal volume to 300 mL			
4	ventilate with Ppeak 30 cm H2O, PEEP 5 cm H2O			
5	Wait 10 seconds	A tidal volume alarm is provided	passed	

XTC-126 HEPA filter warning sticker (TC-173)

INSPECTION
Show that the device has a warning sticker above the expiratory air connector to not forget to connect a HEPA filter

1
Final housing and labeling
Quality Control OperationAIR
2020/04/24
passed
Passed

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-127 IFU packed with device (TC-162)

DEMONSTRATION

Show that the IFU is available for download online, and show packaging list includes a printed IFU

1

Documentation

Quality Control OperationAIR

2020/04/24

passed

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-128 Back-up battery empty alarm (TC-84)

TEST

Confirm that an alarm is issued when the back-up battery is almost empty

1

Prototype

Quality Control OperationAIR

2020/04/24

failed

Alarm is directly issued when mains power is disconnected. Battery percentage shown is 0%, while battery is fullly charged

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Disconnect power supply mains			
3	Ventilate with Ppeak 60, PEEP 5 cm H2O, Freq 30/min, FiO2 21%			

4	Keep ventilating until battery almost runs out	An alarm is issued	failed	

XTC-129 Back up battery warning (TC-69)

Confirm that the device indicates when it is running on the back-up battery power source

1

Prototype

Quality Control OperationAIR

2020/04/24

failed

Device immediately alarms for empty battery, while battery is fully charged

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Connect device to test lung			
2	Ventilate with Ppeak 20 cm H20, PEEP 10 cm H2O			
3	Cut off mains power supply	Device displays a warning that it is running on battery power supply	failed	

XTC-130 Measurement Reliability (TC-106)

TEST
Confirm that the same ventilation settings at different times lead to the same output

1

Prototype

Quality Control OperationAIR

2020/04/24

passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Alternate the following settings: ventilate with Ppeak 25 cm H2O, PEEP 5 cm H2O, Freq 20, I:E 0.5, FiO2 21% at least 10 times with different settings throughout the testing period.	The set variables result in values that change maximally 5%	passed	

XTC-131 Flow Sensor (TC-169)

DEMONSTRATION

Show that all conductive components near the flow sensor are grounded to the bottomplate

1

Documentation

Quality Control OperationAIR

2020/04/24

passed

Most components near the flowsensor are non-conductive. The conductive components are grounded

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-133 Open Source (TC-175)

Documentations are Open source available via https://osf.io/mn7xq/

1

Legal OperationAIR

2020/04/24

passed

Documentations are Open source available via https://osf.io/mn7xq/

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-134 Fail safe valve test during production (TC-111)

INSPECTION
Show that the Production Documentation mention testing each fail safe valve

1

Documentation

Quality Control OperationAIR

2020/04/28

passed

Stated in IV.Z8113020xx A4

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect production documentation		passed	

XTC-135 IFU: regulatory requirements (TC-165)

The instructions must contain:

- the name of the device;
- the manufacturer of the device;
- the adress of the manufacturer;
- Indications and contra-indications,
- intended use and intended user;
- the clinical benefit for the patient;
- the performance characteristics;
- the degree of accuracy for the parameters of the device;
- how to verify if the right accessories are used;
- undesirable side-effects;
- preperation of the device before use;
- that users must receive a training before using the device;
- information on maintenance and cleaning of the device and accessories;
- information on cleaning and disinfection between the use on different patients;
- all the warnings that will lead to malfunction of the device and/or changes in the working of the device that will lead to risks to the patient. This will include enviromental changes, like diagnostic or therapeutic procedures;

- how the device can safely be disposed;
- publication or printing date with version number;
- that SAE's must be meantioned to the manufacturer;
- how to safely use the software on the device.

1

IFU v1.5

Quality Control OperationAIR

2020/04/29

passed with deviation

All requirements are filled. SAE's are not mentioned as such, but the instruction to contact the manufacturer in case of problems is.

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-136 IFU Review (TC-43)

DEMONSTRATION
Show that the IFU has been checked by experts

1

IFU v 1.5

Quality Control OperationAIR

2020/04/29

passed

Usability approval
QC approval

Step	Action Result	Expected Result	Passed/Failed	Comment
1				
2				
3				

XTC-137 Label: regulatory requirements (TC-164)

The label must contain:

- the device name;
- a serial number;
- the manufacturer with address;
- the manufacturing date, as part of the serial number or seperatly;
- immediate warnings with icons.

All will be written in text or official icons.

1

Label

Quality Control OperationAIR

2020/04/28

passed

Passed

Step	Action Result	Expected Result	Passed/Failed	Comment

XTC-138 Vocabulary and Semantics (TC-71)

INSPECTION

Confirm that the nomenclature, definitions, vocabulary and semantics used in all user communication correspond with BS ISO 19223:2019

1

Documentation IFU 1.5, final label

Quality Control OperationAIR

2020/04/29
passed
Passed

Step	Action Result	Expected Result	Passed/Failed	Comment
1	Inspect IFU, GUI and training materials		passed	