Risk Analysis (Top/Down)
- AAU AAU Pandemic Ventilator

Revision History			
Rev	**ECO**	**Changes**	**Author**
1	N/A	Initial release	

Table of Contents

1 Purpose/Scope

The purpose of the present document is to perform the top down risk analysis for the AAU Pandemic Ventilator .

2 References

Ref 1. EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
Ref 2. VENT-10-002-DOC Technical Requirements

3 Terms

PO	the probability of occurrence of harm
SEV	the consequences of that harm, that is, how severe it might be

Harm	physical injury or damage to health of people, or damage to property or the environment
Hazard	potential source of harm
Hazardous situation	circumstance in which people, property or the environment are exposed to one or more hazard(s)
Residual risk	risk remaining after risk control measures have been taken
Risk	combination of the probability of occurrence of harm and the severity of that harm

4 Ratings

The following subsection describes the ratings used in the present analysis and establish the criteria for acceptable residual risk. However, as described above the risk should always be reduced as far as possible even though the risk is acceptable.

Degree of severity - SEV		**Probability of occurrence - PO**	
Negligible - Inconvenience or temporary discomfort	**S1**	**Improbable** – Likely never to occur	**O1**
Minor - Results in temporary injury or impairment not requiring professional medical intervention	**S2**	**Remote** – Will only occur in rare cases	**O2**
Serious - Results in injury or impairment requiring professional medical intervention	**S3**	**Occasionally** - will occur with some devices	**O3**
Critical - Results in permanent impairment or life-threatening injury	**S4**	**Probable** - with most devices	**O4**
Catastrophic - Results in patient death	**S5**	**Frequent** - with every use	**O5**

Table 1: Qualitative severity levels and semi-quantitative probability levels – Top Down

		Degree of severity - SEV				
		Negligible S1	**Minor S2**	**Serious S3**	**Critical S4**	**Catastrophic S5**
Probability of occurrence - PO	**Frequent O5**					
	Probable O4					
	Occasionally O3					
	Remote O2					
	Improbable O1					

Unacceptable risk

Acceptable risk

Table 2: Risk evaluation matrix – Top Down

Risk control option analysis is performed for each risk.

5 Risk control option analysis (RCA)

The Risk Control Options are to be treated as follows:

A Inherit by design

If the design removes the risk completely or if a standard provides an explicit specification/verification and is followed the PO can be set to N/A and risk listed as “acceptable”.
If the design partly removes or changes the Hazard or Harm the Severity and/or PO can be lowered.

B Protective measures in the MD itself or in the manufacturing process
For this RCM only the PO can be lowered.

C Information for safety
The PO or Severity cannot be lowered by Information for safety.

6 Harms

The Harms and their severity depicted below shall be followed.

Harms	Harm	Severity	Comments
Therapy related	Death (Suffocation)	S5	
	Minor discomfort (no damage)	S1	
	Pain	S1	
	Muscle fatigue	S1	
	Tissue damage (e.g. alveoli barotrauma)	S4	
Electrical injury	Tissue damage (Leakage current)	S3	
	2nd Degree burn (Line voltage)	S3	
	Heart Defibrillation (Line Voltage)	S4	
	Death (Line voltage)	S5	
Skin reaction (chemical)	Toxicological response	S3	
	Sensitization response	S2	
	Irritation response	S1	
Skin reaction (other)	Infection	S3	
	Non critical component damage	S2	

Product damage	Critical component damage	S4	
Environmental	Minor environmental affect	NA	
	Major environmental affect	NA	

Table 3: Identified harms

7 Risk analysis structure

The risk analysis is performed using the life-cycle of the AAU Pandemic Ventilator, deviced into the following structure of categories:

1. Design of the AAU Pandemic Ventilator
    a. Ensuring electrical design
    b. Ensuring mechanical design
2. Use of the AAU Pandemic Ventilator in crisis situations
    a. Risk to health care professionals and/or patients
    b. Combination with other devices
3. End of life
    a. Disposal of parts and consumables
    b. Wear our of parts
4. Foreseeable misuse (Foreseeable misuse is divided into two categories as stated in the Usability Standard (EN 62366).)
    a. Worst case use scenarios
    b. Reasonably foreseeable use scenarios

8 Risk analysis

8.1 Explanation of risk analysis tables

The risk analyses are organized in the following table format:

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

1. ID: Unique identifier of this risk analysis item. Format is RA.#z-##, where #z is the category (#) and sub-category (z) as described in section **Error! R eference source not found.** and ## is a consecutive number within each sub-category.
2. Hazard: Potential source of harm. For possible hazards see table E.1 in EN 14971.
3. Reasonably foreseeable sequence or combination of events possibly leading to the hazardous situation.
4. Hazardous situation: Circumstance in which people, property or the environment are exposed to one or more hazard(s)
5. Harm: Physical injury or damage to health of people, or damage to property or the environment. See **Error! Reference source not found.** for possible h arms.
6. PO: Probability of occurrence of harm before risk control according to Risk evaluation and acceptance.
7. SEV: Severity of harm before risk control according to Risk evaluation and acceptance.
8. Acc: Acceptability of risk (yes/no) before risk control according to risk evaluation as defined in Risk evaluation and acceptance.
9. Risk Control Option Analysis.
10. RCM Implementation: Risk mitigation strategy to reduce the risk to a lower level.
11. Technical requirement: Reference to the technical requirement that implements the risk control measure.
12. Risk control verification: Reference to the verification specification where verification of the RCM implementing requirement is described.
13. PO: Probability of occurrence of harm after risk control REF _Ref415056074 \r \h
14. SEV: Severity of harm after risk control.
15. Acc: Acceptability of risk (yes/no) after risk control.

9 Design of the AAU Pandemic Ventilator

9.1 Ensuring electrical design

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
RA.10-01	suffocation	1) a power supply break down occur 2) the electrical cord is pulled out 3) This would cause the ventilator to stop working	The patient would no longer receive the critical ventilation	Death	O3	S5	No	A B B	Internal battery is installed Alarm if electrical cord is pulled Alarm if battery is discharged	TR-03-002 TR-06-002 TR-06-009				
RA.10-02	Suffocation	1) the on/off button is unintendedly pressed 2) the ventilator will stop working	The patient would no longer receive the critical ventilation	Death	O3	S5	No	A	Alarm screen appear to verify shut down	TR-06-010		O2	S5	NO

9.2 Ensuring mechanical design

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
RA.11-01	Fire	1) 100% oxygen is delivered 2) a spark occur from electrical equipment	This could potentially cause a fire in the system	Skin burns or death	O2	S4, S5	No	A	All components in the inspiratory circuit are O2 and fire safe	TR-04-005		O1	S4, S5	Yes
RA.11-02	Lung barotrauma	1) A pressure controlling software or hardware error occur 2) Wall pressure (>1bar) is introduced to the patient	This would cause irreparable lung damage	Death	O2	S5	No	A	Pressure reduction valves are attached in the inspiratory inlet	TR-04-006		O1	S5	Yes
RA.11-03	Lung barotrauma	1) A pressure controlling software or hardware error occur after reduction valves	This could cause lung overtension and potentially moderate barotrauma in aveoli of the patient	Moderate reduction of lung function	O2	S4	No	B	An over pressure listener is coded in the software, so if inspiratory circuit pressure reaches 40cmH2O, the inspiratory	TR-04-007	.	O1	S4	Yes

		2) >40cmH2O pressure is introduced in the patient							valve closes and expiratory valve opens					
RA.11-04	Lung barortauma	1) A pressure controlling software or hardware error occur 2) TR-04-007 solution does not work 2) dangerous (>80cmH2O) pressure is introduced in the patient	This could cause lung overtension and thus irreparable barotrauma in the aveoli of the patient	Severe reduction of lung function or death	O2	S4, S5	No	A	Individually tested and certified mechanical safety release valves are inserted in the inspiratory circuit	TR-04-008		O1	S4,S5	Yes
RA.11-05	suffocation	1) The ventilator is dropped on the floor 2) The ventilator stop working	The patient would no longer receive the critical ventilation	death	O3	S5	No		All components are secured inside the metal cabinet	TR-04-009				
RA.11-06	Oxygen intoxication	The pressurized air and O2 hose is interchanged	If low O2 is required, but high O2 delivered there is risk of O2 intoxication	Death	O3	S5	No	C	Inform technical departments that connectors should follow standards and cannot be connected to wrong supply line	TR-07-006		O3	S5	No
RA.11-07	suffocation	Air or O2 supply stops	If air/O2 supply is empty, the patient cannot receive required ventilation	Death	O2	S5	No	B	Alarm will sound and warning displayed on screen	TR-06-001		O2	S5	No

10 Use of the AAU Pandemic Ventilator in crisis situations

10.1 Risk to health care professionals and/or patients

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc

RA.20-01	Suffocation	1) Patient breath by him/herself. 2) Patient/ventilator asynchrony.	Patient does not receive enough air. Patient uses more forces and requires more air, stress, heart failure.	Death	O4	S5	No	A	Add a warning that the patient should be further sedated.	TR-07-001				
RA.20-02	contamination	1) Droplets from contaminated expiratory gas come into contact with the inspiratory side of the ventilator 2) The ventilator is subsequently used on another patient suffering from a different disease	Patient 2 and health care staff risks infection	Infection potentially death	O3	S3	No	B B	The expiratory exit port is located in the opposite side of the inspiratory inlet side, so that the risk of contamination from expiratory gasses are moved away from the "low" pressure side and the direction pointing towards the doctor Proper inter-patient cleaning is specified in the user manual	TR-04-010 TR-07-005		O2	S3	yes
RA.20-03	contamination	1) Droplets from contaminated expiratory gas come into contact with the inspiratory side of the ventilator 2) The ventilator is subsequently used on another patient suffering from a different disease	Patient 2 and health care staff risks infection	Infection potentially death	O3	S3	No	B	Before the expiratory gas enters the ventilator, it will pass through a water trap that will catch most of the water, saliva etc from the patient	TR-04-011		O2	S3	Yes
RA.20-04	contamination	1) Droplets from contaminated expiratory gas come into contact with the inspiratory side of the ventilator 2) The ventilator is subsequently used on another patient suffering from a different disease	Patient 2 and health care staff risks infection	Infection potentially death	O3	S3	No	B	Before the inspiratory gas exits the ventilator, it will pass through a disposable antibacterial filter	TR-04-012		O2	S3	Yes
RA.20-05	Patient harm	1) patient receives lower tidal volume and/or respiratory rate than set on the ventilator	Insufficient minute ventilation	Patient hypoxemia and hypercapnia, potential death	O3	S5	No	B	Measurement of tidal volume and respiratory rate and calculation of minute ventilation for user to detect mismatch	TR-06-011				

									between set and delivered.					
RA.20-06	Patient harm	1) patient receives higher tidal volume than set on the ventilator	Dangerous tidal volume	Lung injury (volutrauma)	O3	S4	No	B	Measurement of tidal volume for user to detect mismatch between set and delivered	TR-06-011				
RA.20-07	Patient harm	1) patient receives different PEEP than intended by clinician	Too low: Patient's lungs empty more with risk of collapsing lung units Too high: patient exposed to higher than intended airway pressures	Too low: lung trauma (atelectrauma), hypoxemia due to lung collapse Too high: lung injruy (barotrauma)	O3	S4	No	B	Measurement of PEEP for user to read the level of PEEP patient is subjected to. Measurement of peak and plateau airway pressure for user to check risk of lung injury due to high pressure.	TR-06-012				
RA.20-08	Patient harm	Components malfunction or gas leakage occur	Insufficient minute ventilation	Patient hypoxemia and hypercapnia, potential death	O2	S5	No	A	A pre use check validating supply and function is specified in Instructions for use	TR-06-019 TR-07-007				

10.2 Combination with other devices

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
RA.21-01	Interfering or disturbing frequency emission	1) the ventilator emits high frequencies	other critical devices malfunction due to this emission	Death	O3	S5	No	B	The ventilator is built from electrical parts that follow the EMC standard. The ventilator is located in a metal box (faraday principle)	TR-02-003 TR-02-004				

11 End of life

11.1 Disposal of parts and consumerables

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
RA.30-01	contaminatio n	1) Shortage of filters/hoses occur	Single use items are contaminated and reused	infection	O2	S3	Yes	c	It is specified in the manual that items in direct contact with the patient are single use	TR-07-002		O2	S3	Yes

11.2 Wear out of parts

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control Option Analysis	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc
RA.31-01	Suffocation	1) the ventilator runs for more than the required 14 days 2) some parts malfunction due to wear and tear	The patient will be under ventilated or not ventilated	Oxygen deprivation or death	O2	S5	No	A b	All mechanical parts have a guaranteed life cycle past 14 days operation Pre use check will detect malfunction of parts before ventilation is started	TR-02-005 TR-06-019				

12 Foreseeable misuse

12.1 Worst case use scenarios

ID	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	PO	SEV	Acc	Risk Control	Risk Control Measure (RCM)	RCM Implementation	Risk control verification	PO	SEV	Acc

								Option Analysis					
RA.40-01	Patient harm	1) pediatric appliance	The ventilator is connected to a child and can cause barotrauma	Severe reduction of lung function or death	O3	S5	No	B	Label/Sticker: “for adult patients only” Add warning to manual	TR-07-003 TR-07-004	Test case			

12.2 Reasonably foreseeable use scenarios

ID	**Hazard**	**Reasonably foreseeable sequence or combination of events**	**Hazardous situation**	**Harm**	**PO**	**SEV**	**Acc**	**Risk Control Option Analysis**	**Risk Control Measure (RCM)**	**RCM Implementation**	**Risk control verification**	**PO**	**SEV**	**Acc**
RA.41-01	Use error	1) User accidentally selects to Stop ventilator support while patient is on ventilator 2) Ventilator stops ventilating patient	Patient is unable to breath on his/her own and receives no ventilator support	Patient apnea, hypoxemia and death	O3	S5	No	B	Pop-up screen informs user of action and its consequence. User confirmation by clicking another button is required for stop to be performed	TR-06-013				
RA.41-02	Use error	1) User want to change one setting but accidentally modifies another 2) setting is changed by one or more levels	Patient receives too much or too little ventilator support, by normal clinical magnitude of changes	Hypoxemia, hypercapnia and/or lung injury	O3	S4	No	B	- Status icon indicates which setting is selected and modifiable. Dark grey: not selected, light green: selected. - Only one setting can be selected at a time - Change of settings only takes effect after short period allowing user to realize and correct error before taking effect	TR-06-014 TR-06-015 TR-06-016				

RA.41-03	Use error	1) User in middle of modifying extra setting or reviewing alarms or measurements when change of FiO2, Vt, RR or I:E is critical 2) Critical change in setting is delayed	Short period of too little or too high ventilator support	Patient recovery delayed and state worsened	O3	S3	No	B	It is always possible to access FiO2, Vt, RR and I:E directly by clicking F1 analog button, regardless of which screen is being accessed/reviewed in the rest of the HMI	TR-06-017				
RA.41-04	Use error	1) User modification of ventilator settings results in dangerous airway pressures 2) User does not detect resulting measured high pressure	Patient subjected to dangerous levels of pressure	Barotrauma	O3	S4	No	B	- Software controlled pressure release valve is activated at a threshold level to safeguard against dangerous pressures. - This threshold can be set by the user according to the state of the current patient. - Airway pressure high alarm shown on user interface.	TR-04-013 TR-06-018 TR-06-004				

13 Residual risk evaluation

Preliminary risk evaluation:

The following ID’s have not been risk mitigated to acceptable levels:

RA.11-06

RA.11-07

Under the circumstances that the ventilator is only used in deeply sedated patients with severe ARDS, and that no other CE marked ventilators are available, we find it ethically sound to use the system despite this unacceptable requirement. In the case that the ventilator would not be used in aforementioned cases – the patient would die.

The following ID's have not been tested:

RA.10-01

RA.11-05

RA.20-01

RA.20-05

RA.20-06

RA.20-07

RA.21-01

RA.31-01

RA.40-01

RA.41-01

RA.41-02

RA.41-03

RA.41-04

Consequently, residual risk cannot be assessed with satisfactory quality. All tests are designed and will be carried out shortly after this first submission. If the ventilator do not comply, additional features will be implemented.