TRAILS

Configurability

The ability of the system to be configured to perform a task or reconfigured to perform different tasks. This may range from the ability to re-program the system to be able to alter the physical structure of the system (e.g. by changing a tool).

Level	Achieved?	Scenario
Static Configuration	Satisfied	Software configuration: the user cannot change language, units of measurement, and default values of ventilation parameters and alarms. Mechatronic configuration: the user cannot change the plug and voltage because they are configured by the manufacturer.
Start-up Configuration	Satisfied	Software configuration: the user can change ventilation parameters and alarm thresholds before ventilation starts. Mechatronic configuration: the user can change the ventilation mask, PEEP, and set the fraction of inspired oxygen using the gas blender.
User Run-time Configuration	Satisfied	Software configuration: if the user changes the operation mode from PSV to PCV, PCV ventilation parameters can be changed; the user can update alarm thresholds during ventilation. Mechatronic configuration: the user can change the fraction of inspired oxygen using the gas blender
Run-time Self Configuration	Satisfied	Software configuration: the ventilator changes from PSV to PCV in presence of apnea, which occurs when a patient does not take a new breath within the allowable apnea lag time. Mechatronic configuration: the power supply changes from ADC to the backup battery
Autonomous Configuration	Improvable (low effort)	Software/Mechatronic configuration: if a pressure sensor fails, the ventilator is capable of autoconfiguring.

Adaptability

The ability of the system to adapt itself different work scenarios, different environments, and conditions (may also include the patient). Adaptation may take place over long or short time scales.

Level	Achieved?	Scenario
No adaptation	Not applicable	MVM changes its ventilation mode in response to the patient's breath.
Recognition of the need for adaptation	Satisfied	MVM raises alarms (e.g. tube obstruction, high inspired volume, oxygen level too high) but it does not know how to correct them.
Adaptation of individual components/parameters/tasks	Improvable (low effort)	In ASV (Adaptive Support Ventilation) mode the MVM alters pressure and respiratory rate to guarantee the computed target volume leading to the minimum WOB (Work Of Breath).
Process chain adaptation / Multiple parameters adaptation	Improvable (high effort)	Parameters ventilation are automatically computed based on a stochastic model of the patient.
Communicated component/parameter adaptation	Unable	Unable: MVM is a single agent device.

Dependability

The ability of the system to perform its given task(s) without systematic errors. Dependability specifies the level of trust that can be placed on the system to perform.

Level	Achieved?	Scenario
No dependability	Not applicable	-
Mean failure dependability	Not applicable	-
Fails Safe	Satisfied	The MVM is set in fail-safe mode (ventilation is interrupted, input valve is closed and output valve is open) if a severe condition is detected (e.g. the pressure measured in the entrance to the patient's airway is above the threshold PAW max)
Failure Recovery	Improvable (low effort)	The ventilator resumes ventilation using the last set of configuration parameters when an alarm that brings out MVM in fail-safe mode is resolved.
Graceful Degradation	Improvable (low effort)	If MVM is using the backup battery, especially when the level of the battery is low, MVM saves energy gracefully by shutting down some functions (e.g., by reducing display brightness, reducing the

		monitoring frequency of some sensors, etc.).
Task dependability	Improvable (low effort)	During the ventilation, the system can constantly measure leaks (e.g., at the level of the patient's mask or of the breathing circuit) and compensate them to avoid future errors/alarms.
Mission dependability	Improvable (high effort)	The MVM may be endowed with a remote control dashboard so operators can monitor failure conditions instantaneously and actuate real-time adjustments to the ventilation process. For example, a low level of oxygen concentration is revealed through the dashboard, so the operator decreases the value of inspiratory pressure.
Predictive dependability	Improvable (high effort)	By registering the system's failures and the related patient's state over time, specific situations could be predicted, for example, that he or she is about to go apnea. So the MVM or its remote control dashboard can be equipped with a predictive model to forecast severe situations and eventually prescribes/plans adjustments proactively.

Autonomy

The ability of the system to act autonomously. Nearly all systems have a degree of autonomy. It ranges from a simple autonomous task (e.g., when it reacts to sensors reading) to the ability to be self-sufficient in a complex environment.

Level	Achieved?	Scenario
No autonomy	Not applicable	-
Basic action	Not applicable	-
Basic decisional autonomy	Not applicable	-
Continuous basic decisional autonomy	Satisfied	d MVM continuously monitors the patient's breath to decide the pressure to be applied by the input valve and the status of the output valve.
Simple autonomy without environment model	Satisfied	MVM continuously monitors the patient's breath to decide to change ventilation mode and set backup parameters when it changes from PSV to PCV in case of apnea.
Simple autonomy with environment model	Improvable (low effort)	MVM implements an Adaptive Support Ventilation (ASV), already used by several ventilators. In ASV, MVM estimates the resistance and compliance of the patient by using a mathematical model of him and decides at every breathe the inspiratory pressure and the respiratory rate following the Otis curve.
Task autonomy	Improvable (high effort)	When ventilating a patient, to provide the necessary oxygen (higher-level task), the MVM uses the oxygen from the air line of the hospital but it can be supplied by an oxygen concentrator too. When an external unpredictable event reduces the oxygen concentration of the mainline, MVM uses the oxygen concentrator to continue ventilation.
Constrained task autonomy	Improvable (high effort)	As above, but in this case, MVM takes into account also the maximum quantity of oxygen the concentrator can provide before switching to it.
Multiple task autonomy	Unable	-
Dynamic autonomy	Unable	-
Mission oriented autonomy	Unable	-
Distributed autonomy	Unable	-

Interaction

The ability of a system to interact physically, cognitively and socially either with users, operators or other systems around it. The ability to interact may be as simple as the use of a communication protocol, or as advanced as holding an interactive conversation in a social context. The ability to interact is critical to many areas of application. Interaction depends on both the medium of interaction and on the context and flow of the interaction. The ability to interact takes place in three distinct ways physical interaction, cognitive interaction and social interaction. The description of the levels of Interaction Ability include these three types of interaction.

Human-System Interaction

Level	Achieved?	Scenario
No interaction	Not applicable	-
Direct control	Not applicable	-
Direct physical interaction	Satisfied	The physician can control the ventilation through the GUI. E.g. he or she can start the ventilation and set ventilation parameters.
Task selection	Satisfied	MVM can execute several tasks in order (from self-test to ventilation).
Traded autonomy	Satisfied	During ventilation (both in PCV and PSV) the MVM can operate autonomously, but the operator can intervene to change the ventilation mode.
Task sequence control	Satisfied	When MVM restarts and it has been shut down for less than 15 minutes, it autonomously decides if a self-test is necessary or not. When performing a self-test, the operator selects the next sub-task to test the MVM components (e.g. spirometer calibration and leak check), then MVM performs each sub-task autonomously.
Supervised autonomy	Satisfied	During ventilation (both in PCV or PSV) the MVM can operate autonomously. If a connection error (obstruction or disconnection of the tube) is detected, MVM requires the user to resolve the error and restart the ventilation.
Task alternatives selection	Satisfied	Once the user has selected ventilation mode, MVM can autonomously ventilate the patient.
Mission Goal setting	Improvable (low effort)	Once the patient is connected to the ventilator, it decides the ventilation mode depending on the patient's profile.

Human-System Interaction Feedback

Level	Achieved?	Scenario
No feedback	Not applicable	-
Visual feedback	Not applicable	-
Vision data feedback	Satisfied	MVM gives visual and acoustic feedback to the operator through the GUI and LEDs.
Haptic feedback	Improvable (low effort)	The MVM GUI can be empowered with haptic feedback. Specific haptic patterns can be introduced to complement the visual communication when unusual/unsafe configuration parameters are set.
Tele-presence	Improvable (high effort)	The MVM may be endowed with a remote control dashboard or app so operators can monitor and control the ventilation remotely.

System to System Interaction

Level	Achieved?	Scenario
No interaction	Not applicable	-
Communication of own status	Satisfied	MVM is connected with the IT system of the hospital (the MVM sends alarms to the central system of the hospital).
Communication of task status	Improvable (high effort)	Two or more MVMs can share oxygen equipment and synchronize with each other to optimize oxygen consumption and avoid wasting it.
Communication of environment information	Improvable (high effort)	In critical situations, the IT system of the hospital can ask the ventilator to optimize its resources (e.g. oxygen and energy). Moreover, MVM can transfer ventilation information to the cloud to persist sense-data knowledge.
Team communication	Improvable (high effort)	MVM can communicate with other devices to administer therapy (e.g. it can require the use of the infusion pump), or it can use data from other devices to update ventilation parameters (e.g. it can use data from an oximeter).
Team coordination	Unable	

Capability Communication	Unable	

Human-System Interaction Safety

Level	Achieved?	Scenario
Intrinsic safety	Not applicable	-
Basic safety	Satisfied	MVM has an emergency red button, if it is pushed by the operator it stops the ventilation and set the ventilator into safe mode (input valve closed and output valve open).
Basic operator safety	Unable	-
User detection	Unable	-
Work space detection	Unable	-
Dynamic User detection	Unable	-

Human-System Interaction Safety - Context

Level	Achieved?	Scenario
Intrinsic safety	Not applicable	-
Reactive safety	Satisfied	In case of an error that could harm the patient, MVM is set to fail-safe mode.
Context dependent safety	Satisfied	Whenever the obstruction alarm condition occurs, the controller shall drive input and output valves to their safe state, within no more than one respiratory cycle.

Perception

The ability of the system to perceive its environment. It includes the ability to interpret information and to make informed and accurate deductions about the environment based on sensory data.

Perception

The following levels refer to the generic ability of a system to perceive which are generally speaking categorised by abstracting sensor data in each level.

Level	Achieved?	Scenario
No external perception	Not applicable	-
Direct Single and Multi-parameter sensing	Satisfied	MVM has sensors to measure pressure, temperature, flux, oxygen concentration, etc. Based on the values provided by the sensors, MVM alters its behavior, e.g. if the temperature is out of range the corresponding alarm is raised.
Low Level processing parameter sensing	Improvable (low effort)	A barcode reader can be used to scan the patient medical record to extract some information for the ventilation e.g. weight and height. Additionally, the operator can have a badge with a QR code that allows the MVM to identify him/her as a doctor or simple operator, and consequently, the system can show a complete or simplified command interface.
Multi-Parameter Perception	Improvable (low effort)	Currently, MVM sets the parameters of the input valve control according to a model of the patient's lung (resistance and capacity) during the first 3 breaths. This is done at the startup or on-demand through two sensors that measure the volume of inhaled/exhaled air. Additionally, MVM could integrate

		information coming from multiple sensors (both of the machine and attached to the patient) to build and update a breathing model of the patient (for instance, resistance and compliance). The periodically updated model of the patient can be used to drive the ventilation policies adopted by the ventilator.
Feature based perception	Unable	-
Grouped feature detection	Unable	-
Object identification	Unable	-
Property identification	Unable	-
Hidden state identification	Unable	-

Object recognition

This ability may range from being able to recognise instances of a single object, to being able to distinguish between many different objects or even identify objects that fit a generic pattern.

Level	Achieved?	Scenario
No Recognition	Satisfied	MVM has no recognition ability.
Feature detection	Unable	-
Object detection	Unable	-
Object recognition - single instance	Unable	-
Object recognition - one of many	Unable	-
Parameterised object recognition	Unable	-
Context based recognition	Unable	-
Object variable recognition	Unable	-
Novelty recognition	Unable	-
Unknown object categorisation (Rigid)	Unable	-
Object property detection	Unable	-
Flexible object detection	Unable	-
Flexible object classification	Unable	-
Animate objects	Unable	-
Pose estimation of animate objects	Unable	-

Scene perception

In many applications systems will need to be able to interpret the context of a wider scene, identifying static elements in the scene such as walls doors ceilings floor etc. as well as the delineation of objects. This scene interpretation is not related to the recognition of specific objects but to the wider identification of spaces and objects within a working environment.

Level	Achieved?	Scenario
No scene perception	Satisfied	MVM has no scene perception ability.
Basic feature detection	Unable	-
Static Structures	Unable	-
Combined Structures	Unable	-
Multiple object detection	Unable	-
Object arrangement detection	Unable	-
Dynamic object detection	Unable	-

Cognitive

The ability to interpret the task and environment such that tasks can be effectively and efficiently executed even where there exists environmental and/or task uncertainty. The ability to interpret human commands delivered in natural language or gestures. The ability to interpret the function and interrelationships between different objects in the environment and understand how to use or manipulate them. The ability to plan and execute tasks in response to high-level commands. The ability to work interactively with people as if like a person. Currently, different aspects and faculties of the Cognitive Ability as a whole have different degrees of maturity and pose different challenges.Attempting to combine these differences into a single rating or overarching target is likely to lead to invalid or misleading conclusions. The assessment of cognitive ability is therefore divided into several components or faculties. The assumption is that the cognitive ability of a system can be assembled and described more accurately by referring to a mixture of component abilities.

Action

It concerns the ability of the system to act purposefully within its environment and the degree to which it is able to carry out actions and plan those actions. These abilities build on perception and decisional autonomy abilities. Action ability also co-depends on the other cognitive abilities.

Level	Achieved?	Scenario
No Action Ability	Not applicable	-
Defined action	Satisfied	Predefined actions are executed in self-test mode, which can be interrupted by the operator.
Decision based action	Satisfied	The MVM continuously monitors the patient's breathing and decides to change modes (ventilation algorithms) and set the backup parameters in the transition from PSV to PCV in case of apnea. The MVM is also able to continuously monitor the patient's breathing and decides the inlet valve pressure and outlet valve status.
Sense driven action	Improvable (low effort)	By introducing the additional ASV ventilation algorithm, a threshold-based parametric adaptation decision is realized by the MVM: when the ventilator is operating in PCV mode, based on the monitoring of patient parameters (respiratory rate and target volume) and the relative distance from the Otis curve, the MVM switches to ASV mode to ensure minimum breathing effort (WOB: work of breathing).
Optimized action	Improvable (low effort)	MVM extended with the ASV mode can calculate the optimal breathing pattern that involves the minimum WOB for the patient (it optimizes the inspiratory pressure and the respiratory rate to reach a target value).
Knowledge driven action	Improvable (high effort)	The MVM embeds a knowledge base where all the information (e.g. patient state, ventilation failures, etc.) is stored. These historical data are used for data analytics, user profiling, and improving the system's dependability.
Plan driven action	Improvable (high effort)	MVM is extended with descriptive analytics: it can plan ventilation strategies according to the accumulated knowledge.
Dynamic planning	Improvable (high effort)	MVM is extended with predictive analytics: it can dynamically change the ventilation plan in response to its level of success. For example, in ASV mode, the MVM may monitor the overall life cycle of the ventilation process in terms of a specific flow of activities, and predict how and which parameters to modify to calibrate the ventilator according to the current values of the patient's parameters; in this case, the MVM assists the doctor in the clinical use of the ventilator in ASV mode.
Task action suggestions	Improvable (high effort)	MVM is extended with prescriptive analytics based on a predictive model of the patient (e.g., a stochastic runtime model of the patient). The MVM can provide prescription actions to calibrate the ASV ventilation based on the comparison between the patient's real monitored data and the data prescribed by the patient model.
Mission proposals	Unable	-

Intepretive

The interpretation of sense data is key to the ability to identify, recognise, classify and parameterize objects in the environment. It particularly refers to the ability to amalgamate multi-modal data into unified high-level object descriptions that create knowledge for tasks to draw on. The ability to interpret also engages knowledge sources to build increasingly complex interpretations of the environment and human interaction, in particular building frameworks of relationships between the environment and objects and between objects.

Level	Achieved?	Scenario
No interpretive Ability	Not applicable	-
Fixed sensory interpretation	Satisfied	The MVM measures the inspiratory pressure of the patient, the environmental temperature, the respiratory rate, etc. to collect sensor data to be used to interpret the patient's health parameters and condition.
Basic environment interpretation	Satisfied	The MVM estimates the flow starting from the measure of two pressures according to the Venturi effect.
Object delineation	Unable	-

Object category interpretation	Unable	-
Structural interpretation	Unable	-
Basic semantic interpretation	Unable	-
Property interpretation	Unable	-
Novelty interpretation	Unable	-
Environmental affordance	Unable	-

Envisioning

Envisioning refers to the ability of the system to assess the impact of actions in the future. This may reduce to prediction but in the higher levels involves an assessment of the impact of observed external events.

Level	Achieved?	Scenario
No envisioning ability	Satisfied	MVM has no envisioning ability.
Function projection	Improvable (low effort)	MVM can modulate the alarm loudness depending on the noise of the local room to guarantee the actual effectiveness of the alarm sound.
Basic environment envisioning	Improvable (low effort)	MVM can observe the patient's condition and predict the effect on its functioning, e.g., if the MVM observes that the patient needs a consistent amount of assistance (in terms of oxygen), it can predict that the request for oxygen to the hospital system will increase and, thus, may consequently require a better organization of the stock of oxygen.
Envisioning safety	Improvable (low effort)	During the ventilation, the system can constantly measure leaks (e.g., at the level of the patient's mask or of the breathing circuit) and compensate them to avoid future errors/alarms.
Envisioning user responses	Improvable (high effort)	MVM can envision, for example, an increase in the patient's sweating in response to the increase of the surrounding environment's temperature, and use such information to better guide ventilation based on a model of the patient (that includes in addition to the breathing parameters - resistance and compliance - also other vital parameters, like the temperature itself, and their relationships).

Acquired knowledge

Operating environments will always contain a number of unknowns. In many proposed application areas systems will encounter unknown situations as a normal part of task execution. The acquisition of knowledge about the new situations is fundamental to the success of these new application areas.

Level	Achieved?	Scenario
No Acquired Knowledge	Not applicable	-
Sense data and property knowledge	Satisfied	The MVM can sense several patients' vital signs (e.g., inspiratory pressure, the respiratory rate, etc.).
Persistent sense data knowledge	Improvable (low effort)	The MVM may record in ASV mode the tidal volume of the last 8 respiratory cycles, to compute their average value, compare it with the target volume and decide the new respiratory rate and inspiratory pressure to be used in the next cycle.
Deliberate acquisition	Improvable (low effort)	MVM autonomously executes an expiratory pause maneuver to gather some extra information about the patient.
Place knowledge	Improvable (low effort)	MVM can recognize the severity or not of the patient's clinical conditions according to a given category of a pre-established clinical classification.
Knowledge scaffolding	Unable	-
Requested knowledge	Improvable (low effort)	MVM does not know the weight and height of the patient and asks the user to insert these data.

Distributed knowledge	Improvable (low effort)	MVM can download from an external DB the patient's record with all necessary data for the initial configuration of the ventilation.
Interaction acquisition	Unable	-
Object function	Unable	-
User knowledge	Unable	-
Critical feedback	Unable	-
Long term observation	Unable	-
Patterns of behaviour	Unable	-
Observation learning	Unable	-

Reasoning

Reasoning ability is the glue that holds the cognitive structures together. Perception, knowledge acquisition, interpretation and envisioning all rely to a certain extent on the ability to reason from uncertain data. As application tasks become more complex the need to provide task and mission level reasoning increases.

Level	Achieved?	Scenario
No Reasoning	Not applicable	-
Reasoning from sense data	Satisfied	MVM controls the input valve to reach the desired inspiratory pressure.
Pre-defined reasoning	Satisfied	MVM monitors the drop of pressure to trigger the inspiration phase.
Basic environment reasoning	Satisfied	MVM in PCV monitors the inspiratory flow and when it falls below a threshold, it starts the expiratory phase.
Reasoning with conflicts	Satisfied	MVM lets the inspiratory phase end in PCV, when it observes a rapid increase of the pressure, even if the inspiratory time is not expired yet (possible coughing).
Dynamic reasoning	Improvable (low effort)	In the ASV ventilation mode, the MVM continuously decides the necessary respiratory rate and inspiratory pressure to be used for achieving a target tidal volume.
Safety reasoning	Improvable (low effort)	In the ASV ventilation mode, the MVM continuously checks that the tidal volume does not exceed a maximum limit and does not drop below a minimum threshold.
Task reasoning	Unable	
Task hypothesis	Unable	

Human interaction

The following set of levels relate to different levels of human interaction with a system that have a cognitive element. They specifically relate to the interaction between a human and a single system. Where multiple systems are involved a corresponding set of levels applies.

Level	Achieved?	Scenario
No Cognitive Human Interaction	Not applicable	-
Fixed interaction	Satisfied	The physicians can interact with MVM by using its GUI, which allows giving commands (e.g., the ventilation mode to be used, the values of the ventilation parameters, etc.) and shows the measured health parameters.
Task context	Unable	-

interaction		
Object and location interaction	Unable	-
System triggered interaction	Unable	-
Social interaction	Unable	-
Complex social interaction	Unable	-
Intuitive Interaction	Unable	-