LENS

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	The user cannot change language, units of measurement, and default values of ventilation parameters and alarms. The user cannot change the plug and voltage because they are configured by the manufacturer.
Start-up configuration	Satisfied	The user can change the ventilation mask, PEEP, and set the fraction of inspired oxygen using the gas blender before the start-up phase. The user can change ventilation parameters and alarm thresholds before the task ventilation-on or ventilation-off starts.
User run-time configuration	Satisfied	PCV ventilation parameters can be changed when the user changes the operation mode from PSV to PCV. The user can update alarm thresholds during ventilation-on.
Run-time self configuration	Satisfied	The ventilator changes ventilation mode 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. The power supply changes from ADC to the backup battery.
Autonomous configuration	Improvable (low effort)	If a pressure sensor fails, the ventilator is capable of autoconfiguring.

Adaptability

The ability of the system to adapt itself to different work scenarios, different environments, and conditions. Adaptation may take place over long or short time scales. Adaptability is divided into two sub-abilities, namely adaptation trigger and adaptation object.

Adaptation trigger

The focus of this sub-ability concerns the trigger of the adaptation, i.e. the parts of the system or history of collected data that cause an adaptation. Indeed, the system will observe the environment, both physical environment and human environment, and the system itself (e.g. a malfunction of the system).

Level	Achieved?	Scenario
No adaptation	Not applicable	
Human-triggered adaptation	Satisfied	MVM changes its ventilation mode in response to the patient's breath.
Adaptation triggered by a single part of the system	Satisfied	MVM raises alarms in case of faulty parts (e.g., tube obstruction, high inspired volume, oxygen level too high) having different priorities (High, Medium, Low).
Adaptation triggered by various parts of the system	Improvable (low effort)	MVM can be extended with an alarm managing component responsible for aggregating all triggered alarms and prioritizing them using a Fault Tree Analysis(FTA) technique.
Adaptation triggered by collected data, trends on data, history	Improvable (high effort)	By maintaining a history of the alarm system and the patient's state over time, MVM could be equipped with a predictive model to forecast severe situations, for example, when the patient is about to go into apnea status.

Adaptation object

The focus of this subability concerns the objects of the adaptation and how the system alters its behavior or structure (parameters, components, modes, or tasks) after the adaptation.

Level	Achieved?	Scenario
No adaptation	Not applicable	
Adaptation of a single part of the system	Satisfied	The triggering of an apnea alarm results in the switching of the MVM from pressure supported ventilation (PSV) to pressure controlled ventilation (PCV) mode with parameters set by the user.
Adaptation of various parts of the system	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).

Collective adaptation	Improvable (high effort)	Although MVM is a single-agent device, ventilation parameters could be automatically computed on the base of a stochastic model of the patient, executed by a different agent. The adaptation is executed by the MVM agent.

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
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, or the obstruction alarm condition occurs).
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 maskor 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.
Prescriptive 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 exploit predictive models to forecast severe situations and prescribes adjustment plans 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 sensor reading) to the ability to be self-sufficient in a complex environment.

Level	Achieved?	Scenario
Basic action	Not applicable	
Basic decisional autonomy	Not applicable	
Continuous basic decisional autonomy	Satisfied	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) mode, already used by several ventilators. In ASV mode, 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 main line, 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 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 Interaction Ability consists of the following four types of interaction.

Human-system interaction

The following set of levels relate to the interaction between users and the system. This set of ability levels are distinct from the cognitive human-system interaction levels, as they define the method of interaction independently of the cognitive context.

Level	Achieved?	Scenario
No interaction	Not applicable	
Direct control	Not applicable	MVM is endowed with a GUI for the human control (no direct control).
Direct physical interaction	Satisfied	The physician controls 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 physician 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 and 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

The ability to command a system depends on the user’s perception of the state of the system. This set of levels defines how this state information can be fed back to a user who is operating the system.

Level	Achieved?	Scenario
No feedback	Not applicable	
Basic feedback	Not applicable	
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.
Multi-modal feedback	Improvable (high effort)	The MVM may be endowed with a remote control dashboard or WEB-app, so operators can monitor and control the ventilation remotely.

System to system interaction

The following set of levels relate to the interaction between systems in carrying out a task or mission. No distinction needs to be made between separate systems that communicate and dependent systems that carry out a task. However, there is a distinction between systems that rely on a central controller and those that use distributed decision-making.

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 centralsystem 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

The following levels only apply to systems that have an inherent level of unsafety in the interaction between the human and the system. For example, if a system is safe at Level 0 then there is no need for it to reach Level 1 safety. For this reason, each successive level relates to systems that exhibit increased levels of potential harm. It is assumed that all systems meet safety criteria appropriate to their environment with respect to electrical and battery safety requirements, typically specified by European CE marking criteria. It is also expected that appropriate safety criteria have been applied with respect to consumables used by the system, for example heated liquids, liquids under pressure, or chemical agents.

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 sets the ventilator into safe mode (input valve closed and output valve open).
Basic operator safety	Unable	
User detection	Unable	
Workspace detection	Unable	
Dynamic user detection	Unable	

Perception

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

General perception

The following levels refer to the generic ability of a system to perceive environmental state by sensor data.

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	
Element identification	Unable	
Property identification	Unable	
Hidden state identification	Unable	

Element recognition

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

Level	Achieved?	Scenario
No recognition	Satisfied	MVM has no recognition ability.
Feature detection	Unable	
Element detection	Unable	
Element recognition - single instance	Unable	
Element recognition - one of many	Unable	
Parameterised element recognition	Unable	
Context-based recognition	Unable	
Element variable recognition	Unable	
Novelty recognition	Unable	
Unknown element categorisation (rigid)	Unable	
Element property detection	Unable	
Flexible element detection	Unable	
Flexible element classification	Unable	
Animate elements	Unable	
Pose estimation of animate elements	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 elements 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
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 atarget 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 elements in the environment. It particularly refers to the ability to amalgamate multi-modal data into unified high-level element 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 elements and between elements.

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 parametersand condition.
Basic environment interpretation	Satisfied	The MVM estimates the flow starting from the measure of two pressures according to the Venturi effect.
Element delineation	Unable	
Element 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 maskor 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

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 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, 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 can autonomously execute 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 can ask 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 initialconfiguration 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

The 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 under uncertainty	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	

Mission reasoning	Unable	

Cognitive human interaction

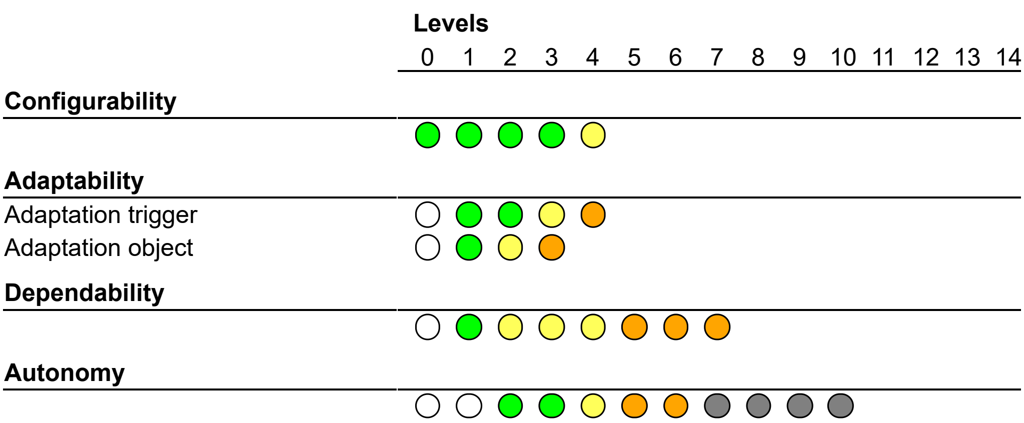
The following levels relate to different levels of human interaction with a system that has a cognitive element. They specifically relate to the interaction between a human and a single system. Where multiple systems are involved a corresponding set of levels applies.

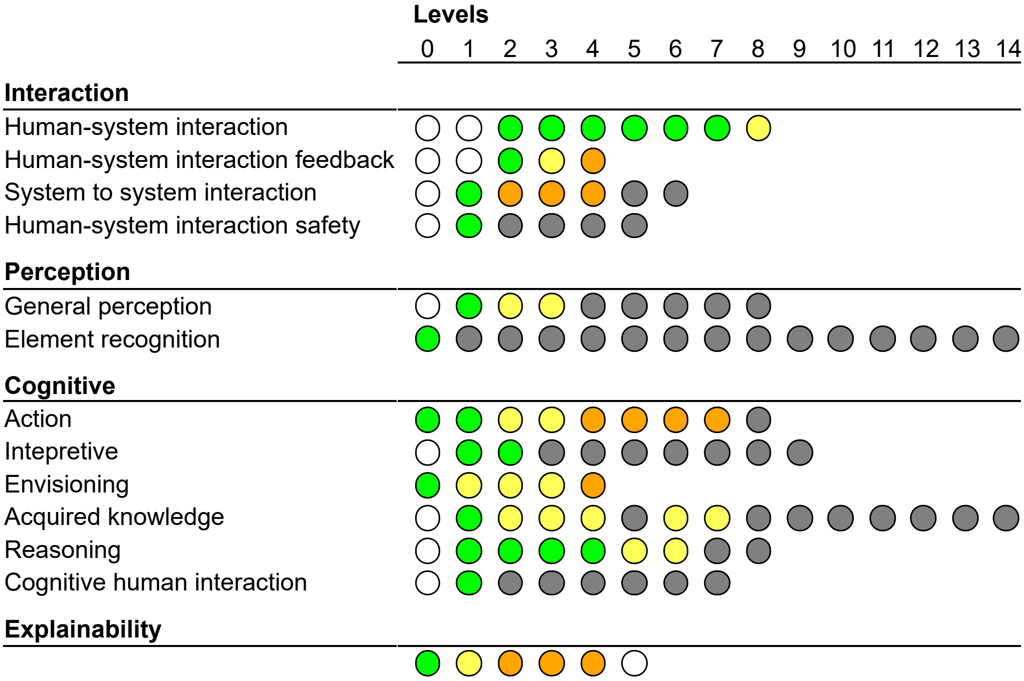
Level	Achieved?	Scenario
No cognitive human interaction	Not applicable	
Fixed interaction	Satisfied	The physician interacts with MVM by using its GUI, which allows giving commands (e.g., the ventilation mode to be used, the values of the ventilation parameters, etc.) and shows the measured health parameters.
Task context interaction	Unable	
Element interaction	Unable	
System-triggered interaction	Unable	
Social interaction	Unable	
Complex social interaction	Unable	
Intuitive interaction	Unable	

Explainability

The explainability is the ability of the system to make the entire control/adaptation process transparent and comprehensible by explicitly providing an explanation to humans. This explanation should be provided for the relevant behavioral aspects of the system’s decision making (i.e., why a control task/adaptation is requested, the reasoning behind a control task/adaptation decision, the effects/outcomes of the control task/adaptation) in a given operating condition (i.e., the observable features of the semantic space – environment and configuration dimensions with their own type and domain) to meet the control/adaptation goals (e.g., satisfy the system-level requirements). These include the use of interpretable models (e.g., linear models or decision trees) and of model-agnostic interpretation tools for local or global explanations.

Level	Achieved?	Scenario
No explanability	Satisfied	MVM has no explainer component.
Passive recognition of the need of explainability	Improvable (low effort)	MVM could be endowed with a component for data and events continuous recording.
Active recognition of the need of explainability	Improvable (high effort)	MVM could be endowed with a component for data and events continuous recording and machansms for exploring and deriving knowledge from collected data.
Local aspect explainability	Improvable (high effort)	In addition, MVM could be endowed with an explainer mechanism that analyses control/adaptation requests to provide explanation of local control/adaptation aspects.
Global aspect explainability	Improvable (high effort)	In addition, MVM could be endowed with an explainer mechanism that analyses the outcome (i.e., either success or failure) for all control/adaptation decisions as a whole to provide explanation of global control/adaptation aspects.
Collective explainability	Not applicable	




Levels
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14
Interaction
Human-system interaction
Human-system interaction feedback
System to system interaction
Human-system interaction safety
Perception
General perception
Element recognition
Cognitive
Action
Intepretive
Envisioning
Acquired knowledge
Reasoning
Cognitive human interaction
Explainability