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3	
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Practical principles for reducing risks arising from measurement parameters in equipment operation (on the example of an artificial lung ventilation apparatus)

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Abstract: The purpose of this study is to analyze the risks associated with the key clinical parameters of an artificial lung ventilation (ALV) device—tidal volume (VT), respiratory rate (RR), positive end-expiratory pressure (PEEP), peak inspiratory pressure (PIP), and fraction of inspired oxygen (FiO₂)—using digital technologies, the HFMEA methodology, and GOST ISO 14971:2021, and to integrate the results into the equipment's technical condition index. Risk identification, assessment, control, and residual risk monitoring were performed according to the NCPS HFMEA approach. The initial assessment showed that 65.5% of the analyzed parameters were classified as high risk. After implementing control measures, VT and PIP were reduced to low risk, RR and PEEP to medium risk, while FiO₂ remained at high residual risk. Consequently, the proportion of high-risk parameters decreased from 65.5% to 32.5%, and the maximum risk score was reduced from 12 to 8 points. Integrating HFMEA results into the technical condition index enables quantitative assessment of ventilator safety.

Keywords: FMEA, HFMEA, GOST ISO 14971:2021, ALV apparatus, risk analysis, technical condition index, digital technologies, technical equipment

1. Introduction

Safety requirements for the use of medical equipment are a key component of the healthcare system. This issue is especially critical for artificial lung ventilation (ALV) apparatuses used in resuscitation and intensive care units, as it is directly related to patient lives.

A study conducted by scientists Arkeliana Tase, Melody Z. Ni, and Peter W. Buckle, who analyzed the U.S. Food and Drug Administration (FDA) database, identified 290,141 serious injuries and deaths related to medical equipment over a 20-year period. Another analysis indicates that between

2008 and 2017, medical devices may have caused 1.7 million injuries and 80,000 deaths.[1]

In an analysis by Dutch scientist Mees C. Baartmans, a review of the medical histories of 2,998 patients who died in a hospital proved that approximately 1.9% of the deaths resulted from preventable adverse events related to medical equipment. Examples cited include internal bleeding caused by endoscopes and the improper use of artificial respiration tubes.[2]

Studies confirm that the majority of medical errors arise not from equipment failure itself, but rather from a doctor or nurse misunderstanding a complex interface (an ergonomic error) or incorrectly configuring the device.

Table 1

The most high-risk equipment and causes [1,2]

No.	Equipment Type	Most Common Risks and Consequences
1	Artificial lung ventilation (ALV)	Lung injuries and severe pneumonia caused by selecting the wrong mode or by contaminated filters. Administration of an excessively high dose of a toxic drug to the patient.
2	Infusion Pumps (Dosimeters)	Due to incorrect data entry when setting the medication dosage.
3	Cardiac Monitors	Improperly silencing alarm signals or medical staff failing to respond to the signal in time.

Failure Modes and Effects Analysis, or FMEA, was originally developed in 1949 as a U.S. military standard and

was later widely adopted in high-risk sectors such as NASA, civil aviation, and the automotive industry [3,4].

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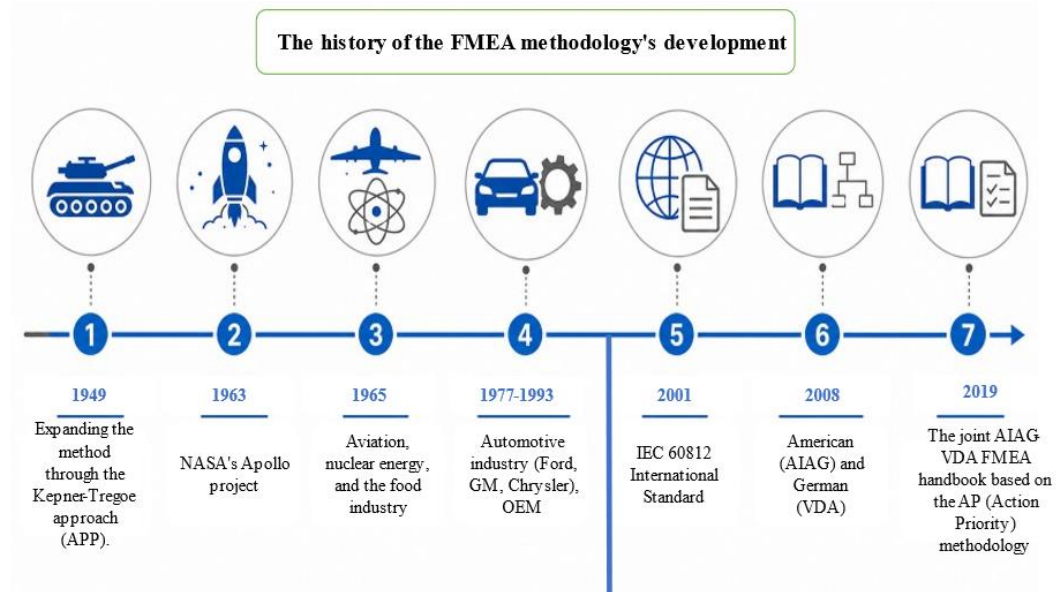


Fig. 1. A chronological history of the development of FMEA and HFMEA methodology

Today, FMEA has become a primary risk management methodology in the automotive, aerospace, nuclear, manufacturing, IT, medical, and service sectors.

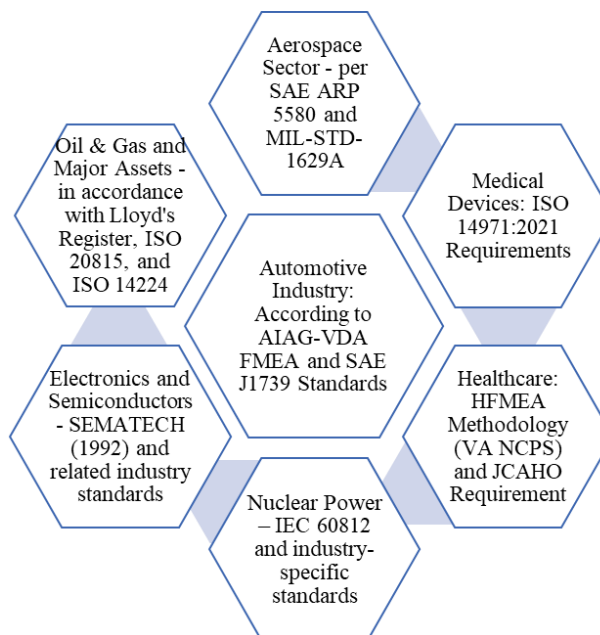


Fig. 2. Application of FMEA as an international standard in various industries [3,4,5,6,7]

HFMEA has been established as a proactive risk management tool focused on patient safety in the medical field, and when applied in conjunction with GOST ISO 14971:2021, it creates a comprehensive risk management framework for medical devices.

Incorrect settings or malfunctions of the mechanical ventilator's main parameters, such as VT, RR, PEEP, PIP, and FiO₂, can lead to severe clinical consequences including volotrauma, apnea, atelectasis, barotrauma, and hypoxia.

Therefore, a parameter-oriented HFMEA model was developed in this study, and its results were linked to a technical condition index.

2. Research methodology

The GOST ISO 14971:2021 standard and the HFMEA handbook recommended by the VA NCPS were chosen as the methodological basis for this study, as they define the interconnected stages of risk analysis, evaluation, management, and monitoring for medical devices.

In medicine, the ISO 14971:2021 standard and the official HFMEA handbook are utilized for risk identification, management, and control. These two requirements are considered complementary. To conduct a



comprehensive risk analysis, it is necessary to apply several of them in combination.

In this work, the ISO 14971:2021 standard was chosen as the legal and structural basis for the risk assessment methodology of the ALV apparatus. The standard is an internationally binding document that regulates the risk management process for all medical devices and also directly requires the implementation of HFMEA in

healthcare facilities. According to this standard, the risk management process consists of five interconnected main blocks, as shown in Figure 3. The process begins at the "Start" point and, at each stage, moves to the next or returns to the previous one based on "Yes" or "No" decisions—this cyclical approach ensures that risks are thoroughly addressed.

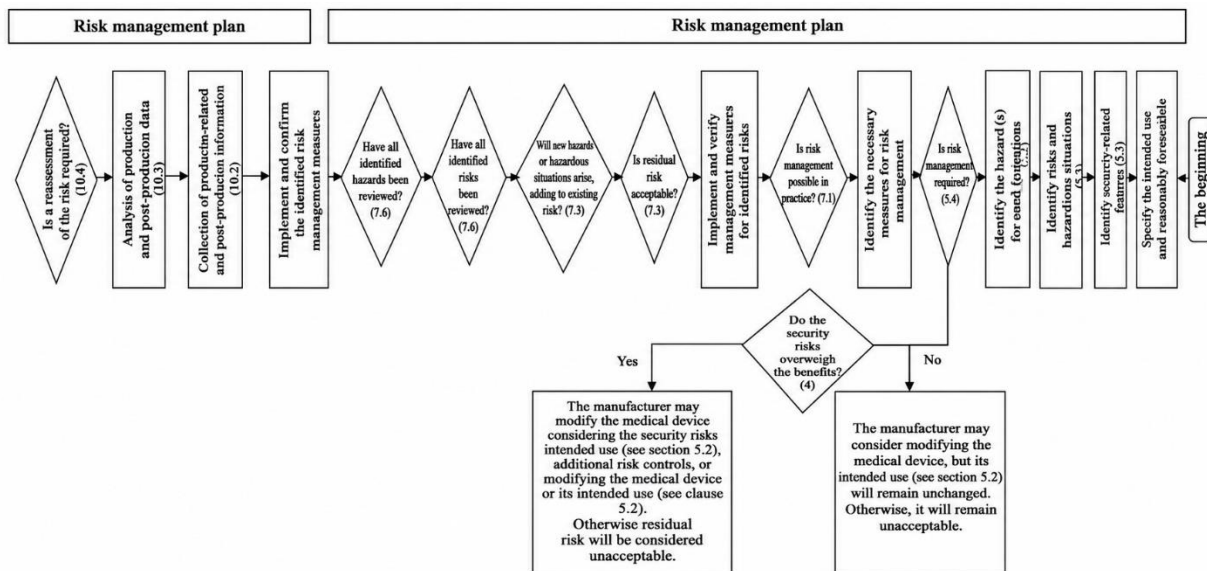


Fig. 3. A complete schematic diagram of the medical device risk management process according to the ISO 14971:2021 standard

HFMEA was developed for healthcare as a variant of this approach adapted to the clinical setting; unlike the classic RPN model, it utilizes an S×P risk score and a decision tree.

The risk management process was organized into five blocks: risk analysis, risk assessment, risk control, residual risk assessment, and post-production monitoring.

The HFMEA analysis, developed by the U.S. Department of Veterans Affairs (VA) National Center for Patient Safety, consists of 5 main steps (Figure 4).

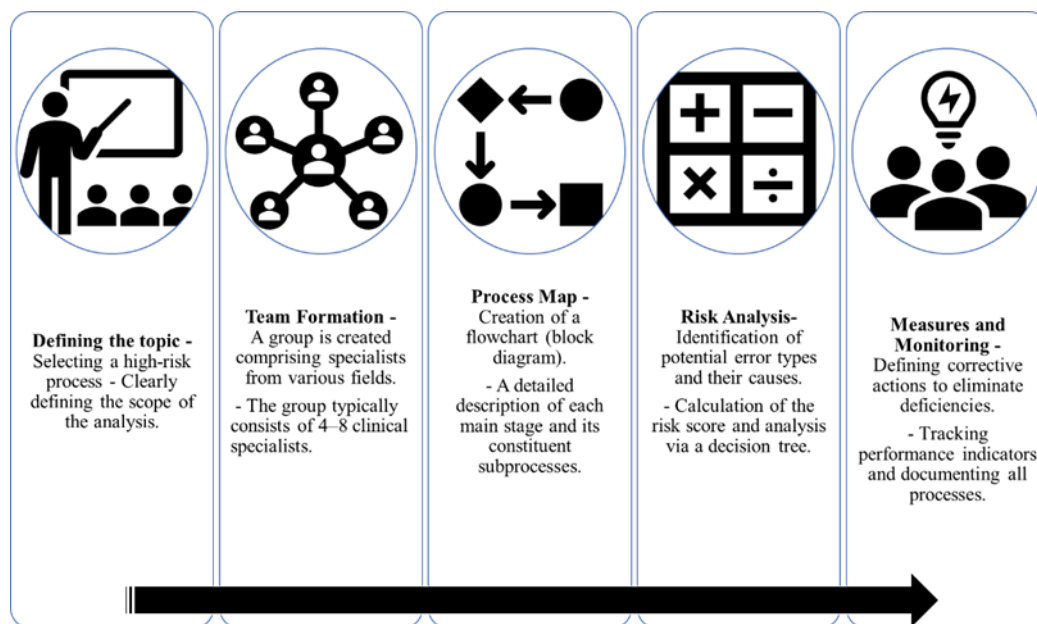


Fig. 4. The 5 main stages of HFMEA analysis



The main ventilation parameters of the ventilator—VT, RR, PEEP, PIP, and FiO₂—were designated as the object of study, while electrical supply and general infrastructure risks were left outside the scope of this work.

The team included an anesthesiologist-reanimatologist, a head nurse, a biomedical engineer, a metrologist, a service engineer, and a representative from the quality management department (Table 2).

Table 2

Risk matrix according to the ISO 14971 standard and the official HFMEA guide

Severity \ Probability	Light	Medium	Serious	Fatal
Rarely	1	2	3	4
Sometimes	2	4	6	8
Often	3	6	9	12
Frequently	4	8	12	16

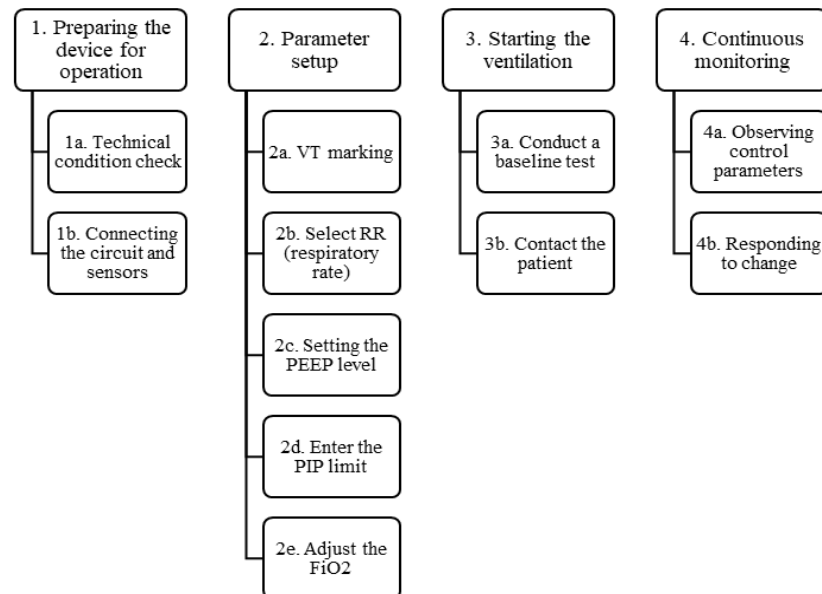


Fig. 5. Flowchart of the clinical process for using the ALV apparatus

The process map included the stages of preparing the device for operation, setting parameters, starting the ventilation, and continuous monitoring.

A 4×4 matrix was used for the risk assessment, based on severity and probability indicators.

The risk score was calculated using the formula $R=S \times P$.

Subsequently, each risk was evaluated using a four-question HFMEA decision tree, and control measures were developed where necessary.

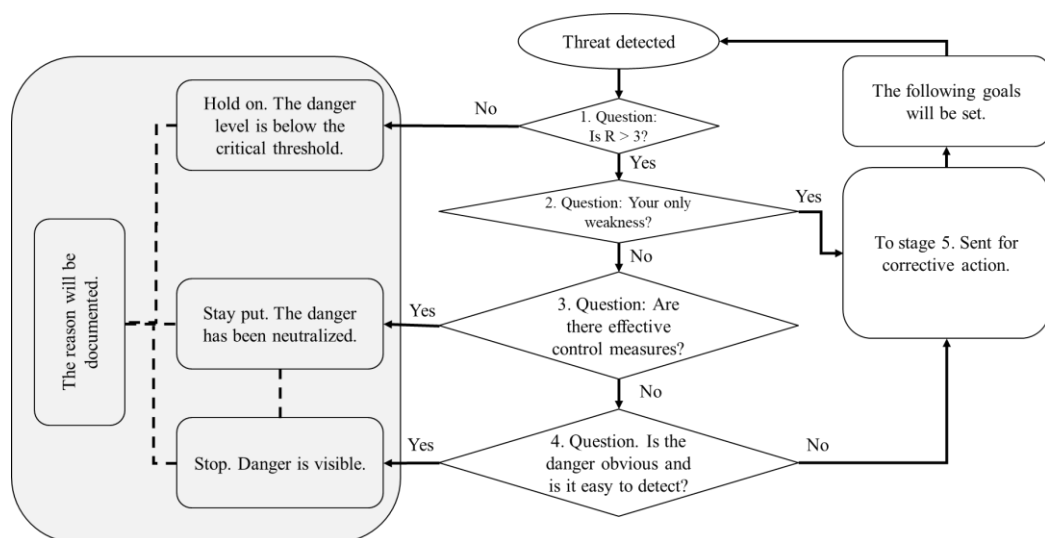


Fig. 6. HFMEA Stage 4: Risk Assessment Decision Tree — a 4-Question Filtering Algorithm



3. Results and discussion

We will begin the risk analysis for the five main parameters of the ALV apparatus, in accordance with Appendix 1, by defining the topic and forming the team.

Step 1: Select and define the boundaries of the process to be examined.

Process selection criteria: Processes are identified where human factors may contribute to process or system vulnerabilities. Examples include communication errors, inadequate training, staffing issues, problems with shift handovers, and obstacles such as unclear rules/procedures.

HFMEA (process/equipment/system to be examined):

Evaluation, using the HFMEA method, of potential failure modes that may occur during the process of setting,

adjusting, and monitoring the main ventilation parameters—VT, RR, PEEP, PIP, and FiO₂—of an artificial lung ventilation (ALV) device (e.g., Dräger SAVINA 300), their clinical consequences, and the constructive, software, and organizational control measures. The HFMEA results are used as the basis for the ISO 14971 risk management file and the technical condition index (Ht).

Scope of the topic:

The analysis focuses on the main clinical parameters of the ALV apparatus (VT, RR, PEEP, PIP, FiO₂). Risks related to the power supply, gas sources, and general infrastructure will be considered in separate projects. The method is applied as a common platform for all essential medical equipment (monitoring systems, ECG, ultrasound, endoscopes, laboratory analyzers).

Step 2. Team formation.

Table 3

Composition of the Risk Identification and Assessment Team

Position	Specialty / Area of Expertise
Anesthesiologist-Reanimatologist	Clinical process and outcomes
Senior Nurse (ICU / Resuscitation)	Practical use, operating procedure
Biomedical Engineer (BME) – HFMEA Coordinator	Technical specifications, service, ISO 14971
Metrologist – Calibration Department	MSA, GRR, measurement system analysis
Service Engineer	Ventilator and monitoring technical service
Quality Management Department Representative	ISO 13485, ISO 9001, QMS integration

A complete map of the clinical process for using the mechanical ventilator was created for Stage 3 of the HFMEA (Figure 4). According to the requirements of the VA NCPS HFMEA Guidebook (2021), the process map must sequentially reflect all sub-steps of the process being analyzed, show the connection between each step, and serve as the basis for the subsequent Stage 4 (hazard analysis). The created map includes four main stages: (1) preparing the ventilator for operation—technical status check (1a) and connecting the circuit and sensors (1b); (2) setting the parameters—sequentially defining the tidal volume VT (2a), respiratory rate RR (2b), positive end-expiratory pressure PEEP (2c), peak inspiratory pressure limit PIP (2d), and fraction of inspired oxygen FiO₂ (2e); (3) initiating ventilation—initial ventilator test (3a) and connecting to the patient (3b); (4) continuous monitoring—observing alarm

parameters (4a) and responding to clinical changes (4b). The five sub-steps in Stage 2 (2a–2e) are the direct objects of the hazard analysis in the document and correspond to all the parameters (VT, RR, PEEP, PIP, FiO₂) presented in Table 4.

According to the ISO 14971 standard, a complete, international-standard risk management scheme for an artificial lung ventilation (ALV) apparatus and its practical schedule are formulated as follows.

Based on the ISO 14971 standard, the ALV manual, and its technical passport, the responsible HFMEA group conducted an audit of the equipment's parameters, the results of which indicated a high risk across all indicators. Control measures were developed by the HFMEA group and implemented into the process (Table 4).

Table 4

Results of the preliminary audit of equipment parameters by the HFMEA team

Parameter	Risk type	Clinical outcome	P Probability	S - Seriousness	Risk Level	Control Measures
VT	Expiratory valve blockage	Lung rupture (Volotrauma)	3	4	High-risk	Strictly set the maximum volume limit via the software.



RR	Processor freeze	Respiratory arrest (Apnea, Asphyxia)	2	4	High-risk	A standalone timer activates the backup mode.
PEEP	Circuit disconnect	Alveolar collapse (Atelectasis)	3	3	High-risk	Provide a visual and 80 dB audible signal on the screen via a periodic pressure sensor.
PIP	Electronic sensor error	Lung barotrauma, pneumothorax	3	3	High-risk	Install a mechanical valve that operates even when the electronics are off.
FiO ₂	Mixer valve rusted	Hypoxia, brain death	3	4	High-risk	Automatically calibrate the galvanic O ₂ cell each time the device is turned on.

Table 5
Risk Level According to Preliminary HFMEA Results

Risk level				
VT	RR	PEEP	PIP	FiO ₂
12	8	9	9	12

As the table indicates, each evaluated parameter was found to have a "High Risk" level. In the next stage, a risk analysis is performed according to the algorithm in Figure 5.

Stage 4. The Risk Assessment Decision Tree. In Stage 4 of the HFMEA, each identified risk is evaluated using a four-question decision tree (Figure 5). Question 1: Is the Hazard Score $R > 3$? — If no, the risk is considered to be below the critical point, and the reason is documented. If yes — Question 2: Is this the single point of failure for the process? — If yes, the risk is sent directly to Stage 5 (corrective actions). If no — Question 3: Is there an effective control measure in place? — If yes, the risk is marked as under control and documented. If no — Question 4: Is the risk obvious and easy to detect? — If yes, the risk is considered detectable; if no, it is sent to Stage 5. This four-question filtering algorithm replaces the $RPN = S \times O \times D$ formula from classical FMEA and allows for more precise prioritization for clinical processes.

Stage 5: Corrective actions and monitoring.

VT (lung rupture as a result of expiratory valve blockage). Control measure: "Design-based: strictly limit the maximum volume threshold via software."

- Analysis: Limiting the maximum VT at the device level physically restricts the maximum volume that can be delivered to the patient; therefore, the maximum energy for volotrauma is reduced, and the severe pneumothorax/rupture scenario becomes both less likely and shifts toward a relatively milder injury.

Therefore:

P: The probability of excessive pressure being applied due to a blockage is reduced.

S: Due to the design limit, mild barotrauma scenarios are more likely than the typical outcome of "severe lung rupture." The S=4 indicator can be re-evaluated as S=3.

RR (apnea, asphyxia resulting from processor freeze). Control measure: "Protection system: a self-acting timer activates the backup mode."

Analysis: An independent timer quickly detects when the processor fails and switches the ventilator to a backup mode; ventilation does not stop completely, even without staff intervention. This significantly reduces the clinical impact of this failure mode on the patient, but processor freezing can still occur.

Therefore:

S: instead of a scenario where ventilation stops completely, leading to death, short-term failure and restart are often observed; therefore, a reduction from S=4 to S=3 is justified.

PEEP (alveolar collapse due to circuit disconnection, atelectasis)

Control measure: "Information/signal: a visual signal on the screen and an 80 dB audible alarm, triggered by the periodic pressure sensor."

- Analysis: A strong audiovisual alarm immediately signals the staff member when the circuit is disconnected, which increases the likelihood of reconnection before atelectasis can develop; in HFMEA, this is typically considered a measure that reduces P.

Therefore:

- P: The probability of loss of control is reduced from P=3 to P=2.

- PIP (barotrauma, pneumothorax due to electronic sensor failure)

- Control measure: "Protection system: install a mechanical valve that functions even if the electronics fail."

- Analysis: The mechanical valve physically limits the maximum pressure and releases any excess pressure, even in the event of an electronic failure; this significantly reduces the peak inspiratory pressure (PIP) that can reach the patient.



Therefore:

P: While the frequency of sensor errors may not necessarily change, the number of incidents leading to barotrauma/pneumothorax will decrease sharply, reducing the risk from P=3 to P=2.

S: The spectrum of maximum clinical harm typically shifts from "severe barotrauma/pneumothorax" to "mild barotrauma, infrequent pneumothorax." As a result, S was re-evaluated from S=3 to S=2.

FiO₂ (hypoxia, brain death due to mixer valve corrosion)

Control measure: "Design-related: automatic calibration of the galvanic O₂ cell each time the device is turned on."

Analysis: Automatic calibration reduces the drift of the FiO₂ sensor, lowering the probability of operating with an incorrect oxygen concentration; however, hypoxia can still occur if the mixer valve is mechanically blocked.

Therefore:

o P: The frequency of clinical hypoxia episodes associated with incorrect FiO₂ delivery will decrease from P=3 to P=2.

o S: The risk of brain death or severe neurological deficit due to hypoxia theoretically remains, as the potential for mechanical mixer failure is not fully eliminated, staying at S=4.

As a result of applying control measures and conducting a repeat HFMEA by the HFMEA group, the highest risk level of R=12 was reduced to R=8, yielding the indicators shown in Table 6. These indicators will serve as the basis for determining the weight coefficient when calculating the equipment's technical condition index.

Table 6

Audit Results After the Application of Control Measures for Equipment Parameters by the HFMEA Group

Parameter	Risk type	Clinical outcome	P Probability	S - Seriousness	Risk Level
VT	Expiratory valve blockage	Lung rupture (Volutrauma)	1	3	Low Risk
RR	Processor freeze	Respiratory arrest (Apnea, Asphyxia)	2	3	Moderate Risk
PEEP	Circuit disconnection	Alveolar collapse (Atelectasis)	2	3	Moderate Risk
PIP	Electronic sensor error	Lung barotrauma, pneumothorax	1	3	Low Risk
FiO ₂	Mixer valve rusted	Hypoxia, brain death	2	4	High Risk

The results presented in the table meet the criteria for residual risk acceptability in accordance with ISO

14971:2021, §7.4; the FiO₂ parameter requires additional monitoring (§10.2).

Changes in HFMEA Results

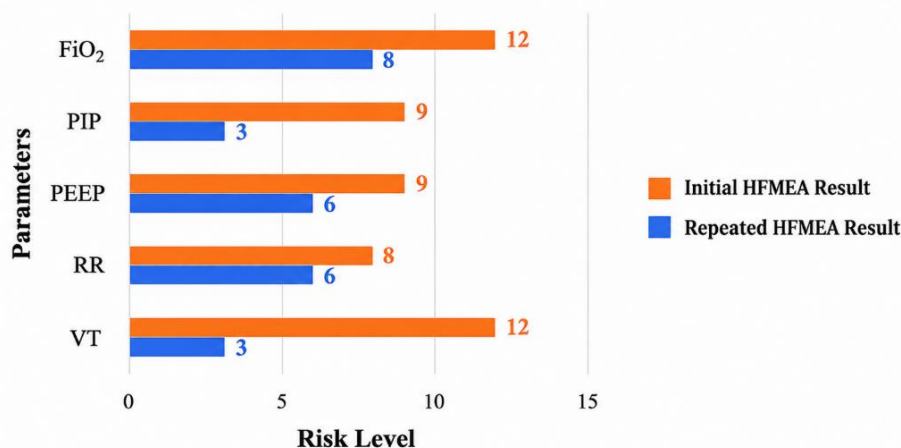


Fig. 7. HFMEA results after implementing control measures

Discussion

The results of this study indicated that for reducing risks associated with the primary measurement and control parameters of an ALV device, the HFMEA methodology is more adaptable and practically effective for a clinical setting

compared to traditional FMEA. The main reason for this is that HFMEA is not limited to merely calculating risk scores; it also evaluates the clinical significance of the risk based on a decision tree, assesses the adequacy of existing control measures, and determines the presence of a single point of



failure, which makes decision-making in intensive care settings considerably more precise.

The analysis results showed that not all parameters in the artificial lung ventilator (ALV) pose a threat through the same mechanism, and therefore, applying a uniform management approach is insufficient. For instance, the design and mechanical safety measures applied to the VT and PIP parameters reduced not only the probability of an incident but also the severity of harm to the patient, thereby lowering the residual risk for these parameters to a low level. For the RR and PEEP parameters, however, risk reduction was primarily achieved through alarms, backup modes, and monitoring mechanisms, which, while not completely eliminating the risk, brought it down to a clinically manageable, moderate level.

The results obtained for the FiO₂ parameter are particularly noteworthy, as this parameter retained a high residual risk despite automatic calibration measures. This indicates that malfunctions related to the mechanical mixer system, which forms the oxygen mixture, cannot be fully resolved by software or sensor-level corrections. Therefore, reducing the risk associated with FiO₂ requires not only automatic calibration but also periodic metrological inspections, functional tests, shorter service intervals, and potentially the introduction of additional redundant control channels.

A key aspect of this research is that the HFMEA results were utilized not only as a descriptive summary but also as a quantitative basis for calculating the technical condition index. The approach of generating weighting coefficients from the residual risk scores of the parameters allows the overall technical reliability of the ALV apparatus to be expressed as a single numerical indicator, simplifying decision-making for service engineers, metrologists, and quality management specialists. Viewed from this perspective, this approach moves beyond simple risk analysis to become a management tool for prioritizing digital monitoring and service.

The study is also important from a practical implementation standpoint, as it clearly indicates which parameters should be prioritized for monitoring in mechanical ventilators. Specifically, it was proven that a parameter-oriented strategy for managing ventilator safety is more effective than a general preventive approach, because the VT and FiO₂ parameters initially had the highest risk scores, while PIP and PEEP demonstrated a strong link between technical and clinical consequences.

However, the research has certain limitations. First, the analysis is confined to a single type of mechanical ventilator and five primary parameters, and does not fully encompass all risks related to the gas supply system, power failures, software interface errors, or user-related factors. Second, because some of the risk scores are based on expert evaluation, the results may differ to some extent when conducted by different teams. Third, the study did not incorporate real-time IoT monitoring or predictive technical diagnostics based on machine learning, which represents an important direction for future research.

Nevertheless, the obtained results have shown that it is possible to create a systematic, reproducible, and digitally adaptable risk management model for mechanical ventilators by integrating the requirements of HFMEA and ISO 14971:2021. This model is not limited to ventilators and can also be adapted for other medical equipment, such as

monitoring systems, infusion pumps, defibrillators, and laboratory analyzers.

4. Conclusion

In this study, a risk analysis of the main clinical and measurement parameters of the ALV apparatus—VT, RR, PEEP, PIP, and FiO₂—was systematically performed based on the HFMEA methodology and the requirements of the ISO 14971:2021 standard. The initial audit revealed that all five parameters fell into the high-risk zone, confirming the necessity of an in-depth, parameter-specific analysis when assessing the safety of ALV devices.

As a result of developing and implementing control measures, the risk for the VT and PIP parameters was reduced to a low level, and for RR and PEEP to a medium level, while the FiO₂ parameter remained at a high residual risk. This result indicates that improving ventilator safety requires a differentiated approach tailored to the technical nature, clinical consequences, and detection characteristics of each parameter, rather than universal measures for all parameters.

Based on the research findings, the following scientific and practical conclusions can be drawn:

- The HFMEA methodology is an effective tool for identifying and prioritizing clinical risks in mechanical ventilators.
- The HFMEA model, when integrated with ISO 14971:2021, creates a complete management cycle, from risk identification to residual risk monitoring.
- A significant reduction in risk can be achieved when constructive, protective, informational, and metrological control measures are applied in accordance with the relevant parameters.
- In cases where a high residual risk remains, such as with the FiO₂ parameter, enhanced metrological monitoring and periodic functional verification must be mandatory.
- Integrating residual risk scores into the technical condition index allows the overall safety status of the equipment to be assessed using a quantitative indicator.

From a practical standpoint, this approach can be applied to plan the servicing of ventilators used in resuscitation and intensive care units, prioritize preventive technical inspections, and establish the frequency of metrological control. Furthermore, it serves to create a unified decision-making platform for biomedical engineers, metrologists, and quality management departments.

For future research, it is advisable to expand this model to other medical equipment, integrate it with real-time IoT monitoring systems, introduce predictive failure analysis based on artificial intelligence, and validate the technical condition index. Therefore, parameter-oriented risk analysis using HFMEA is recommended as a promising scientific and practical solution for enhancing the operational safety of medical equipment, reducing the impact of human error and technical failures, and establishing a digital risk management system within healthcare institutions.

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T. Alimov, J. Shukurov, Y. Ergashev, N. Abdujabarov <i>An integrated framework for multidisciplinary design optimization of unmanned aerial vehicles.....</i>	61
E. Khujamkulov <i>Digital national microprocessor-based semi-automatic interlocking system for improving the throughput capacity of Uzbekistan Railways.....</i>	67
O. Mukhitdinov, S. Khudaykulov, D. Kaniev <i>Energy equations of a channel suspension-carrying flow with full account for the work of interphase interaction forces.....</i>	71
Mu Zhendi <i>Network diagnosis and governance-coupled optimization in seaport–dry port multimodal transport corridors under the Maritime Silk Road.....</i>	78
N. Sotivoldieva <i>Scientific and theoretical foundations of resource management in ensuring product quality and safety at light industry (sewing and knitting) enterprises.....</i>	87
B. Botirov <i>Experimental investigation of mechanical properties of A-III reinforcing steel bars with a diameter of 10 mm.....</i>	92
Kh. Abduvokhidov, Z. Juraev <i>Practical principles for reducing risks arising from measurement parameters in equipment operation (on the example of an artificial lung ventilation apparatus)</i>	96