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Assessment Of The Safety Of Ultrasonic Equipment Using The Fmea Method

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Annotation: In this article, we conducted research on the safety of ultrasound equipment using the FMEA method. The work performed in this study was carried out in accordance with the requirements of the international standard "IEC 60601-2-37:2024 Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment" and "ISO 14971:2019 (E) Medical devices - Application of risk management for medical devices". The study was conducted at the "YYY" diagnostic center in Andijan. The study is based on the results obtained from 150 patients over a three-month observation period. During the study, the initial average RPN level was 175.8, and due to corrective measures, it was reduced by 44.7, or 74%. The work in the study is part of the results of my scientific research on the topic "Improvement of the quality assurance system for ultrasound examinations in medicine based on international standard requirements".
Keywords: UZI, FMEA- Failure Mode Effect Analysis, risk analysis, RPN- Risk Priority Number, IEC 60601-2-37:2024, ISO 14971:2019 (E), medical devices.

Ultrasound is heard at a frequency above 20,000 Hz, which is a frequency that the human ear cannot hear. In recent years, ultrasound for diagnostic evaluation in medicine has become a visual basis for diagnosis, allowing for non-invasive assessment of the whole body. Ultrasound examination in imaging diagnostics accounts for 30% of examinations worldwide[1].

The first clinical trials of ultrasound in medicine were conducted at the end of 1938 at the Martin Luther Hospital in Berlin[2]. Although the experiments were initially not very successful, they laid the foundation for future successes.

The FMEA method is a systematic process that identifies potential failures in the design of a product or process before they occur in order to eliminate them or minimize the associated risk. The method was mainly used in the automotive industry, but it is now also an effective tool for identifying potential failures in a variety of natural products and processes. Therefore, its application in the medical field is increasingly increasing. This includes improving patient safety[3], analyzing risk points in the implementation of smart devices, its application in radiotherapy, or quality management in a clinical laboratory[4]. The FMEA method has two stages of process evaluation:

- identify failure.
- evaluate failure.

Determining the Risk Priority Number (RPN):
(RPN) = (S) x (O) x (D)
where:
(S) significance is the value of the potential nonconformity (failure) that is important to the system or user. "Significance" applies only to consequences that have occurred and can be reduced by changing the design.
(O) probability of occurrence is the degree of chance that the specific cause/mechanism will be realized.
(D) probability of detection is the probability that the cause/mechanism of the potential nonconformity will be discovered.
(S), (O) and (D) are rated on a scale of 1 to 10.
Risk Priority Number (RPN) Reduction:
(S) Reduction of the significance level is achieved by revising the design or process.
(O) Reduction of the occurrence level is achieved by revising the design or process, eliminating or reducing one or more causes, studying the variability of the process output using statistical methods:

- replacing the design with a fault-tolerant design to eliminate the defect;
- reviewing the dimensions and allowances in the design;

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- revising the design to replace the weak component;
- adding a duplicate system;
- revising the material specifications.

Risk Priority Number (RPN) Reduction[5]:

(D) Reduction of the detection rate can be achieved by increasing the number of design verification/validation activities:

- safeguards against errors;
- planning experiments on process outputs;
- reviewing process flow sheets, work instructions or maintenance plans;
- reviewing test/experimentation plans;
- experiment/test results;
- design analysis and results;
- drawings, schematics or models to support changes in physical properties;
- robustness test results.

The standard for implementing risk management for medical devices provides a structural diagram for conducting an FMEA:

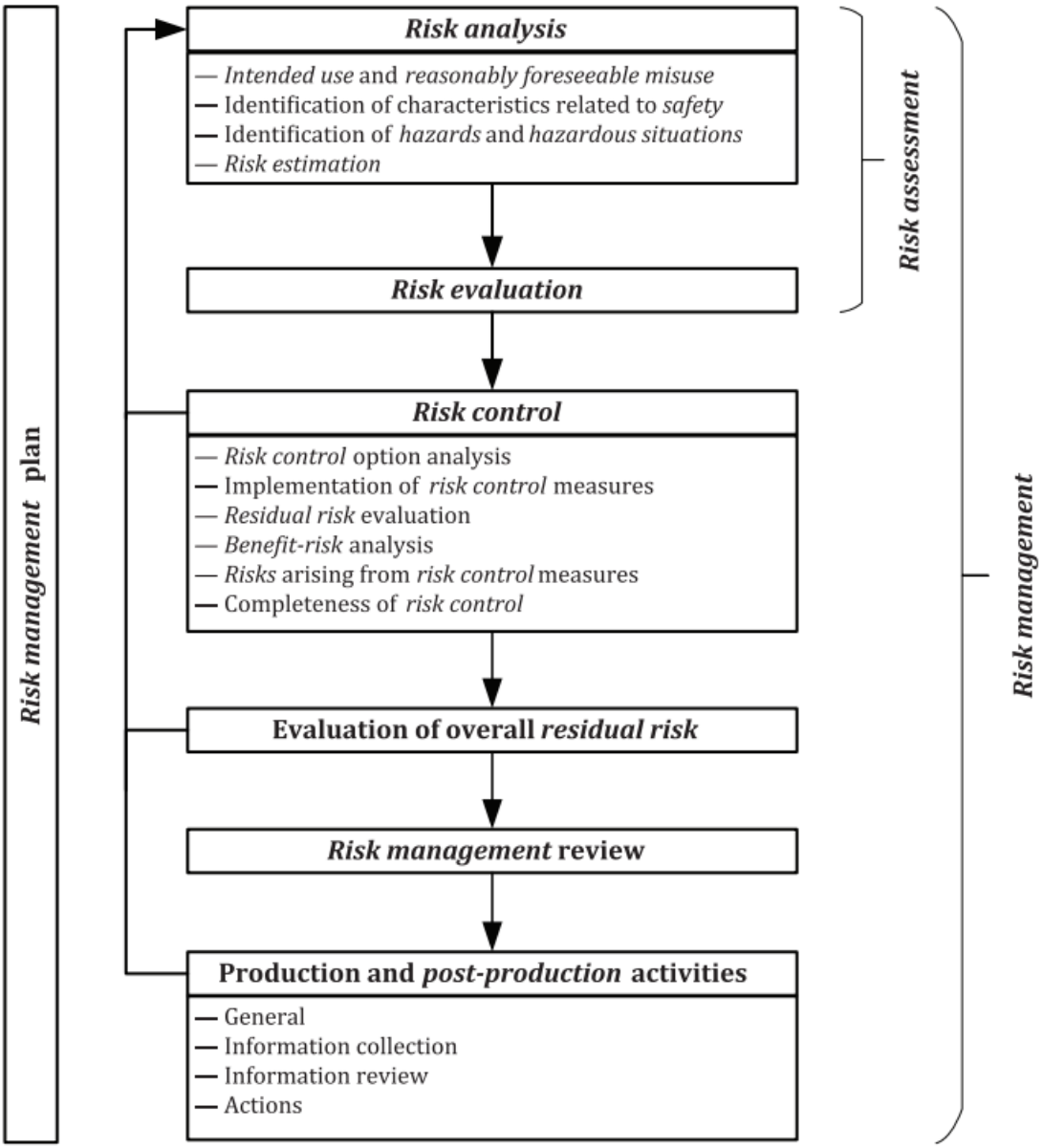

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Figure 1. Schematic representation of the risk management process[6].

We have developed a risk management plan as required by the standard (Table1).

Table 1. Risk Management Activities Table.

Phase	Activity	Document	Responsible	Frequency/Timeline
5. Analysis	FMEA table (10 risks)	FMEA_UZI. (.xlsx)	Quality Manager	Quarterly
6. Evaluation	RPN >200 assessment	Pareto_Report.pdf	Auditor	Monthly
7. Control	Checklist implementation	Operator_Checklist.pdf	Chief Physician	Immediate
8. Residual	Residual risk report	Residual_Risk.docx	Quality Department	Monthly
9. Review	RPN trend analysis	Monthly_Trend.xlsx	Director	Monthly

The 10 selected risks were assessed using three indicators and the RPN indicator was calculated (Table 2).

Table 2. FMEA table[7].

№	Stage	Error Mode	Reason	Impact	S	O	D	RPN
1	Preparation	Cable Damage	Obsolescence	Shock	8	4	5	160
2	Gel	Air Bubbles	Incorrect push	Artifact	5	7	6	210
3	Focus	Incorrect Depth	Fatigue	Diagnostic Error	8	7	6	336
4	Gain	Excess	Error	Incorrect DX	7	5	7	245
5	TI/MI	>1.0 Ignore	Signal off	Fetal Injury	8	5	4	160
6	Doppler	PRF High	Error	HISS Error	6	4	5	120
7	Contrast	MI>1.9	Subject	Cavitation	8	3	6	144
8	Storage	DICOM Error	Server	No Data	4	6	8	192
9	Service	Calibre Out of Date	No test	IEC Violation	7	2	4	56
10	Operator	Certificate Expiry	No training	All	9	3	5	135

During the observations, 10 types of risks were identified in the use of the ultrasound machine. We divided the identified risks into six areas according to the Ishikawa diagram (Figure 2).

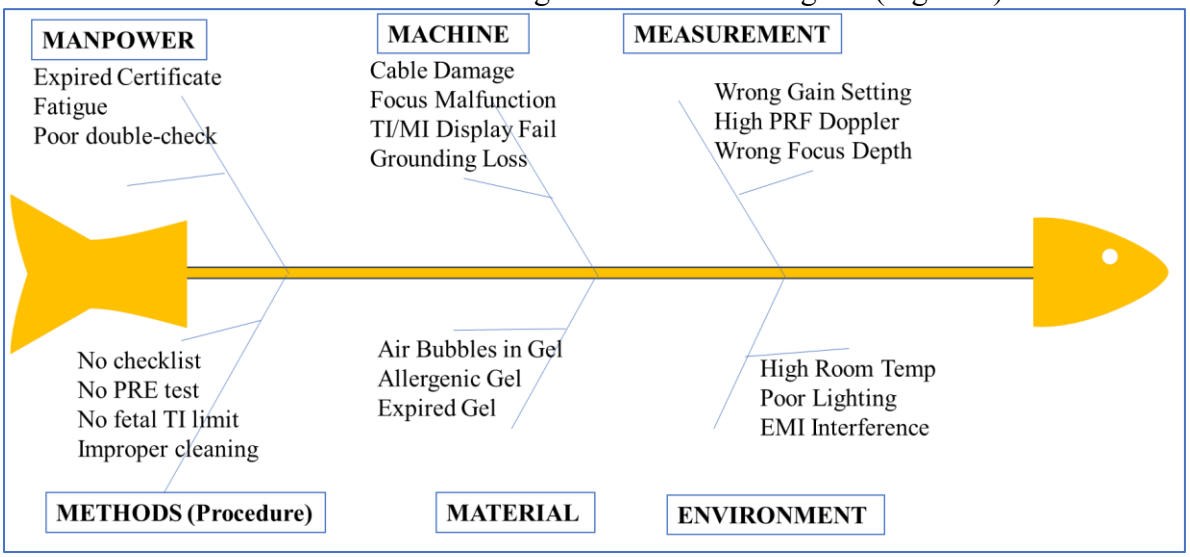

Figure 2. Fishbone diagram.

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After the development and implementation of corrective measures, the RPN indicators became as follows (Table 3).

Table 3. Corrective measures.

№	Stage	Error Mode	Corrective action
1	Preparation	Cable Damage	Daily visual inspection; weekly multimeter test
2	Gel	Air Bubbles	Standard push protocol (2x check); trainer gel
3	Focus	Incorrect Depth	Multi-focus mode; focus checklist (2x depth check)
4	Gain	Excess	Auto-gain function; two operators double-check
5	TI/MI	>1.0 Ignore	Automatic power reduction (at TI>1.0); red warning signal
6	Doppler	PRF High	Auto-PRF adjustment algorithm; Doppler checklist
7	Contrast	MI>1.9	MI auto-limitation (at contrast ≤0.9); contrast protocol
8	Storage	DICOM Error	Dual PACS backup; USB offline storage; auto-export
9	Service	Calibre Out of Date	Microsoft Access reminder system ; annual IEC 62359 tests
10	Operator	Certificate Expiry	Annual certification; Access auto-reminder (90 days ago)

As a result of the measures taken, the RPN levels decreased significantly. However, the significance of the cable wear level during the preparation phase increased over time (Figure 3).

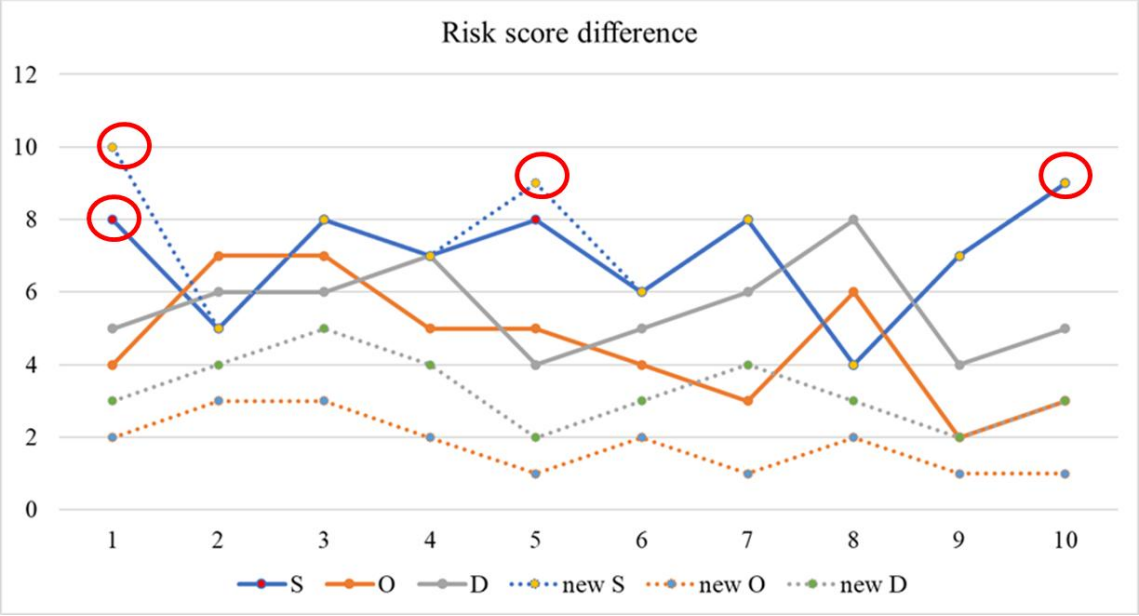

Figure 3. Risk score difference

With a high level of cable wear, the subsequent RPN score was observed to decrease by 63% from the previous RPN score due to a decrease in the probability of detection and discovery (Figure 4).

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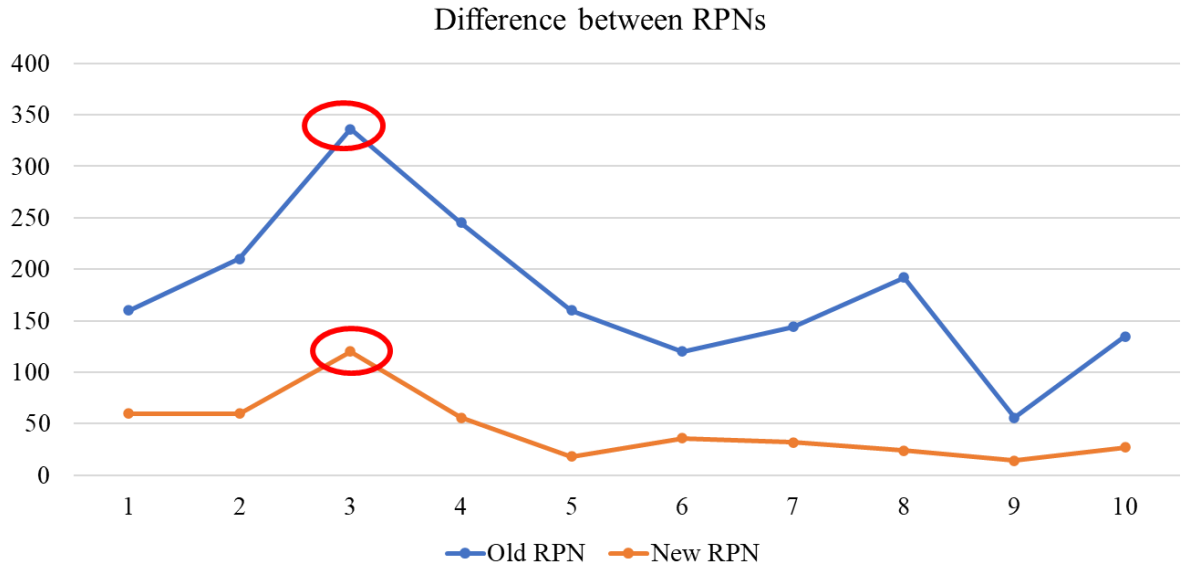

Figure 4. Difference between RPNs

Point 3 in Figure 4, i.e., due to the human factor causing diagnostic errors, the RPN exceeded 300, and as a result of corrective measures, this indicator was also reduced by 64%.

Conclusion.

In medicine, diagnosis has always been of great importance for treatment. The folk proverb "A correct diagnosis makes a patient healthy, an incorrect one makes him a fool" is relevant. Currently, the role and importance of ultrasound machines in medical diagnosis is incomparable. As a result of this study, we observed an increase in efficiency in reducing errors by applying the FMEA and Ishikawa methods to medical equipment.

As a result of this study, 10 main risks of ultrasound machines were identified, analyzed, and corrective measures were developed in the Andijan Diagnostic Center using the FMEA method. The initial average RPN decreased from 175.8 to 44.7 (74% reduction), which is fully compliant with the requirements of IEC 60601-2-37:2024 acoustic safety (TI≤1.0, MI≤1.9) and ISO 14971:2019 risk management.

The highest risk - focus error (RPN=336 to 120, i.e. 64% reduction) was eliminated using the multi-focus mode and checklist. TI/MI monitoring with auto-limitation system gave 90% efficiency (180→18). Ishikawa diagram divided the risks into 6M categories, showing Machine (30%) and Manpower (25%) as the largest risk sources.

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