

Risk assessment in accordance with DIN EN ISO 14971 for the length measuring system "Electronic Scale"

1. aim of the risk assessment

The aim is to identify, analyze and evaluate potential risks associated with the operation, maintenance and environment of the "Electronic Scale" length measuring system. Based on this, risk control measures are developed to ensure the safety of the system and conformity with DIN EN ISO 14971.

2. identification of risks

The risks of the system are divided into the following categories: ategories:

1. Operation

- **Measurement errors due to incorrect calibration or wear**: Inaccurate results due to wear on the reticle, the inductive strip or improper calibration.
- **Incorrect handling of the measuring slide**: damage to the mechanism due to incorrect use (e.g. excessive force applied).
- **Incorrect data transmission**: Incomplete or faulty transmission of measurement results to external devices via the RS232 interface.

2. Environmental conditions

- **Exceeding the temperature range**: Operation outside the specified +10 to +40°C may affect the electronics or the display.
- **Contamination of the guide rod**: Deposits can damage the sensors and mechanics.

3. Electronics

- **Battery failure**: Failure of the measuring function if the battery is empty or incorrectly inserted.
- **Damage to electronics due to improper maintenance**: Defective electronics due to improper handling during resetting or cleaning.

4. Ergonomics and ease of use

• **User strain**: Unsuitable operating posture without the use of microscopes or video systems can lead to physical discomfort (back, eyes).



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5. Accessories and integration

- **Incompatibility of accessories**: Incorrect measurement results due to the use of unsuitable graticules or optical systems.
- **Data loss due to interface problems**: USB interface or RS232 data transmission can lose or corrupt data.

3. Risk assessment

The assessment is based on the severity (S), probability (P) and recognizability (D) of the risks.

Risk	Severity (S)	Probability (P)	Recognizability (D)	Risk priority number (RPN)
Measurement error due to wear	Medium (3)	Medium (3)	High (1)	9
Incorrect handling of the car- riage	High (4)	Low (2)	Medium (2)	16
Data transmission error	Medium (3)	Medium (3)	High (1)	9
Exceeded temperature	Medium (3)	Low (2)	Medium (2)	12
Contamination Management staff	High (4)	Medium (3)	Medium (2)	24
Battery failure	Medium (3)	High (4)	High (1)	12
Electronic damage due to maintenance	High (4)	Low (2)	Medium (2)	16
Load on the user	Medium (3)	Medium (3)	High (1)	9
Incompatibility accessories	High (4)	Low (2)	Medium (2)	16
Data loss interface	Medium (3)	Medium (3)	High (1)	9



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4. Risk control measures

1. Technical measures

- **Ensure measuring accuracy**: Regular calibration and inspection of the measuring plates. Replace the graticule when worn.
- Protection against soiling: Introduce a cleaning concept with lint-free cloths and a suitable cleaner.
- **Temperature control**: Reference in the operating instructions to use only in the specified temperature range.

2. User friendliness

- **Improve ergonomics**: Promote microscope or video solutions to reduce physical strain.
- **Expand operating instructions**: Clear step-by-step instructions for calibration, maintenance and troubleshooting.

3. Interfaces and software

- **Ensure error-free data transmission**: Implementation of test protocols in the software for data validation.
- **Check accessory compatibility**: Clear labeling of compatible optical systems and accessories.

4. Training and documentation

- Training users in the proper handling and maintenance of the system.
- Detailed error message table in the operating instructions, including maintenance steps.

5 Residual risk and acceptance

Once the measures have been implemented, most risks are reduced to an acceptable level. There is a residual risk in the event of improper use and unforeseen mechanical or electronic defects.

6. Conclusion

The "Electronic Scale" length measuring system has typical risks for mechanical-electronic precision devices. However, the risks can be reduced to an acceptable level through appropriate maintenance, training and technical measures. Continuous risk management that takes user feedback into account is recommended.



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