UDecide

RISK MANAGEMENT REPORT   
DOCUMENT REFERENCE NUMBER: UD-RMR  
  
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SCOPE: This document contains a report from the risk management process. All results in this report can also be found in the risk analysis “UD-UM-analysis.xls”

REFERENCES: UD-RM-analysis

REVISION HISTORY:

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| --- | --- | --- | --- |
| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sofie Bjørn | 03.05-2021 | First version |
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APPROVAL:

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| --- | --- | --- | --- |
|  | *Name and job function* | *Signature* | *Date* |
| *Author:* |  | | |
| *Reviewer:* |  | | |
| *Independent reviewer:* |  | | |

Identified hazards:

1. Electric energy
2. Immunological, irritants
3. Operational, use error
4. Operational, function
5. Data availability
6. Patient identity and information

Subsequent potential harm:

1. Nerve damage
2. Skin irritation
3. Suboptimal treatment (from wrong input)
4. Suboptimal treatment (from outdated algorithm)
5. Deterioration of symptoms
6. Misuse of health information and identity

Risk evaluation:

In the risk evaluation each hazard is quantified through definitions regarding severity and probability of occurrence. The definitions are found in UD-RMP.

The product of these two values indicates a risk level, which must be below 8 to accept the risk.

Hazard number 3 regarding wrong input and hazard number 5 regarding data availability are the only ones accepted in the first evaluation.

The others have risk values of 8 - 12 and thus needs risk control measures.

Even though the hazard of wrong input is acceptable a risk control measure was defined to lower the risk further.

Risk control:

As risk control measures a list of additional requirements or design choices are listed. They are

* UDecide shall not be able to recommend a higher frequency than 20 Hz.
* UDecide shall recommend the treatment with the shortest stimulation time as possible. 🡪 UDecide shall highlight the recommended treatment with the shortest stimulation time.
* UDecide shall have a range check for inputs and show a warning to force the specialist to check twice.
* Periodically update of the system
* Validation of login

These are implemented in the UD-SRS with references to this risk analysis.

Residual risk evaluation:

* From the control measures all risk values are below the risk acceptance criteria. This means that all risks are accepted, when the control measures are implemented.