**UTreatment**

**Risk management file**

**Document reference number:** UT**-**RMF

**Scope:** This document contains the risk assessment and risk management for UTreatment.

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**References:** UT**-**RMR

**Revision history:**

| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| --- | --- | --- | --- |
| 1.0 | Emma Rothmann, Katrine Stephansen, Louise Leonhard and Saaluja Sriharan | 16.03.2022 | First version |
| 2.0 | Emma Rothmann and Saaluja Sriharan | 01.05-2022 | Second version |

**Risk analysis**

Identification of hazards and hazardous situations:

| **ID** | **Hazard** | **Cause of hazardous situation** | **Sequence of events** | **Hazardous situation** | **Harm** |
| --- | --- | --- | --- | --- | --- |
| H1 | Electric energy | Software failure | 1. UTreatment recommends a current above the patient’s personal limit.  2. Clinician agrees with UTreament recommendation. | Patient is exposed to high current | Uncomfortable sensation, skin irritation or bruising |
| H2 | Data  (access) | Software failure | 1. Login function fails | Unauthorized access is granted | Misuse of sensitive personal data |
| H3 | Data  (confidentiality) | Software failure | 1. Upload of sensitive personal data to cloud based solutions fails. | Unauthorized access is granted, permitting access to sensitive personal data | Misuse of sensitive personal data |
| H4 | Functionality | Software failure | 1. UTreatment recommends suboptimal stimulation strategy.  2. Clinician agrees with UTreament recommendation. | Worsening of patient symptoms | Potential impact on quality of life |
| H5 | Operational (user error) | Wrong input | 1. Clinician inputs wrong data | Patient receives suboptimal treatment. | Potential impact on quality of life |

**Risk evaluation and control**

| **ID** | **Severity** | **Probability** | **Risk** |
| --- | --- | --- | --- |
| H1 | 1 | 2 | Acceptable (2) |
| H2 | 4 | 1 | Acceptable (4) |
| H3 | 4 | 1 | Acceptable (4) |
| H4 | 2 | 4 | Not acceptable (8) |
| H5 | 2 | 5 | Not acceptable (10) |

| **Risk evaluation** | | **Risk control** | | |
| --- | --- | --- | --- | --- |
| **ID** | **Risk evaluation (acceptable / not acceptable)** | **Risk control option: Inherent safety by design** | **Risk control option: Protective measures** | **Risk control option: Information safety** |
| H4 | Not acceptable (8) | Design of user interface that allows clinicians to update patient information in UTreatment. |  |  |
| H5 | Not acceptable (10) |  | Implementation of an “approve”- button. |  |

Evaluation of residual risk

| **ID** | **Risk control** | | | |
| --- | --- | --- | --- | --- |
|  | **Risk control option:** | **Implementation of risk control measures (Ref to requirements and verifications)** | **Residual risk evaluation** | **Information to disclose in accompanying documents** |
| H4 | Inherent safety by design | References:  **requirements:**  FR4  **Verifications:**  VeTP3 and VeTR3 | Sev = 2  Prop = 3  Risk = 6  Acceptable | Not found |
| H5 | Protective measures | References:  **Requirements:**  FR5, FR11 and FR15  **Verifications:**  VeTP1, VeTR1, VeTP2, VeTR2, VeTP3 and VeTR3 | Sev = 2  Prop = 3  Risk = 6  Acceptable | Not found |

No additional risks have been identified after risk control. The risk evaluation and control are therefore finished.