UDecide

DOCUMENT TITLE   
DOCUMENT REFERENCE NUMBER:   
  
DATE:   
 REVISION NUMBER:

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SCOPE: This document contains….

REFERENCES:

REVISION HISTORY:

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| --- | --- | --- | --- |
| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
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APPROVAL:

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

Identification of hazards:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Hazard** | **Cause of hazardous situation** | **Sequence of events** | **Hazardous situation** | **Harm** |
| UD-H1 | Nerve damage | UCon stimulates at a frequency too high | 1. UDecide recommends a stimulation paradigm, and the specialist agrees.  2. UCon malfunctions and stimulates at a high frequency | Patient is exposed to high frequency stimulation | Nerve damage |
| UD-H2 | Deterioration of symptoms | Wrong recommendation or overall treatment. | 1. UDecide recommends a suboptimal stimulation paradigm  2. Specialist recommends the same  OR  The DGN stimulation is suboptimal for the specific patient | Patient is subject to suboptimal treatment. | Potentially increased impact on quality of life |
| UD-H3 | Chemical irritants | Use of surface electrodes with adhesive agent | 1. UDecide recommens a stimulation paradigm and the specialist agrees.  2. Patient uses the surface electrodes and feels irritation on the skin | Patient is exposed to adhesive gel that can irritate the skin | Irritation of the skin |

Quantification of risk:

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Severity** | **Probability** | **Risk** |
| UD-H1 | Serious (3) | Remote (2) | 6 |
| UD-H2 | Negligible (1) | Frequent (5) | 5 |
| UD-H3 | Minor (2) | Occasional (3) | 6 |

Risk control

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ID | Acceptance? | Control measure | New risk score: |  |
| UD-H1 | Acceptable according to table “Risk acceptance criteria” | Frequency settings lies with InnoCon. |  |  |
| UD-H2 | Acceptable |  |  |  |
| UD-H3 |  | UDecide can use “sensitive skin” as an input and thus prioritize the percutaneous electrode |  |  |