UDecide

Validation test protocol 01   
DOCUMENT REFERENCE NUMBER: UD-VaTPr01  
  
DATE: 06-05-2021  
 REVISION NUMBER: 2.0

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SCOPE: This document contains the verification test protocol for UD-CRS-01, UD-CRS-03, UD-CRS-04, UD-CRS-05, UD-CRS-06, UD-CRS-07 and UD-CRS-10. A traceability between

REFERENCES:

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sigrid Stang | 05-05-2021 | First version of validation test protocol number 01. |
| 2.0 | Emma Elbo | 06-05-2021 | Second version of validation test protocol number 01. Acceptance criteria, prerequisites, test subjects and procedure are added. |
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APPROVAL:

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

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| **CRS ID** | **Requirement** |
| UD-CRS-01 | The UDecide system shall assist the specialist in clinical practice in choosing the most beneficial stimulation paradigm |
| UD-CRS-03 | The UDecide system shall have a simple graphical user interface to the specialist in clinical practice. |
| UD-CRS-04 | The UDecide system shall be simple to integrate in the current workflow and in the clinical environment. |
| UD-CRS-05 | The UDecide system shall be based on an algorithm, that takes in inputs which are already registered in clinical practice. |
| UD-CRS-06 | The output of the UDecide system shall support the dialogue between the specialist and the patient when deciding which stimulation paradigm should be used in the treatment. |
| UD-CRS-07 | The output of the UDecide system shall recommend treatment strategies attached to an “effectiveness score” |
| UD-CRS-10 | The UDecide system shall be able to take patient preferences as update to the output of the algorithm. |

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| **TestID** | VaTPr01 |
| **Acceptance criteria** | The OAB specialist considers the system to be a supportive tool for choosing stimulation treatment for the patient and for the system to support the dialogue between the OAB specialist and the patient. |
| **Prerequisites** | The UDecide system is implemented in clinical practice and has been used in minimum ten consultations. |
| **Test subjects** | The OAB specialist |
| **Procedure** | 1. Make an interview guide based on the UD-CRS-01, UD-CRS-03, UD-CRS-04, UD-CRS-05, UD-CRS-06, UD-CRS-07 and UD-CRS-10 requirements and the OAB specialist use of the UDecide system. 2. Conduct the interview with the OAB specialist. 3. Analyze, based on the interview, whether the requirements are met. |