UDecide

Validation test report 01   
DOCUMENT REFERENCE NUMBER: UD-VaTR01  
  
DATE: 07-05-2021  
 REVISION NUMBER: 1.0

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SCOPE: This document contains the validation test report for UD-CRS-01, UD-CRS-03, UD-CRS-04, UD-CRS-05, UD-CRS-06, UD-CRS-07 and UD-CRS-10.

REFERENCES: UD-CRS

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Emma Elbo | 07-05-2021 | First version of validation test report number 01. |
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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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| **Test ID** | **VaTR01** |
| **Test protocol** | VaTP01 |
| **Results** | Not conducted |
| **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. |
| **Validated** | Not validated |