UDecide

CUSTOMER REQUIREMENTS SPECIFICATION  
DOCUMENT REFERENCE NUMBER: UD-CRS  
  
DATE: 05-04-2021  
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SCOPE: This document contains customer requirements for the UDecide information system.

REFERENCES:

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sigrid Stang, Sofie Bjørn, Emma Elbo & Amalie Koch | 16-03-2021 | First version |
| 2.0 | Emma Elbo & Amalie Koch | 23-03-2021 | The customer requirement specification has been updated based on the information collected from a meeting with InnoCon Medical and based on an interview with a Gynecologist. |
| 2.1 | Amalie Koch | 05-04-2021 | Requirements UD-CRS-12 and UD-CRS-13 is added. Regarding that the UDecide system should be able to create a patient profile and able to save data. |
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APPROVAL:

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

**Custumer requirement specification**

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| **UD-CRS-ID** | **CUSTOMER REQUIREMENT SPECIFICATION** |
| UD-CRS-01 | The UDecide system shall assist the specialist in clinical practice in choosing the most beneficial stimulation paradigm |
| UD-CRS-02 | The UDecide system shall be compatible with the product UCon, by InnoCon Medical |
| 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-08 | The output of the UDecide system concerning stimulation paradigm shall be compatible with the stimulation possibilities that the UCon stimulator provide |
| UD-CRS-09 | The UDecide system shall be able to update the algorithm periodically based on data from UCon |
| UD-CRS-10 | The UDecide system shall be able to take patient preferences as update to the output of the algorithm |
| UD-CRS-11 | The output of the UDecide system shall weight the output, so that a minimal stimulation-time relative to high effect is weighted as the most beneficial stimulation paradigm |
| UD-CRS-12 | The UDecide system should be able to create patient profiles for the OAB patients. |
| UD-CRS-13 | The UDecide system should be able to save the data from the output of the algorithm. This data should be saved to the patient’s profile in the UDecide system. |