UDecide

SYSTEM REQUIREMENTS SPECIFICATION  
DOCUMENT REFERENCE NUMBER: UD-SRS  
  
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SCOPE: This document contains system requirement specifications (SRS) for the UDecide information system. A document with traceability between SRS, customer requirement specification and risk management can be seen in document: UD-SRS-traceability.

REFERENCES:

UD-SRS-traceability

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sofie Bjørn & Amalie Koch | 07-04-2021 | First version of the system requirement specification for the UDecide system. |
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APPROVAL:

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

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| **SRS ID** | **Requirement** |
| UD-SRS-01 | The interface shall recommend and visualize at least three treatment strategies for the specialist |
| UD-SRS-02 | The interface shall rank the recommended  treatment strategies from best expected effect |
| UD-SRS-03 | The interface shall convey practical information about the treatment to the specialist. The practical information shall include a describtion of the electrode and typical usage. |
| UD-SRS-04 | The predetermined parameters defined by InnoCon Medical shall be implemented in the algorithm and outputted on the interface. |
| UD-SRS-05 | The Udecide system shall consist of three user interfaces: Login, Choose patient and Estimate effectiveness score |
| UD-SRS-06 | User interface "Estimate effectiveness score" shall contain information about stimulation paradigm, parameters and effectiveness score to give the specialist the opportunity to get a quick overview. |
| UD-SRS-07 | The output shall be visualized for the specialist in a list of the recommended treatment strategies |
| UD-SRS-08 | The output shall be conveyed through graphs and graphical illustrations |
| UD-SRS-09 | The information from the output shall be conveyed in medical terms |
| UD-SRS-10 | The treatment strategy with the best expected effect shall be highlighted |
| UD-SRS-11 | The Udecide system shall be compatible with a computer |
| UD-SRS-12 | The software shall be programmed in a platform independent language |
| UD-SRS-13 | The system shall be able to take inputs to the algorithm entered by the specialist. Those inputs shall be: sex, age, OAB symptoms and data collected from specific OAB-test in clinical practice |
| UD-SRS-14 | The output of the system shall represent pros and cons for each recommended treatment strategy |
| UD-SRS-15 | The output of the system shall be graphically represented |
| UD-SRS-16 | The Udecide system shall inform the specialist, which impact the treatment will have for the patient's every day. |
| UD-SRS-17 | The recommended treatment strategies shall contain specific stimulation paradigm, specific stimulation parameters and an attached effectiveness score. The effectiveness score shall be represented as a percentage. |
| UD-SRS-18 | Stimulation paradigm recommended in the output from the Udecide system shall be either: "Urge", "Time Limited" or "Constant". The output of stimulation parameter: "Intensity limit" shall be divided into 5 levels (level 1 = low, level 5 = high) and the output of stimulation parameter "Session time" shall be either: "60 second", "15 minutes", "30 minutes", "4 hours" or "constant". |
| UD-SRS-19 | The Udecide system shall be connected to a database. |
| UD-SRS-20 | Patient preferencenses shall be an opportunity to input through check boxes . |
| UD-SRS-21 | The recommended treatment with the least time of stimulation pr. day shall be highlighted on the interface. Time of stimulation pr. day is calculated based on stored data in the database. |
| UD-SRS-22 | The "Choose patient" interface shall include input fields for creating a new patient profile. Those field shall be: "CPR", "Name" and "Sex". The patient profile shall be stored in the database. |
| UD-SRS-23 | The "Login" interface shall consist of a "Username" and "Password" to enter the Udecide system, to secure protection against unauthorised acces. |