UDecide

SYSTEM REQUIREMENTS SPECIFICATION  
DOCUMENT REFERENCE NUMBER: UD-SRS  
  
DATE: 07-04-2021  
 REVISION NUMBER: 1.0

*AUTHOR:* Sofie Bjørn & Amalie Koch

*REVIEWER:* Sigrid Stang & Emma Elbo

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. |
| 2.0 | Sofie Bjørn | 21-04-2021 | Update of requirements according to guidance from Suzan and group discussion in plenum. Including alignment of spelling. |
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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** | **Functional requirements** |
| UD-SRS-01 | The interface shall recommend and visualize three treatment strategies for the specialist |
| UD-SRS-02 | The interface shall rank the recommended treatment strategies from best to least expected effect |
| UD-SRS-03 | The interface shall convey practical information about the treatment to the specialist. The practical information shall include a description of the electrode and typical usage. |
| UD-SRS-04 | The predetermined parameters defined by InnoCon Medical shall be shown on the interface. |
| UD-SRS-05 | The UDecide system shall consist of three functionalities: Login, search patient and estimate effectiveness score and report effect. |
| UD-SRS-06 | The user interface "Estimate effectiveness score" shall contain information about stimulation paradigm, parameters and effectiveness score to give the specialist the opportunity to get an overview. |
| UD-SRS-07 | The system shall be able to update the algorithm with new data on the research field periodically. |
| UD-SRS-08 | The output shall be conveyed through 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-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 clinical practice. |
| UD-SRS-16 | The algorithm shall be based on data from UCon collected by InnoCon Medical. |
| 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 seconds, 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 regarding electrode type, shall be an opportunity to input to the Udecide system. |
| UD-SRS-21 | The recommended treatment with the least time of stimulation pr. day shall be highlighted on the interface. |
| UD-SRS-22 | The "Search patient" interface shall include input fields for creating a new patient profile. Those field shall be: CPR, Name and Gender. The patient profile shall be stored in the database. |
| UD-SRS-23 | The Udecide system shall validate that user access is granted |

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| **SRS ID** | **Non-functional requirements** |
| 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-17 | The Udecide system shall handle patient data in accordance to general data protection regulation (GDPR) |