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. |
| 2.0 | Sofie Bjørn | 21-04-2021 | Update of requirements according to guidance from Suzan and group discussion in plenum. Including alignment of spelling. |
| 3.0 | Sigrid Stang & Sofie Bjørn | 02-05-2021 | Added requirement about the effect. General wording and the order of appearance has been corrected - also in related documents. |
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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 requirement** |
| UD-SRS-01 | The UDecide system shall consist of four functionalities: login, search patient, estimate effectiveness score and report effect. |
| UD-SRS-02 | The UDecide system shall recommend and visualize three treatment strategies for the specialist |
| UD-SRS-03 | The UDecide system shall be able to calculate an effectiveness score based on inputs regarding symptoms before and after treatment. |
| UD-SRS-04 | The UDecide system shall rank the recommended treatment strategies from best to least expected effect |
| UD-SRS-05 | The treatment strategy with the best expected effect shall be highlighted |
| UD-SRS-06 | Each recommended treatment strategy shall contain information about stimulation paradigm, parameters, and effectiveness score to give the specialist the opportunity to get an overview. |
| UD-SRS-07 | The interface shall convey cautionary notes about the treatment to the specialist. |
| UD-SRS-08 | The recommended treatment with the least time of stimulation pr. day shall be highlighted in the recommendation. |
| UD-SRS-09 | The system shall be able to take inputs to the algorithm entered by the specialist. Those inputs shall be: gender, age, number of incontinence episodes, number of daily urinations, nocturia, number of urgency episodes, bladder capacity, detrusor overactivity and quality of life. |
| UD-SRS-10 | The UDecide system shall have a range check on the data input from the specialist |
| UD-SRS-11 | Stimulation paradigm recommended in the output from the UDecide system shall be either: urge, time limited or constant, and the recommended session time shall be either: 60 seconds, 15 minutes, 30 minutes, 4 hours or constant. |
| UD-SRS-12 | The predetermined stimulation parameters defined by InnoCon Medical shall be shown on the interface. |
| UD-SRS-13 | Information on the actual use of UCon shall be conveyed through graphical illustrations |
| UD-SRS-14 | The questionnaire and the subsequent recommendation shall be conveyed in medical terms |
| UD-SRS-15 | Patient preferences regarding electrode type, shall be possible to input in the UDecide system |
| UD-SRS-16 | The patient profile interface shall include input fields for creating a new patient profile. Those fields shall be: CPR, name, age and gender. |
| UD-SRS-17 | The UDecide system shall only grant access for validated users. |
| UD-SRS-18 | The UDecide system shall be connected to a cloud-based database. |
| UD-SRS-19 | The UDecide system shall be able to update the algorithm with new data on the research field periodically. |
| UD-SRS-20 | The patient profile, questionnaire, chosen treatment and treatment effect shall be stored in the database. |

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| **SRS ID** | **Non-functional requirement** |
| UD-SRS-21 | The UDecide system shall be compatible with a computer |
| UD-SRS-22 | The software shall be programmed in a platform independent language |
| UD-SRS-23 | The UDecide system shall handle patient data in accordance to general data protection regulation (GDPR) |