UDecide

Validation test report 02   
DOCUMENT REFERENCE NUMBER: UD-VaTR02  
  
DATE: 13-05-2021  
 REVISION NUMBER: 2.0

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SCOPE: This document contains the validation test report for UD-CRS-02 and UD-CRS-08.

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 02. |
| 2.0 | Emma Elbo | 13-05-2021 | Added test results to the report |
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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-02 | The UDecide system shall be compatible with the product UCon, by InnoCon Medical |
| UD-CRS-08 | The output of the UDecide system concerning stimulation paradigm shall be compatible with the stimulation possibilities that the UCon stimulator provides. |

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| **Test ID** | **VaTR02** |
| **Test protocol** | VaTP02 |
| **Results** | The UDecide system can recommend following treatment strategy:   * Timed limited stimulation: 4 hours (Intensity: low to high) * Timed limited stimulation: 30 minutes (Intensity: low to high) * Timed limited stimulation: 15 minutes (Intensity: low to high) * Constant stimulation: 24 hours/constant (Intensity: low to high) * Urge stimulation: 60 seconds (Intensity: low to high)     Concludes, the UDecide recommended treatments are compatible with the UCon device |
| **Acceptance criteria** | The UDecide system can be used to choose a treatment paradigm that exist in the UCon device. |
| **Validated** | Validated |