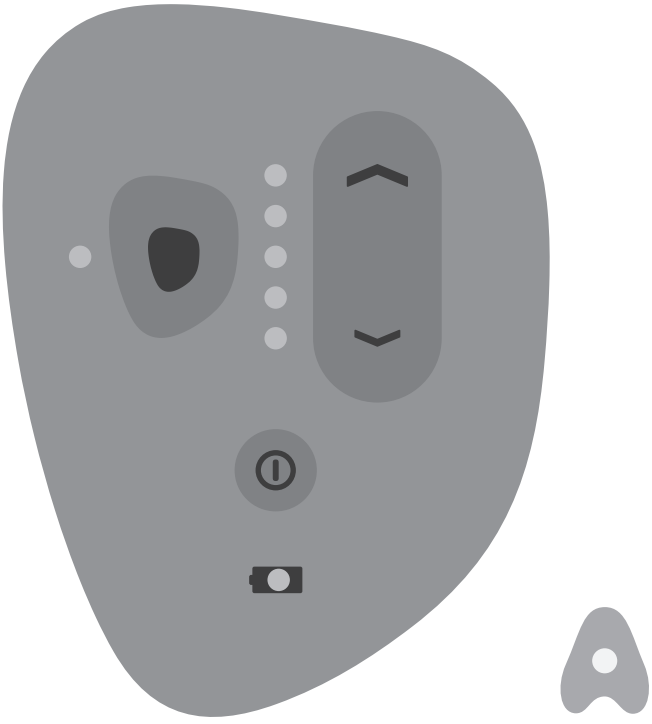
User Manual

for UCon Nerve Stimulator

using Patch Electrode



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1 General Information

1.1 Introduction to UCon

UCon is a nerve stimulator intended for treatment of the symptoms of overactive bladder and bowel dysfunction in humans (see section 3.2.1). UCon electrically stimulates the dorsal genital nerve at the genitals to obtain modulated behaviour of the bladder/bowel musculature e.g., suppressing undesired bladder/bowel activity to relieve the symptoms of the patient (see section 3.2).

UCon consists of the following components (Figure 1):

1. **Control Unit,** which provides electrical stimulation.
2. **Two Electrodes** *(cathode and anode)*, one **Patch Electrode** (cathode), which is attached to the skin at the genitals, and one **Neutral Electrode** (anode) attached to the skin nearby. The Electrodes transfers electrical stimulation from the Control Unit (through the Lead) to the nerve.
3. **Patch Electrode Lead**, which connects the Electrodes to the Control Unit.
4. **Remote Control (optional),** which allows for remote activation of Urge stimulation on the Control Unit.
5. **Charger,** for charging the Control Unit.
6. **Programming Sheet** (only available for healthcare provider), which allows for adjustment of settings of the Control Unit.
7. **Data Transfer Unit** (only available for healthcare provider), which transfers use data from the Control Unit to a computer.

Operating principle

UCon includes a wearable rechargeable Control Unit, which generates electrical pulses. The electrical pulses are delivered from the Control Unit through the Lead to the Electrodes, which enables activation of the nerve, to relieve symptoms.

The electrical pulses can be applied in two different stimulation modes either as Time Limited- or Urge stimulation.

- In Time Limited stimulation, stimulation is provided in time limited sessions (session time: 15 min - continuous). When set to 15 minutes – 4 hours, the stimulation will stop automatically, when the time runs out. When set to continuous, the stimulation will continue until stopped by the user.
- Urge stimulation is activated by pressing the Urge button on the Control Unit or the Remote Control when the user feels urgency. Stimulation will then persist for 60 seconds and automatically turn off until next activation. Urge stimulation can also be stopped before the 60 seconds by pressing the Urge button again.

The healthcare provider configures the stimulation settings of the Control Unit using the Programming Sheet. In order to assess how the user uses the device, the healthcare provider can use the Data Transfer Unit to extract data from the Control Unit. When the Control Unit is connected to a computer via the Data Transfer Unit, the data log is available on the computer. The data log contains information about the user's use of the device, e.g., the duration of stimulation each day, the stimulation intensity, and the mode of stimulation.

1.2 Contents of UCon

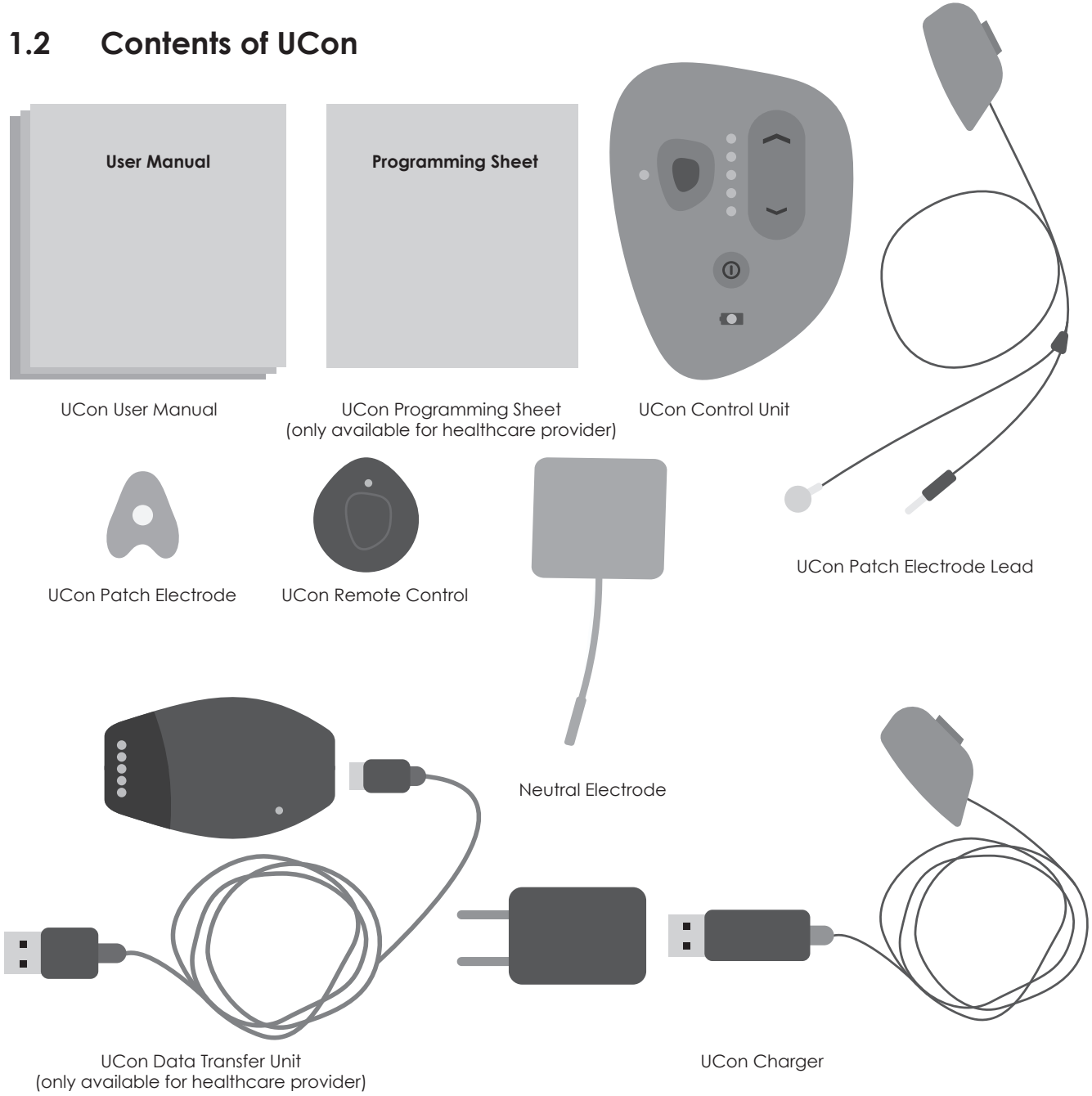


Figure 1: UCon Components

UCon Components	Catalogue No.
UCon Control Unit	90-00-0003
UCon Remote Control	90-00-0004
UCon Programming Sheet [en]	90-00-0030
UCon Charger	90-00-0006
UCon Data Transfer Unit	90-00-0008
UCon Patch Electrode (cathode)	90-00-0027
UCon Patch Electrode Lead	90-00-0010
UCon User Manual (Patch Electrode) [en]	90-00-0029
Neutral Electrode (anode)	90-00-0026

1.3 List of symbols

Symbol	Description
	Temperature limitations
	Keep away from sunlight
	Keep dry
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Medical device
	Single patient multiple use

Symbol	Description
	Quantity
	Type BF applied part
	International protection degree
	Magnetic Resonance (MR) Unsafe
	Direct current
	Class II equipment
	Consult (electronic) instructions for use
	CE mark
	Electronic equipment: Disposal in accordance with Waste Electrical and Electronic Equipment EC Directive (WEEE). Disposal in accordance with Battery and Accumulator Directive 2006/66/EC.

1.4 Warnings and Precautions

1.4.1 Electromagnetic Interference

WARNING: Electromagnetic interference (EMI) may disturb the function of UCon causing it to malfunction. UCon includes functions that protects itself from EMI, and therefore electrical devices and magnets encountered in most environments are unlikely to cause any disturbance of UCon. Strong electromagnetic interference can however result in unwanted or excessive stimulation, lack of stimulation, heating of device, and other device malfunction, which can cause tissue damage.

Use of UCon adjacent to or stacked with other equipment should be avoided as it can result in improper operation. If such use is necessary, UCon and the other equipment should be observed to verify that they are operating normally.

Portable Radio Frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of UCon including cables. Otherwise, degradation of the performance of UCon could occur.

For information on sources of EMI and instructions to reduce risks from EMI, see section 4.8.

1.4.2 MRI Safety Information

WARNING: UCon is MR unsafe. Keep it outside the MRI scanner room.
UCon components present a projectile hazard.

1.4.3 Medical Procedures

WARNING: For medical procedures where an energy is induced to the body of the patient, UCon must be removed. This includes MRI, electrical stimulation (TENS/EMS/NMES), cardioversion, surgical diathermy (electrosurgery/electrocautery), shortwave diathermy (shortwave therapy), microwave diathermy (microwave therapy), and ultrasonic diathermy (therapeutic ultrasound).

For similar medical procedures (e.g., diagnostic imaging (CT, X-ray, ultrasound), radiation therapy), it should also be considered to remove UCon or monitor the functioning of UCon during initial stages of the medical procedure.

In case of medical monitoring devices (EEG, ECG, etc.) the Control Unit should be turned off and Lead disconnected from Electrodes to prevent electrical signals from the Control Unit to interfere with the measurement.

1.4.4 Other Potential User Hazards

WARNING: Be aware that application of Electrodes near the thorax may increase the risk of cardiac fibrillation.

WARNING: Do not apply stimulation:
- Across or through the head
- Directly on the eyes
- Covering the mouth
- On the front of the neck (especially the carotid sinus)
- On the chest and the upper back or crossing over the heart

WARNING: The product contains small components and leads and pose a risk of strangulation/asphyxiation if these components are inhaled, swallowed, or wrapped around the neck.

WARNING: Do not touch the connector contact points on the Lead when stimulating, as it may cause electric shock.

WARNING: Always inspect the packaging of UCon for breaches or damages prior to use. If UCon is damaged e.g., have visible cracks, do not use it, and contact your UCon healthcare provider or InnoCon Medical. Similar, if UCon does not work properly e.g., shows reduced performance, or you feel unwell, or experience pain stop using it immediately.

WARNING: Do not use electrodes and leads other than those specified or provided by InnoCon Medical, as it could result in device malfunction and cause tissue damage.

1.4.5 Usage Situations

CAUTION: Take precautions of using UCon in the following situations:

- After charging the Control Unit, as it may temporarily be uncomfortably warm to carry on body.
- On injured or irritated skin. Electrodes are to be used on intact skin only.
- In humid environments. UCon should be removed when bathing and showering.
- In environments above 40°C, as UCon may be too warm to carry on body.
- Near strong electromagnetic fields (see section 4.8 for more information on EMI related hazards).
- During sexual activity to avoid dislocation of Patch Electrode or unwanted electrical stimulation e.g., of sexual partner. UCon should be removed before engaging in sexual activity.
- During postural changes, and other physical activities, as it may cause a perceived increase in electrical stimulation, which can feel uncomfortable (jolting or shocking sensation). The stimulation intensity should be reduced before engaging in activities that could be unsafe during an unexpected perceived increase in electrical stimulation (e.g. driving, operating power tools).
- In close proximity to credit cards etc., as the magnets of UCon might compromise the functionality of the credit card.

If having troubles to read the visual signals from the Control Unit in direct sunlight, shift position of the Control Unit to let shadow allow for easier reading.

1.4.6 Avoid Extreme Temperatures

WARNING: Avoid exposure of the Control Unit and the Remote Control to temperatures above 60°C, as it may damage the batteries.

1.4.7 Use in Specific Populations

The safety and performance of UCon therapy has not been concluded, and will not be established for:

- Pregnant women, the unborn foetus, and during delivery.
- Paediatric use.
- Individuals with an implanted electronic device (e.g., a cardiac pacemaker). Specialist medical opinion must be obtained.

1.4.8 Healthcare Provider Training

Prescribing healthcare providers should be trained in the use of UCon and be experienced in the diagnosis and treatment of disorders of the pelvis, lower urinary- or intestinal tract.

1.5 Potential Risks / Side Effects

Use of UCon entails risks. These risks include, but are not limited to:

- Transient pain from intense/unexpected stimulation, tingling, or feeling of numbness at stimulation site.
- Irritation or redness at stimulation site.
- Lack of effectiveness on bladder/bowel symptoms.
- Adverse change in voiding function (bladder and/or bowel).
- Change in sexual function.
- Skin reactions to / contact injuries from the material of UCon components, which are in continual contact with the body.

Note that any serious incidents that have occurred due to UCon shall be reported to the manufacturer (section 1.7) and the local responsible authority.

1.6 Component Disposal

For environmental reasons, part of the device may not be disposed of in the household waste at the end of its useful life. Dispose of the device components in accordance with EC directive – WEEE (Waste Electrical and Electronic Equipment and 2006/66/EC battery and accumulators). If in doubt, please contact the local authorities responsible for waste disposal.

The UCon components should be disposed of as follows:

UCon Component	Disposal
Control Unit	Disposed of as electronics
Remote Control	
Patch Electrode Lead	
Charger	
Data Transfer Unit (healthcare provider only)	
Programming Sheet (healthcare provider only)	
Patch Electrode (cathode)	Disposed of as household waste
Neutral Electrode (anode)	
User Manual	

1.7 Manufacturer and Contact Information

InnoCon Medical can provide help and assistance if needed for setting up, using or how to maintain UCon, or in case of unexpected operation or events. Please contact as follows:

InnoCon Medical ApS, Lyngvej 1 9000 Aalborg, DK
www.innoconmedical.com, ucon@innoconmedical.com, +45 93 98 70 33

2 Information for UCon Users

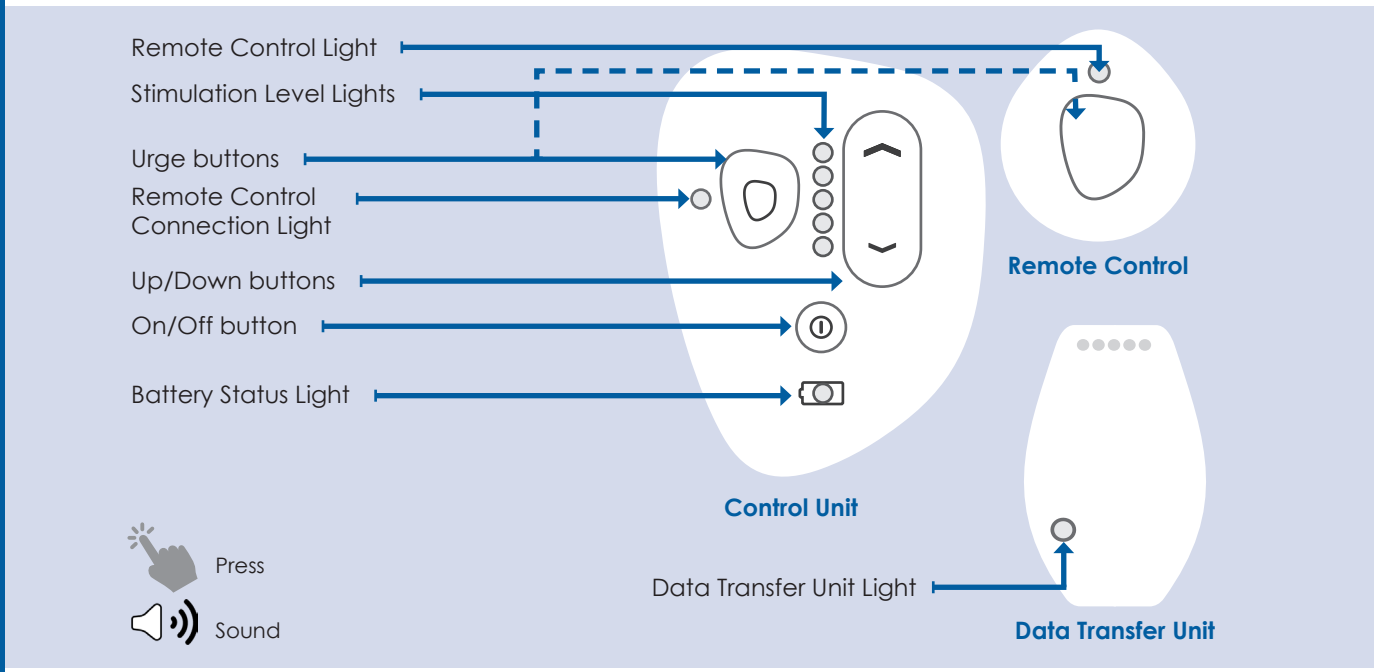
2.1 What is Nerve Stimulation?

Nerve stimulation is a treatment method to relieve various symptoms. The method uses targeted delivery of stimulus, such as electrical stimulation, to alter the nerve activity at specific sites in the body.

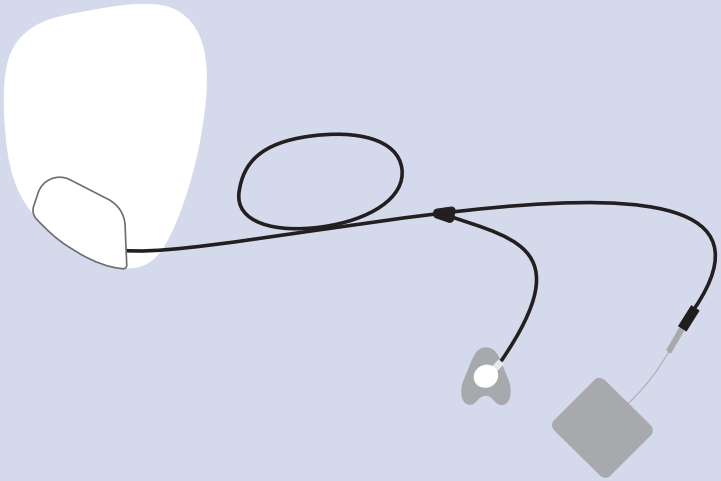
The aim of nerve stimulation for relieving the symptoms of overactive bladder and bowel dysfunction is to induce a therapeutic response directly and acutely or to modulate the behaviour of the lower urinary tract/intestine over time.

2.2 How to use UCon

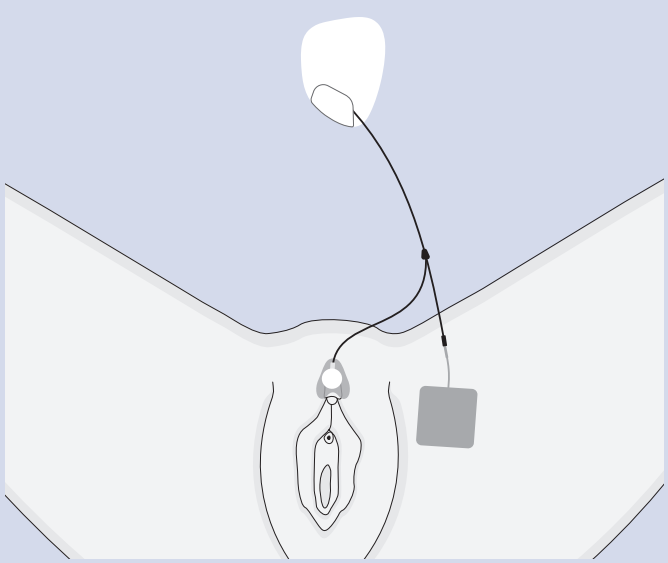
2.2.1 Illustration of UCon

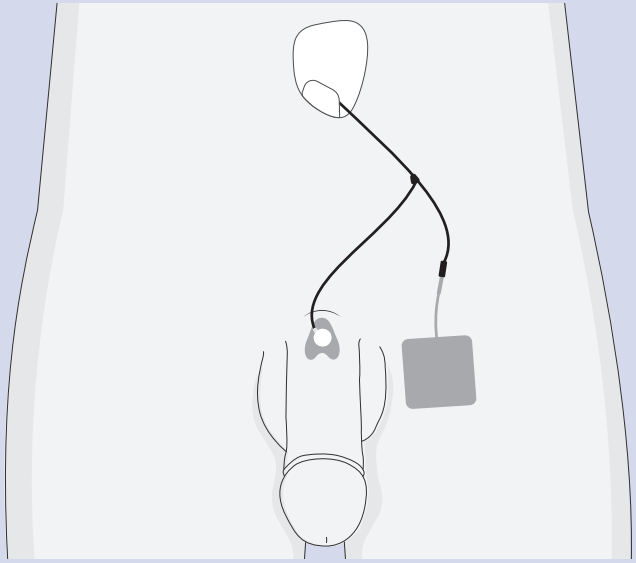


UCon assembled



UCon applied





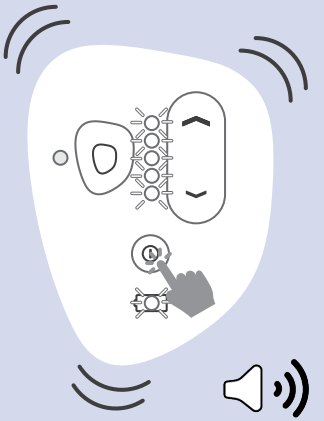
2.2.2 Turn the Control Unit On/Off

Turn on the Control Unit

1. Press and hold the On/Off button ⏻.

The Control Unit will flash the lights, beep, vibrate, and leave the Battery Status Light turned on ⊂⊃.

If the Lead is connected, bottom Stimulation Level Light will start pulsing.

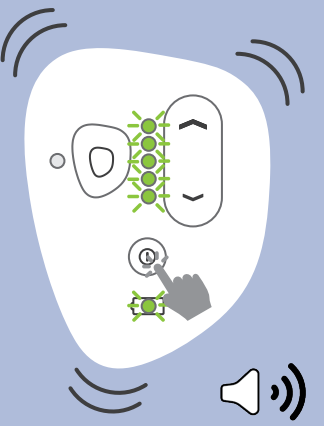


When the Control Unit has not been used for a while, all lights will turn off, except for the Battery Status Light, which will pulse (in colour of battery status).

Turn off the Control Unit

1. Press and hold the On/Off button ⏻.

The Control Unit will flash the lights (in colour of the battery status), beep, vibrate and leave all lights turned off.



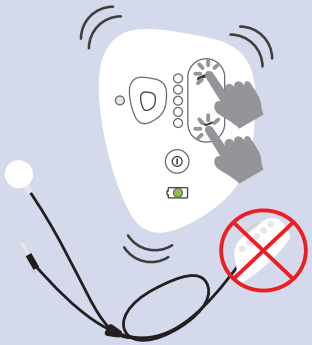
2.2.3 Mute/Unmute the Control Unit

Notice that to mute/unmute the Control Unit, the Control Unit must be turned on and leads must **not** be connected.

Mute the Control Unit

1. Press and hold the Up and Down buttons simultaneously.

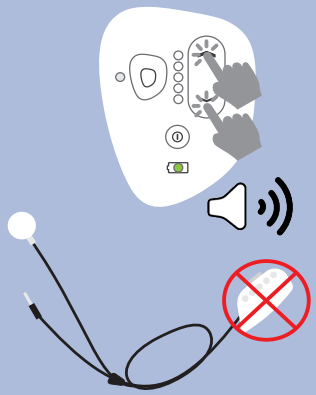
The Control Unit will vibrate, notifying that the Control Unit is muted. All sound notifications from the Control Unit will now be vibration notifications instead.



Unmute the Control Unit

1. Press and hold the Up and Down buttons simultaneously.

The Control Unit will beep, notifying that the Control Unit is unmuted. All sound notifications from the Control Unit will now be active again.



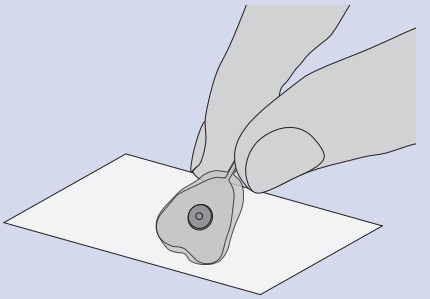
2.2.4 Electrodes

Make sure that:

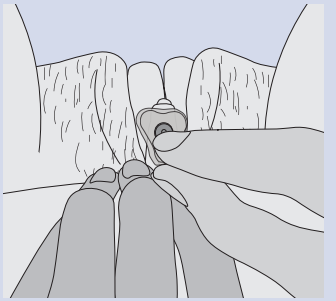
- The Control Unit is not connected.
- The Electrodes do not touch each other.
- The Patch Electrode do not block the urinary outlet.
- No pubic hair is under the Electrodes.
- Skin is clean, dry, and free from lotion.

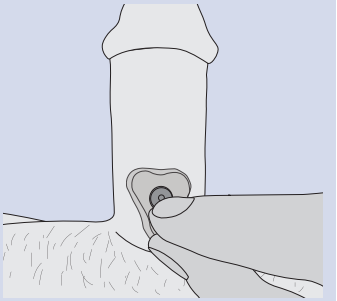
Place the Electrodes

1. Grab the handle of one Patch Electrode and remove from foil.

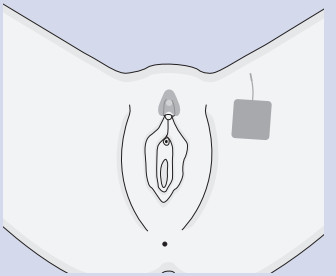


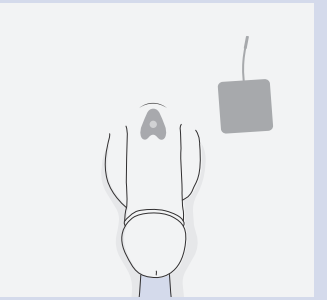
2. Place one Patch Electrode on clitoris or skin fold on top of the clitoris (female) / root of the penis (male).





3. Place one Neutral Electrode nearby e.g., on the inner thigh, in the groin, or on the penis (male).





During toileting the Patch Electrode placed at the clitoris (female) / root of the penis (male) can be removed and placed nearby. Afterwards the Patch Electrode can be placed correctly again. If prefered, the Patch Electrode can also be kept in place during toileting.

Remove the Electrodes

1. Pull the Electrodes off the skin and dispose the Electrodes (see section 1.6).

The Neutral Electrode can be reused according to the guidance on the bag of the Neutral Electrodes.

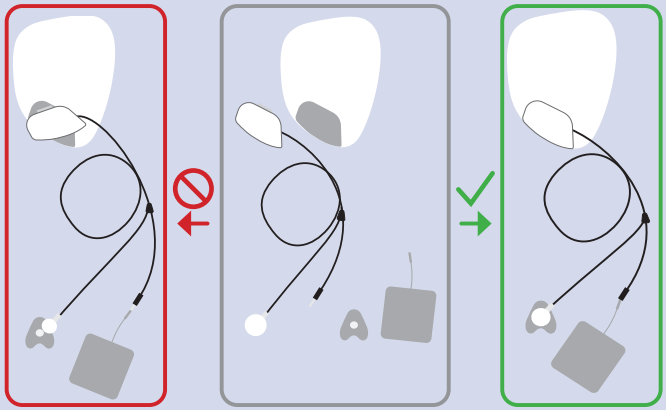
2.2.5 Patch Electrode Lead

Make sure that the Lead is clean and correctly connected to the Control Unit and the Electrodes to avoid:

- Loss of proper connection due to dirt or foreign elements.
- Pinching the skin or genital hair.

Connect Patch Electrode Lead

1. Connect the Patch Electrode and the Lead by use of the magnetic connection.
2. Connect the Neutral Electrode and Lead by inserting pin connection of the Lead into the Neutral Electrode. Make sure that the pin connection is sufficiently inserted into the Neutral Electrode.
3. Connect the Lead to the Control Unit by use of magnetic connection.



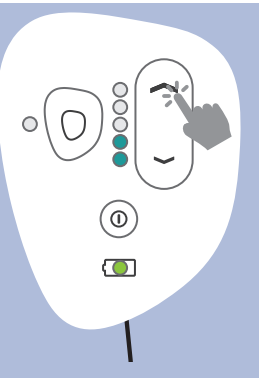
2.2.6 Start/Stop Stimulation

Start Time Limited stimulation

1. Turn on the Control Unit (see section 2.2.2).
2. Press and hold the Up button (⌒).

The Stimulation Level Lights (depicted by turquoise Stimulation Level Lights) will go up as the stimulation level increases.

3. Release the Up button when the desired stimulation level has been reached.

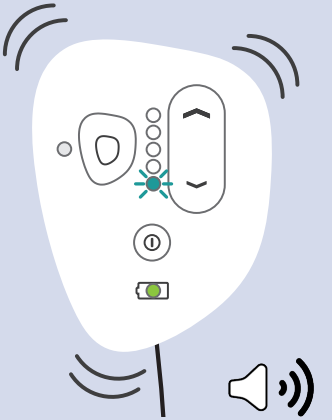


Notice that after the first use of the Control Unit, the stimulation will slowly increase to the previous set stimulation level, when the Up button is pressed once. Press the Down button when the desired stimulation level has been reached.

Automatic stop of Time Limited stimulation

When the Time Limited stimulation is done, the stimulation will stop automatically.

The Control Unit will flash with the bottom Stimulation Level Light, beep, and vibrate.



Manual stop of Time Limited stimulation

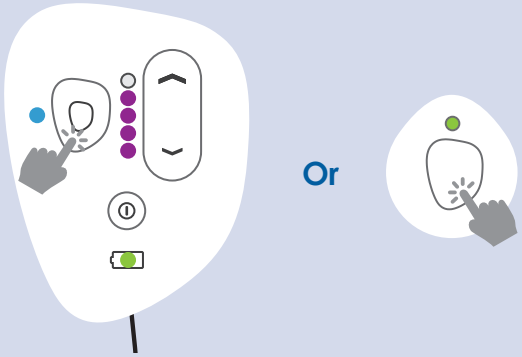
1. Press the On/Off button ⏻.

The stimulation will stop immediately.

Start Urge stimulation

1. Press the Urge button on the Control Unit or Remote Control .

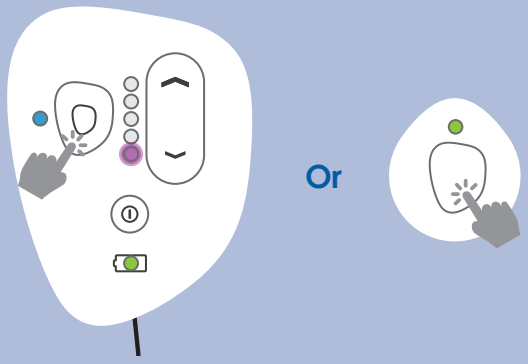
The Control Unit will stimulate with set stimulation level (depicted by purple Stimulation Level Lights) for 60 seconds and the stop stimulation automatically.



Stop Urge stimulation

1. Press the Urge button on the Control Unit or Remote Control .

The stimulation will stop immediately.



Notice that continued activation of Urge stimulation is not a substitute for voiding, and eventually the natural reflexes of voiding will overcome the stimulation resulting in loss of urine/faeces.

When the Stimulation Level Lights are on, the stimulation level of the ongoing stimulation can be adjusted by pressing the Up/Down buttons.

2.2.7 Unable to Deliver Stimulation

The Control Unit will inform when it is unable to deliver the set stimulation level e.g., due to inadequate connection of the Electrodes to the skin, dirt on Lead connections or Lead gets disconnected from the Control Unit or the Electrodes.

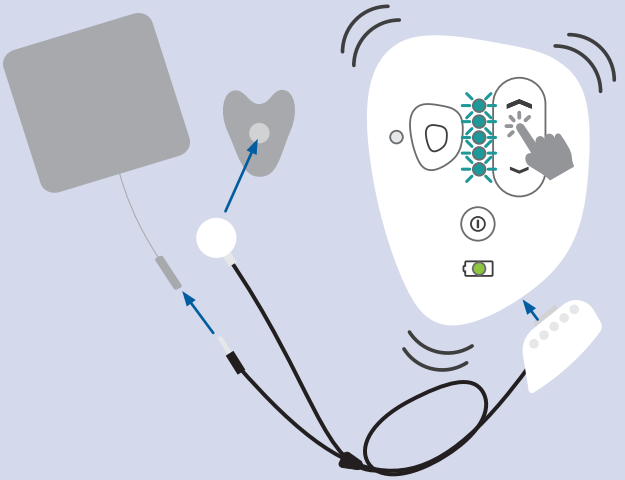
If the Control Unit is able to deliver stimulation, but the connection is suboptimal, the Control Unit will automatically decrease the stimulation level. The Control Unit will flash the Stimulation Level Lights, beep, and vibrate to notify about the new lower stimulation level.

If stimulation is not possible, the Control Unit will flash the Stimulation Level Lights, beep, and vibrate (every 5 seconds).

Act by:

1. Reconnect/adjust the Electrodes/Lead.
2. Make sure Lead connections are clean.

When the Control Unit is able to deliver stimulation again, the stimulation will slowly return to the previous set stimulation level or a lower stimulation level, if the previous set stimulation level is not possible due to suboptimal connection.



All notifications can be stopped by pressing the On/Off button or by turning off the Control Unit (see section 2.2.2).

Notice if the inadequate connection is only temporary, the Control Unit will pause the stimulation shortly and slowly return to the previous set stimulation level automatically.

2.2.8 Remote Control (optional use)

Pair Remote Control and Control Unit

Notice that the Lead must **not** be connected when the pairing procedure is performed. If the Lead is connected, disconnect the Lead.

Make sure that the Control Unit is on, and the Remote Control is activated (by pressing the Remote Control button) and within range of the Control Unit.

1. Press and hold the Urge button on the Control Unit.

The Stimulation Level Lights will alternating flash blue. When the Remote Control is located by the Control Unit, the Remote Control connection light will turn on, and the Control Unit will vibrate.

2. Press the Remote Control button to confirm pairing.

The Control Unit will beep and vibrate.

When the Remote Control Connection Light on the Control Unit is on (blue) the connection is successful. The light on the Remote Control will turn on when the Remote Control button is pressed.

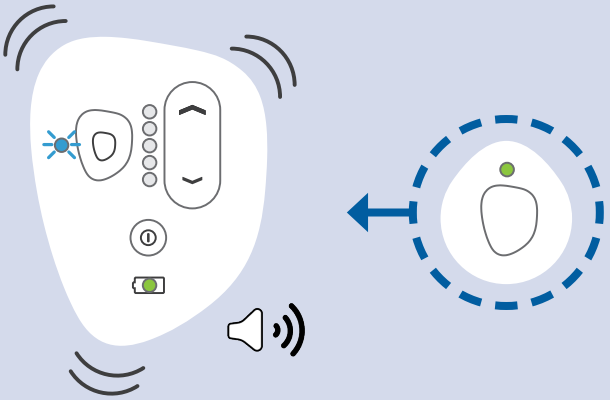
Restore lost Remote Control connection

1. The Remote Control is out of range of the Control Unit.

The Remote Control Connection Light on the Control Unit will flash blue. The Control Unit will beep and vibrate. This is repeated 12 times.

2. Locate the Remote Control and bring it inside range of the Control Unit.

Connection will restore automatically. The Control Unit will beep and vibrate.



If the Remote Control is not located after 5 minutes from lost connection, the Remote Control Connection Light on the Control Unit will turn off. Turn the Control Unit off and on and press the Remote Control button to restore lost connection.

Low battery on the Remote Control

The Remote Control's battery is getting low (approx. 1 month of battery left).

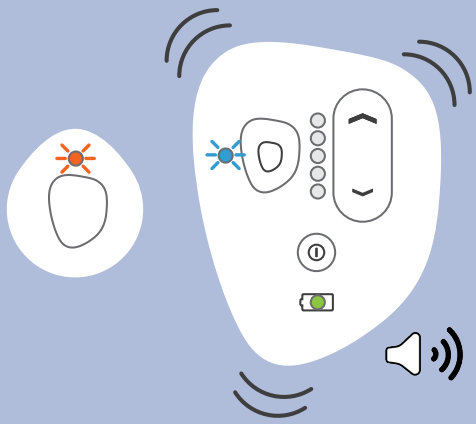
The light on the Remote Control will be amber (when the Remote Control button is pressed).

1. Order and obtain a new Remote Control (see section 4.3).
2. Pair the new Remote Control with the Control Unit (see beginning of section 2.2.8).
3. Dispose of the old Remote Control (see section 1.6).

Critical low battery on the Remote Control

The Remote Control's battery is critical low (approx. 1 week of battery left).

The Remote Control Connection Light on Control Unit will flash amber. The Control Unit will beep and vibrate. The light on the Remote Control will flash amber. This is repeated every 10 minutes.

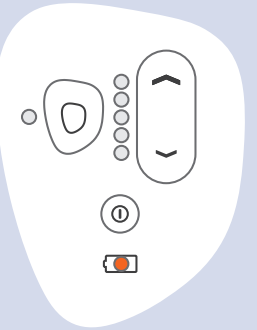


2.2.9 Charging Control Unit

Low battery on the Control Unit

The Control Unit's battery is low (approx. 3 hours of battery left).

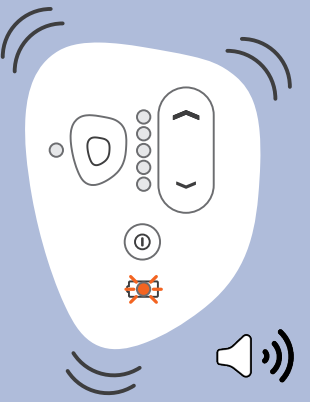
The Control Unit´s Battery Status Light will be amber.



Critical low battery on the Control Unit

The Control Unit's battery is critical low (approx. 1 hour of battery left, depending on use).

The Control Unit will beep and vibrate and the Battery Status Light will flash amber. This is repeated every 5 minutes without the sound notification.



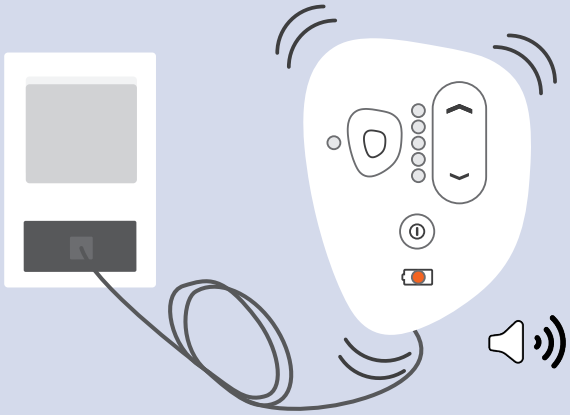
Notice that after charging, the Control Unit may temporarily be uncomfortably warm to carry on body.

Make sure not to leave the Control Unit connected to the Charger for longer periods of time, when not used on daily basis.

Charge the Control Unit

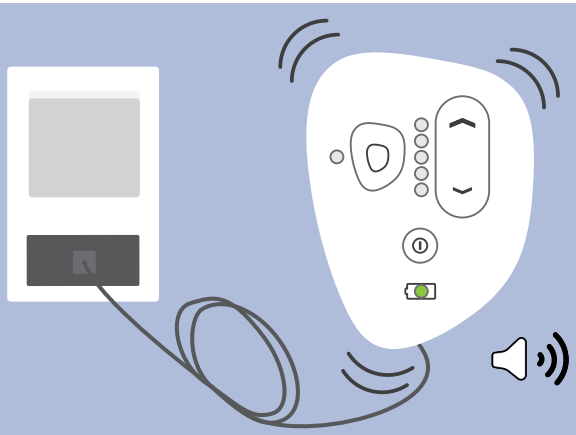
1. Connect the Charger to the Control Unit and plug the Charger in a wall outlet.

The Control Unit will beep and vibrate. The Battery Status Light will flash in the battery status colour, while charging.



The Control Unit is fully charged

The Control Unit´s Battery Status Light will be steady on (green), and the Control Unit will beep and vibrate.



2.3 Cleaning

If cleaning is found necessary, it shall be performed according to the table below.

UCon Component	Cleaning
Control Unit	Rinse under water or wipe with a clean, damp cloth. Excessive amounts of water should be wiped off after cleaning. Mild cleaning detergent, soap and disinfectant can be used. The magnetic connection of the Patch Electrode Lead to the Patch Electrode should be rubbed to remove any dirt.
Remote Control	
Patch Electrode Lead	
Charger	Wipe with a clean dry cloth.
Data Transfer Unit	Wipe with a clean cloth with disinfectant and/or water.
Programming Sheet	
Patch Electrode	Not intended for cleaning. When they are no longer hygienically acceptable, they should be replaced.
Neutral Electrode	

Make sure that the Control Unit is turned off, Leads are disconnected, and Electrodes are removed before cleaning the system.

Notice the importance of maintaining the magnetic connections free of dirt (see appropriate cleaning method in the table above) to secure proper connections.

Always remove UCon components from clothes before washing.

If the components are cleaned by use of improper cleaning methods or agents, the components can be damaged or become non-functional.

Note that cleaning of UCon components is not mandatory for the safe performance of UCon.

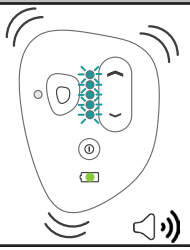
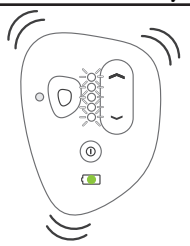
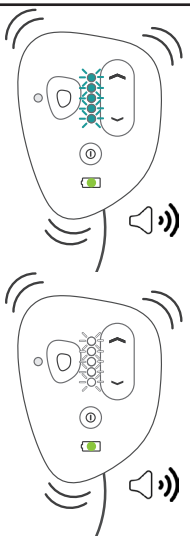
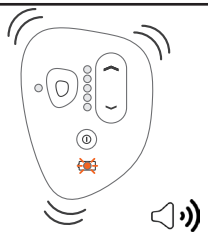
2.4 Troubleshooting

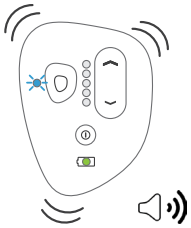
This section describes the most common problems that might be encountered when using UCon. If other problems are experienced, please contact InnoCon Medical or your UCon healthcare provider. Always start by checking the various components of UCon for visible damage and make sure everything is connected properly.

Notice that notifications can be stopped by pressing the On/Off button, or by turning off the Control Unit (see section 2.2.2). The Control Unit can also be muted (see section 2.2.3).

Problem	Reason(s)	Solution(s)
Unsuccessful pairing of Control Unit and Remote Control.	• Remote Control is not activated. • No battery on the Remote Control. • Control Unit is turned off/no battery on the Control Unit. • Remote Control is out of Range of the Control Unit. • Lead is connected to the Control Unit.	Make sure that the Remote Control is activated (by pressing the Remote Control button) and within range of the Control Unit. If the Remote Control runs out of power, order and obtain a new Remote Control (see section 4.3). Make sure that the Control Unit is turned on (see section 2.2.2). Check the battery status on the Control Unit. If the Control Unit is out of power, charge the Control Unit (see section 2.2.9). Bring the Remote Control within range of the Control Unit and repeat the pairing procedure (see section 2.2.8). Disconnect the Lead from the Control Unit.
No stimulation when button on the Remote Control is pressed.	• Remote Control is out of range of the Control Unit, therefore the paired connection is lost. • Control Unit is turned off/no battery on the Control Unit. • No battery on the Remote Control.	Bring the Remote Control within range of the Control Unit and repeat the pairing procedure (see section 2.2.8). If the Remote Control is within range of the Control Unit within 5 minutes, the paired connection will restore automatically. Make sure that the Control Unit is turned on (see section 2.2.2). Check the battery status on the Control Unit. If the Control Unit is out of power, charge the Control Unit (see section 2.2.9). If the Remote Control runs out of power, order and obtain a new Remote Control (see section 4.3).
The Control Unit does not react (Battery Status Light is not on) when connected to the Charger.	• Control Unit is not correctly connected to Charger. • Charger is not plugged into a wall outlet or wall outlet is not turned on. • Control Unit has not been charged for an extended period, and the battery is complete discharged.	Check and adjust the connection between the Control Unit and the Charger. Insert Charger into wall outlet and make sure that the wall outlet is turned on. Let the Control Unit charge for several hours and check the Battery Status Light again.

Problem	Reason(s)	Solution(s)
Dropping of the Control Unit.	• During normal activity, the Control Unit is dropped e.g., Control Unit falls out of pocket.	The Control Unit is designed to withstand a short drop to a hard surface. Pick up the Control Unit and continue use. If the Control Unit is dropped in a moist or dirty environment (e.g., into the toilet), the Control Unit is cleaned (see section 2.3), and the use is afterwards continued. In case the Control Unit has visible damage e.g., exposed internal parts, stop using the device. If the Stimulation Level Lights display multiple colours, stop using the device (see "Signals and Notifications" table).
Dropping of the Remote Control.	• During normal activity, the Remote Control is dropped.	The Remote Control is designed to withstand a short drop to a hard surface. Pick up the Remote Control and continue use. If the Remote Control is dropped in a moist/dirty environment (e.g., into the toilet), the Remote Control is cleaned (see section 2.3), and the use is afterwards continued. In case the Remote Control is lost/non-retrievable, order and obtain a new Remote Control (see section 4.3).
No stimulation (felt).	• Control Unit is turned off. • Lead is not correctly connected or Lead connections are dirty. • Lead is worn. • Electrodes are worn/not positioned correctly. • Stimulation level is set too low.	Make sure that the Control Unit is turned on (see section 2.2.2). Make sure Lead connections are clean and check and adjust the connection between the Lead and Electrodes / Lead and Control Unit until the Control Unit confirms correct delivery of stimulation and appropriate sensation of stimulation is felt (see section 2.2.7). Replace Lead if worn. Make sure that the Electrodes are in firm contact with the skin and reposition/replace the Electrodes until appropriate sensation of stimulation is felt (see section 2.2.7). Make sure that the stimulation level is sufficiently high. Gradually increase the stimulation by pressing the Up button until sensation of stimulation is felt. Note that the Control Unit will automatically turn down the stimulation level, if the set stimulation level is not possible (see section 2.2.7).
Discomfort or pain due to stimulation.	• Stimulation level is set too high. • Electrodes are not positioned correctly. • Electrodes are worn.	Press the Down button until a comfortable sensation of stimulation is felt. Check the Electrodes position and reposition if necessary. Replace the Electrodes.

Signals and Notifications			
Signal		**Reason(s)**	**Solution**
The Stimulation Level Lights flash turquoise/ purple. The Control Unit beeps and vibrates (every 5 seconds).		The Control Unit is unable to deliver stimulation e.g., due to inadequate connection of the Electrodes to the skin, dirt on Lead connections, or Lead gets disconnected from the Control Unit or the Electrodes.	Make sure Lead connections are clean and check and adjust the connection between the Lead and Electrodes / Lead and Control Unit until the Control Unit confirms correct delivery of stimulation. Make sure that the Electrodes are in firm contact with the skin and reposition the Electrodes if necessary.
The Stimulation Level Lights flash white. The Control Unit vibrates.		The function attempted on the Control Unit is not possible: attempting to start stimulation without the Lead is connected to the Control Unit and the Electrodes.	Connect the Lead to the Control Unit and the Electrodes.
The Stimulation Level Lights flash turquoise/ purple or white. The Control Unit beeps and vibrates.		The function attempted on the Control Unit is not possible: attempting to increase/decrease stimulation level more than possible.	It is not possible to increase/decrease the stimulation level, since the stimulation level is already at maximum/ minimum level. OR The Control Unit is not able to deliver stimulation at the set stimulation level and have decreased the stimulation level to what is possible based on the current connection. If a higher stimulation level is needed, make sure Lead connections are clean and check and adjust the connection between the Lead and Electrodes / Lead and Control Unit until the Control Unit confirms correct delivery of stimulation. Make sure that the Electrodes are in firm contact with the skin and reposition the Electrodes if necessary.
The Control Unit´s Battery Status Light flashes amber. The Control Unit beeps and vibrates.		The Control Units battery is critical low.	Charge the Control Unit (see section 2.2.9).

Signals and Notifications				
Signal		**Reason(s)**	**Solution**	
The Remote Control Connection Light on Control Unit flashes amber. The Control Unit beeps and vibrates.		Critically low battery on the Remote Control.	Order and obtain a new Remote Control (see section 4.3).	
The Control Unit´s Battery Status Light is amber.		The Control Units battery is low.	Charge the Control Unit (see section 2.2.9).	
The light on the Remote Control is amber.		The Remote Controls battery is low.	Order and obtain a new Remote Control (see section 4.3).	
The light on the Remote Control flashes amber.		The Remote Controls battery is critically low.	Order and obtain a new Remote Control (see section 4.3).	
The Remote Control Connection Light on Control Unit flashes blue. The Control Unit beeps and vibrates.		Remote Control is out of range of the Control Unit.	Bring the Remote Control within range of the Control Unit and repeat the pairing procedure (see section 2.2.8). If the Remote Control is within range of the Control Unit within 5 minutes, the paired connection will restore automatically. If the Remote Control is not located after 5 minutes from lost paired connection, the Remote Control Connection Light on the Control Unit will turn off. Turn the Control Unit off and on to restore lost connection (see section 2.2.8). If the paired connection is not restored automatically, repeat the pairing procedure (see section 2.2.8). If the Remote Control runs out of power, order and obtain a new Remote Control (see section 4.3).	
The Control Units Stimulation Level Lights display multiple colours.		System failure.	Stop using the device and contact InnoCon Medical or your UCon healthcare provider.	

3 Information for Prescribers of UCon

3.1 Patient Consulting Information

Healthcare providers should provide the following to patients:

- Information about the components of UCon.
- Instructions for using the Control Unit, Electrodes, Lead, Remote Control and Charger.

Also, the healthcare provider should provide each patient with a UCon User Manual and in particular review the following sections with the patient:

- Warnings, including potential patient hazards, and conditions for safe MR imaging (see section 1.4).
- Precautions, including use in specific populations and precautions related to usage situations (see section 1.4).
- Potential side effects related to use of UCon (see section 1.5).
- How to use UCon, including the conditions related to extended use of stimulation (see section 2.2.6 "Start Urge stimulation").

Healthcare providers should also instruct their patients as follows:

- Patients should tell their healthcare providers, including their primary doctor that they have a nerve stimulator system.
- Patients should always bring UCon to UCon-related appointments, including all setting sessions.
- Patients should contact their UCon healthcare provider if they experience any unusual signs or symptoms.

3.2 Indications and Contraindications

3.2.1 Intended Purpose

UCon is a neurostimulator applying electrical stimulation to the dorsal genital nerve for patient operated treatment of the symptoms of overactive bladder and bowel dysfunction.

UCon is intended to provide treatment of patients with symptoms according to the intended purpose and corresponding indications and contraindications as listed below.

3.2.2 Indications - Overactive Bladder

Use of UCon is indicated in adults with symptoms of overactive bladder, which is characterized by urinary urgency, with or without urinary urgency incontinence, and usually with urinary frequency and/or nighttime frequency.

Further, UCon is indicated for adults with no adequate relief of overactive bladder symptoms by conservative treatments such as: bladder training, pelvic floor exercises, fluid management, bladder control strategies.

3.2.3 Indications - Faecal Incontinence

Use of UCon is indicated in adults with symptoms of bowel dysfunction, which is characterized by faecal urgency and/or faecal incontinence (urge/passive), and sometimes with frequent bowel movements.

Further, UCon is indicated for adults with no adequate relief of bowel dysfunction symptoms by conservative treatments such as: dietary modification, stool bulking agents, and pelvic floor exercises.

3.2.4 Contraindications

Use of UCon is contraindicated in the following individuals:

1. People who are unable to operate UCon.
2. People with genital anatomy that do not allow for proper electrode placement or stimulation of the dorsal genital nerve.

3.3 Identifying Patient Groups – Screening

UCon with the Patch Electrode can be used to evaluate the success of nerve stimulation for the symptoms of overactive bladder and bowel dysfunction.

Stimulation with UCon with the Patch Electrode allows the patient to experience stimulation during daily activities and will support the healthcare provider in determining the relevant stimulation parameters for the individual patient.

At the first session with UCon with the Patch Electrode the maximum comfort threshold is determined. For Time Limited stimulation, the patient is informed that stimulation should be provided at this threshold. The patient is further informed that the threshold might change over time, but the target should always be the maximum comfort threshold.

For patients experiencing urgency episodes, Urge stimulation can be enabled (see section 3.4). Patients are instructed to activate the stimulation whenever urgency occurs. Patients are informed that stimulation should be provided just above maximum comfort threshold. The patient is further informed that the threshold might change over time, but the target should always be just above the maximum comfort threshold.

The goals of screening with UCon with the Patch Electrode are to determine:

- Relevant stimulation parameters for the individual patient.
- Whether stimulation is relieving the patient´s symptoms.
- Whether stimulation is well tolerated by the patient.
- Whether the patient can handle and operate UCon.

3.4 Programming of Control Unit

The Control Unit must be programmed prior to the first treatment. Programming is done by use of the Programming Sheet and the following settings can be set/adjusted by the healthcare provider:

- Session time for Time Limited stimulation (Range: 15 min – continuous).
- Maximum stimulation level (Range: Max 1 - Max 5).
  Notice that the session time must be set prior to the maximum stimulation level.
- Enable/disable Urge or Time Limited stimulation.
- Reset settings to factory defaults (Time Limited stimulation is set to continuous, maximum stimulation level is set to highest level (Max 5), and Urge stimulation is disabled).

Program the Control Unit

Notice that leads must not be connected when the Control Unit is placed on the Programming Sheet.
Notice that it is not possible to mute notifications related to programming of Control Unit.

1. Place the Control Unit on the designated area (Reset, Urge, Time Limited) on the Programming Sheet.

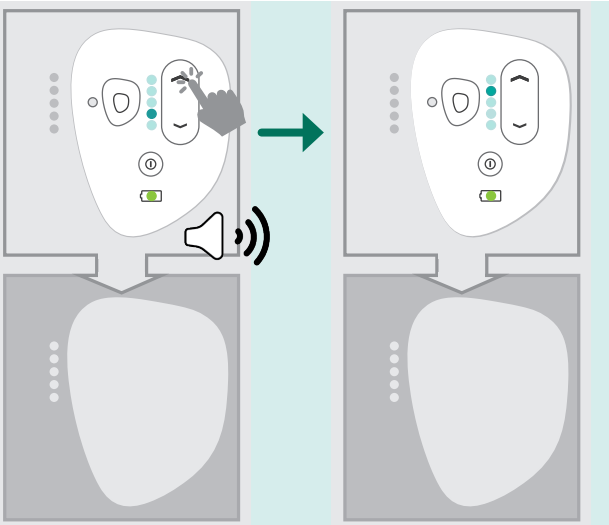
The Stimulation Level Light that indicates set stimulation setting is on. The Control Unit will beep.

2. Press the Up/Down button on the Control Unit to select value/state of setting.

When satisfied with the stimulation setting lift the Control Unit off the Programming Sheet to save the setting.

The Control Unit beeps to confirm the setting.

3. Repeat step 1-2 until all relevant settings are set/ adjusted.



Precautions related to the use of the Programming Sheet:

- Wrong adjustment of the Control Unit (see section 3.6).
- Unintended reading of the Programming Sheet (see section 3.6).

3.5 Access to UCon Data Log

Notice that it is not possible to mute notifications related to accessing UCon data log.

Access UCon data log

1. Connect the Data Transfer Unit to a computer.
2. Turn on the Control Unit and connect it to the Data Transfer Unit.

The Stimulation Level Lights will flash, and the Control Unit will beep.

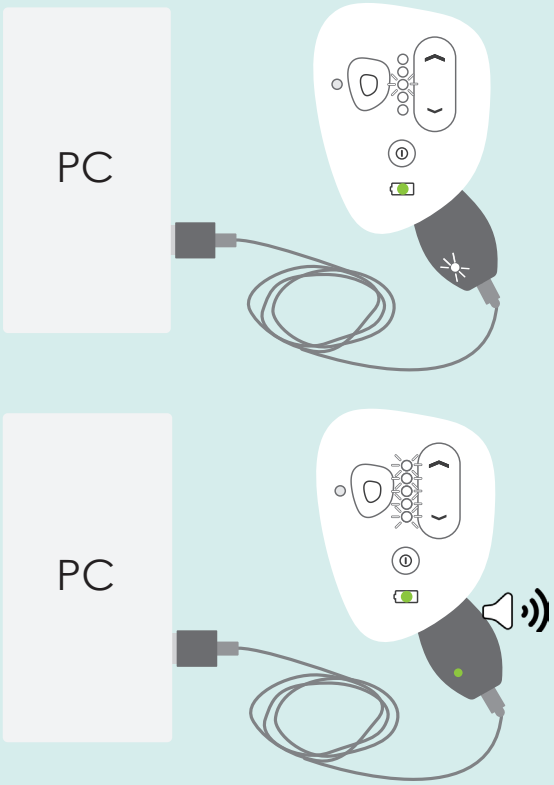
While the data log is transferred to the computer (this may take some time), the Control Unit will alternately flash the Stimulation Level Lights and Data Transfer Unit Light will flash white.

When the data transfer is done, the Control Unit will beep, and all Stimulation Level Lights will be on. The Data Transfer Unit Light will be green.

On the computer a new File Explorer window containing the Control Unit data log file will appear. It is now possible to open the file and read the data log from the Control Unit, and if necessary, download the file.

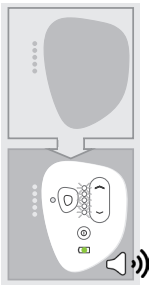
3. When the data log is read/downloaded disconnect the Data Transfer Unit from the Control Unit and the computer.

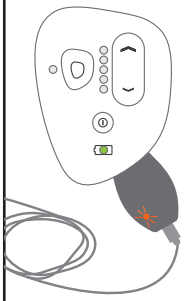
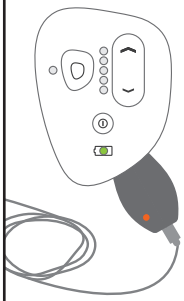
The Control Unit will beep, and the Stimulation Level Lights will turn off.



3.6 Troubleshooting

This section is designed to help solve issues that might be encountered when using UCon.

Problem	Reason(s)	Solution(s)
Wrong adjustment of Control Unit settings.	• The signal that confirms successful setting of the Control Unit is missed. • Unintended reading of the Programming Sheet.	Reposition the Control Unit on designated area(s) on the Programming Sheet to readjust settings.
The Control Unit does not react when positioned on the Programming Sheet.	• A lead is connected to the Control Unit. **Notice** that leads must not be connected when the Control Unit is placed on the Programming Sheet. • The Control Unit is not positioned correctly on the Programming Sheet. **Notice** that the Control Unit must be placed on the Programming Sheet.	Disconnect the Lead from the Control Unit. Reposition the Control Unit on designated area(s) on the Programming Sheet.
The Control Unit flashes all Stimulation Level Lights and beeps when trying to adjust the settings. 	• The settings are adjusted in a wrong order.	Set the settings in the correct order (session time prior to maximum stimulation level).

Problem		Reason(s)	Solution(s)
Cannot get access to data log or Light on Data Transfer Unit flashes amber.		• The Data Transfer Unit is not properly connected to the Control Unit or the computer. • Data log transfer has failed.	Make sure that the Control Unit is turned on. Check and adjust the connection between the Control Unit, the Data Transfer Unit and the computer. When the Data Transfer Unit is connected correctly to the computer, the light on the Data Transfer Unit is green. When the Data Transfer Unit is correctly connected to the Control Unit, the Data Transfer Unit Light flashes white, corresponding to the Control Unit Stimulation Level Lights. If a File Explorer window with the data log is not appearing on computer, the drive is to be found and opened manually using the File Explorer app.
Light on Data Transfer Unit is amber.		• System failure.	Disconnect the Data Transfer Unit from the computer and Control Unit. Connect the Data Transfer Unit to the computer and connect the Control Unit again. If light on Data Transfer Unit is still amber, contact InnoCon Medical (section 1.7).

4 Technical Description of UCon

UCon is for home healthcare use and can be operated by the patient in the environment of the patient.

4.1 Operation Time and Charging Behaviour

On the Control Unit a Battery Status Light indicates the current battery level and when recharging is required.

The Control Unit is charged by plugging the Control Unit into the provided wall Charger.

The internal battery of the Control Unit is designed to last for at least one day of use between charging. Therefore, it is advised to charge the Control Unit once every day, depending on usage. Charging can take up to 6 hours for a fully depleted battery.

If the Control Unit is not used for prolonged periods it shall be fully charged at least every 6 months.

The Remote Control is designed to last for minimum 1 year. Upon depletion of the battery, the Remote Control shall be disposed according to local regulations (see section 1.6). A new Remote Control can be ordered according to section 4.3.

4.2 Description of IP Classification

IP rating also known as Ingress Protection or International Protection ratings are defined to the international standard of EN/IEC 60529. The rating consists of the letters IP followed by two digits. First digit indicates the level of protection against solids, and second digit indicates the level of protection against liquids.

Electrical components of UCon have the ratings as shown in the table below.

UCon Component	IP Classification	Intrusion Protection	Moisture Protection
Control Unit and Remote Control	IP67	Totally protected against dust	Protected from immersion between 15 centimetres and 1 metre in depth for up to 30 min.
Patch Electrode Lead	IPX7	-	Protected from immersion between 15 centimetres and 1 metre in depth for up to 30 min.
Programming Sheet	IP65	Totally protected against dust	Protected from water jets from any direction.

4.3 Acquiring Replacement Components

Depending on the component of UCon, replacement components shall be ordered according to the table below.

UCon Component	Contact for Order
Control Unit	UCon healthcare provider
Remote Control	
Patch Electrode	
Neutral Electrode	
Patch Electrode Lead	
Charger	
Programming Sheet	InnoCon Medical, Lyngvej 1, 9000 Aalborg, DK service@innoconmedical.dk
Data Transfer Unit	

An electronic version of the User Manual can be found using the following link:

Or contact manufacturer for a paper version (see contact information in section 1.7).

4.4 Batteries

The Control Unit contains a Lithium-Ion battery permanently enclosed. The battery is not replaceable. A Battery Status Light is located on the Control Unit and indicates the current battery level and when charging is required.

The Control Unit battery meets the following specifications:

Item	Description
Type	Lithium Ion
Continuous use	One day between charging
Charging time	< 6 hours from an empty battery to full charge
Capacity	315mAh

The Remote Control contains an internal lithium coin cell, which is not replaceable or rechargeable.

4.5 Wireless Link

The link between the Control Unit and the Remote Control is based on a BLE (Bluetooth Low Energy) protocol, where the Control Unit acts as a Central and the Remote Control as a Peripheral. Once the two devices are paired, connection is maintained every 1.5s. Notification latency from Remote Control to Control Unit is up to 200ms. Connection loss is defined as lack of response in 10s. Range of the wireless link is up to 10m line-of-sight.

The link between the Control Unit and the Programming Sheet is based on an NFC (Near Field Communication) protocol, where the Control Unit implements reader function, and the Programming Sheet contains NFC tags. Range is approximately 1cm.

Hereby, InnoCon Medical ApS declares that the radio equipment type Bluetooth Low Energy BLE 4.2 and NFC (Near Field Communication (13.56MHz)) is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.innoconmedical.com/certifications-declarations/

4.6 Classification

UCon is classified as internally powered ME equipment according to EN/IEC 60601-1. The mode of operation is continuous.

WARNING: No modification of this equipment is allowed.

4.7 Technical Specifications

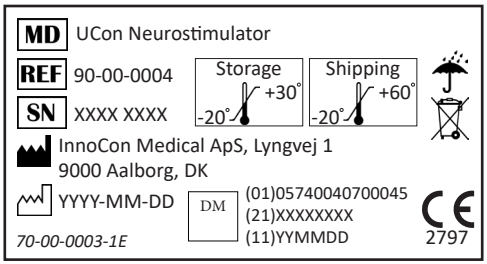
4.7.1 UCon Control Unit

Catalogue No.	90-00-0003
Classification	Type BF applied part
Number of channels	1
Maximum Stimulation Voltage	120V
Stimulation pulse current	0-25mA
Load impedance range	500Ω - 4KΩ
Pulse duration	200µs
Pulse shape	Square, charge balanced
Stimulation mode	Current-controlled, continuous
Frequency	20 Hz
Humidity	15 – 93 % relative humidity non-condensing
Altitude	700 hPa to 1060 hPa atmospheric pressure
Operating conditions	+5°C to +40°C
Storage conditions (at least 1 year)	-20°C to +30°C
Shipping conditions	-20°C to +60°C
Maximum surface temperature (immediately after charging)	43°C
Size	69 x 53mm
Weight	32g
Battery	315mAh Li-ion (non-replaceable)
Charging time	Up to 6 hours
Operating time	Minimum 16 hours between charging
Ingress protection	IP67

Expected lifetime	5 years
Storage lifetime	1 year, requires full charging every 6 months
Control Unit and Remote Control wireless connection	
Technology	Bluetooth Low Energy (BLE)
RF Frequency	2400MHz
RF Channels	40 channels from 2402MHz to 2480 MHz
RF Modulation	GFSK (modulation index 0.5)
RF Spreading	FHSS (2MHz channel)
RF Transmitter Power	+3dBm
Control Unit and Programming Sheet wireless connection	
Technology	Near Field Communication (NFC)
RF Frequency	13.56MHz
RF Channels	1
RF Modulation	ASK - amplitude shift keying
RF Spreading	Up to ± 1.8 MHz
RF Transmitter Power	+3dBm

4.7.2 UCon Remote Control

Catalogue No.	90-00-0004
Humidity	15 – 93 % relative humidity non-condensing
Altitude	700 hPa to 1060 hPa atmospheric pressure
Operating conditions	+5°C to +40°C
Storage conditions (up to 1 year)	-20°C to +30°C
Shipping conditions	-20°C to +65°C
Size	Ø28mm
Weight	5g
Battery	90mAh Lithium coin cell (non-replaceable)
Operating time	Minimum 1 year
Ingress protection	IP67
Expected lifetime	1 year
Storage lifetime	1 year
Remote Control and Control Unit wireless connection	
Technology	Bluetooth Low Energy (BLE)
RF Frequency	2400MHz
RF Channels	40 channels from 2402MHz to 2480 MHz
RF Modulation	GFSK (modulation index 0.5)
RF Spreading	FHSS (2MHz channel)
RF Transmitter Power	+3dBm

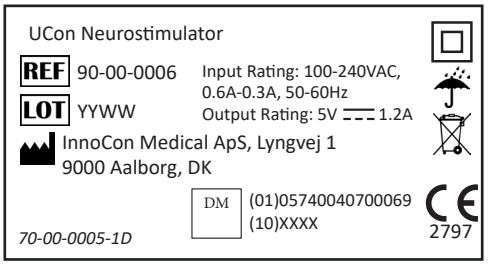


4.7.3 UCon Programming Sheet

Catalogue No.	90-00-0030
Humidity	15 – 93 % relative humidity non-condensing
Altitude	700 hPa to 1060 hPa atmospheric pressure
Operating conditions	+5°C to +40°C
Storage and shipping conditions (at least 1 year)	-25°C to +70°C
Size	21cm x 21cm
Weight	22g
Ingress protection	IP65
Expected lifetime	3 years
Store ligetime	At least 1 year
Type	UCon Programming Sheet is an electronic device

4.7.4 UCon Charger

Catalogue No.	90-00-0006
Input voltage	100 – 240Vac
Input Frequency	50 – 60Hz
Input current	0.6 – 0.3 (@100 and 240Vac)
Output voltage	5Vdc
Output current (max)	1.2A
Humidity	15 – 93 % relative humidity non-condensing
Altitude	700 hPa to 1060 hPa atmospheric pressure
Operating conditions	+5°C to +40°C
Storage and shipping conditions (at least 1 year)	-25°C to +70°C
Size	55 x 27 x 55mm
Weight	50g
Expected lifetime	5 years
Storage lifetime	At least 1 year
Cable length	900mm
Charger and cable connector	USB Type-A male



4.7.5 UCon Data Transfer Unit

Catalogue No.	90-00-0008
Humidity	15 – 93 % relative humidity non-condensing
Altitude	700 hPa to 1060 hPa atmospheric pressure
Operating conditions	+5°C to +40°C
Storage and shipping conditions (at least 1 year)	-25°C to +70°C
Size	38 x 31mm
Weight	9g
Expected lifetime	5 years
Storage lifetime	At least 1 year
Compatible hardware	Standard PC with USB 2.0 or 3.0 port and CE mark in compliance with IEC 62638
Compatible software	Microsoft ®Windows 10 or later
USB characteristics	Full Speed (12 MHz) Maximum 100mA current consumption

The Data Transfer Unit is a storage device with files that are accessible through e.g., File Explorer. Data files are transferred by dividing the content into small packages that are transmitted over USB in bulk transfer mode.

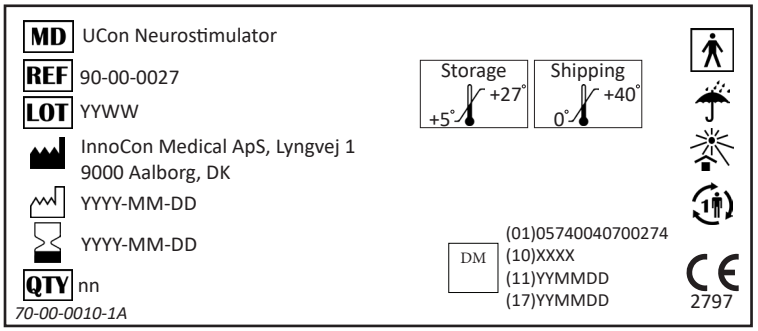
During data transfer, the USB protocol includes mechanisms for error checking to ensure that the data has not been corrupted during transmission. Data files can be read from the Data Transfer Unit, but they cannot be written. This means that malicious code cannot be written and transferred to other computers or networks.

There are no known hazardous situations from failure of connection between the Control Unit and the Data Transfer Unit, other than inability to get the data log from the Control Unit. Failure of connection will be indicated by the Control Unit and/or the Data Transfer Unit (see section 3.6).

The Data Transfer Unit has been designed to avoid cybersecurity threats, however connecting the Data Transfer Unit to an IT network may result in previously unidentified risks to patients, operators, third parties or equipment. These risks should be identified, analysed, evaluated, and controlled by the IT responsible organization.

4.7.6 UCon Patch Electrode

Catalogue No.	90-00-0027
Classification	Type BF applied part
Operating conditions	+5°C to +40°C
Storage conditions	+5°C to +27°C
Shipping conditions	0°C to +40°C
Size	21 x 19mm
Weight	0.5g
Expected lifetime	10 hours
Storage lifetime	2 years
Maximum output at electrode	25mA, 120V

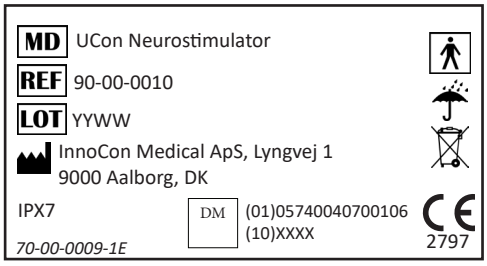


4.7.7 Neutral Electrode

Catalogue No.	90-00-0026
Classification	Type BF applied part
Operating conditions	+5°C to +40°C
Storage conditions	+5°C to +27°C
Size	50 x 50mm
Weight	3g
Expected lifetime	Multiple use. The lifetime of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage and climate.
Storage lifetime	2 years
Maximum output at electrode	25mA, 120V

4.7.8 UCon Patch Electrode Lead

Catalogue No.	90-00-0010
Classification	Type BF applied part
Storage conditions (at least 1 year)	+5°C to +40°C
Shipping conditions	-25°C to +70°C
Operating conditions	+5°C to +40°C
Length	1000mm
Weight	6 grams
Ingress protection	IPX7
Expected lifetime	6 months
Storage lifetime	At least 1 year



4.8 Electromagnetic Interference

UCon has been designed, tested, and demonstrated to comply with the electromagnetic compatibility (EMC) limits for medical devices to the EN/IEC 60601-1-2 standard for EMC. These limits are designed to provide reasonable protection against harmful interference in typical use environments.

Use of electrodes and leads other than those specified or provided by InnoCon Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

It is possible that high levels of radiated or conducted radio frequency electromagnetic interference (EMI) from portable or mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disturbance of UCon. Evidence of disturbance may include unwanted or excessive stimulation, lack of stimulation, heating of device, and other device malfunctions. If this occurs, survey the site to determine the source of disturbance and take the following actions to eliminate the source(s):

- Turn equipment in the vicinity off and on to isolate the source
- Relocate or re-orient the interfering source
- Increase distance between source and UCon

While wearing UCon keep outside fenced areas near e.g., high-voltage transformer stations, microwave communication transmitters and radio transmitting towers.

There are no necessary actions to maintain electromagnetic compatibility during the lifetime of UCon parts. In case of broken or cut leads or damaged enclosures replacement of the affected part is required. More details regarding electromagnetic interference can be seen in the tables below.

Electromagnetic Emissions

UCon is intended for use in the electromagnetic environment specified below. The customer or the user of UCon should assure that it is used in such an environment.

<table>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic Environment — Guidance</th></tr>
<tr><td rowspan="2">RF Emissions according to CISPR 11</td><td>Group 1</td><td>UCon uses RF energy exclusively for its internal function. Therefore, its RF emissions are very low, and it is unlikely that nearby electronic devices will be disturbed.</td></tr>
<tr><td>Class B</td><td rowspan="3">UCon is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions</td><td>Complies</td></tr>
<tr><td>Voltage fluctuations / flicker emissions</td><td>Complies</td></tr>
</table>

Electromagnetic Immunity

UCon is intended for use in the electromagnetic environment specified below. The user of UCon should assure that the device is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be made from wood or concrete or covered with ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/ bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for SIP/SOP Repetition frequency 100 kHz	± 2 kV for power lines Repetition frequency 100 kHz	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts, and fluctuations of the power supply according to IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	-
Supply frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any component of the UCon including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.70\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Transients RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM by 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM by 1 kHz	
IMMUNITY to proximity magnetic fields IEC 61000-4-39	8 A/m, 30kHz CW 65 A/m, 134.2kHz pulse 2.1kHz 7.5 A/m, 13.56 MHz pulse 50kHz	8 A/m, 30kHz CW 65 A/m, 134.2kHz pulse 2.1kHz 7.5 A/m, 13.56 MHz pulse 50kHz	The magnetic field shall be applied only to those surfaces of UCon that are accessible during use.

Test specifications for enclosure port immunity to RF wireless communications equipment

Test Frequency MHz	Band MHz	Service	Modulation	Maximum power W	Distance m	Immunity Test Level V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	Pulse modulation 217 Hz	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 18 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 217 Hz	2	0.3	9
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

InnoCon Medical

UCon

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