English

UM-MAPLe-EN-v10.1

Novuqare®

MAPLe® System manual

Contents

0) Terminology

Rest-tonus
An EMG measurement without contraction.

MVC (Maximal Voluntary Contraction)
The greatest amount of tension a muscle can generate and hold briefly.

Onset
The time it takes to reach a peak muscle contraction from rest.

Offset
The time it takes to relax to rest from a peak muscle contraction.

Endurance
A muscle contraction of the PFM to the maximum of its capacity.

PFM
Pelvic Floor Musculature

EMG
Electromyography

ES
Electro stimulation

Gravida
the number of times the woman has been pregnant, regardless of whether these pregnancies were carried to term.

Partus
the number of >20-week births.

1) Introduction

Dear customer
Thank you for purchasing a product from our Novuqare product portfolio. Novuqare develops products that enhance healthcare for professionals and patients. Please feel free to contact us in case of remarks and/or questions of any kind, concerning the MAPLe system. The Novuqare team is always willing to assist!

The MAPLe system is an electromedical device. The device conforms to the requirements of Directive 93/42/EEC concerning Medical Devices. Furthermore, the MAPLe system conforms to European Standards: IEC60601–1, IEC60601–1–2, IEC60601–2–10, IEC62304, IEC62366 and IEC60601–1–6.

CE 0344

Intellectual Property
The MAPLe system is covered by the following patents:

US patent: US 8,983,627
EU patent: EP2029220
AU patent: AU2007252330
CA patent: CA2653442

2) Important information

Precautions for use

Knowledge of the general safety instructions and applicable law enables the device to be used safely and correctly. This manual provides important information for the installation and safe use of the machine, which must be followed by all persons involved in the installation and use of the device. Attention must be paid to all applicable accident-prevention rules in the country and site where the device is installed and used; these rules must be followed.

The MAPLe system is marked with several symbols. The meaning of these symbols is explained below:

Obligations of personnel working with the machine

Before starting operation of this medical device please read this manual carefully. Everybody involved should pay attention to all accident-prevention rules applicable to the environment in which one is operating. The user is responsible for the proper and safe use of this device.

Safety information

This user manual must always be easily consultable at the site where the device is in use. In addition, all signs and information labels must always be kept in good condition.

Please consult the manual

Caution

Type BF applied part

Safety Warnings

- Contaminated components or occurrence of microbial contamination may be detrimental to health.
- Change, clean and disinfect the MAPLe probe after each use.
- Make sure the probe is attached to the cable when treating a patient.
- The MAPLe handheld will not work when charging.
- Always apply contact/electrode gel to the probe before use. Please note that the gel package should indicate that the gel is suitable for invasive treatment with EMG.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- 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), or from electrodes placed on the chest and the upper back or crossing over the heart.
- It is highly advised to hold the probe in place during use.
- Only connect components to the MAPLe system that have been defined as part of the package contents or as accessory.
- Do not use damaged components. When in doubt, please contact Novuqare.
- Do not use this system for electro stimulation in the presence of confirmed or suspected:
  - Colo-rectal or genito-urinary cancer
  - Pregnancy
  - Implanted electrical devices (e.g. cardiac pacemaker); only after a specialist is consulted
  - High fever
- Keep the MAPLe system out of direct sunlight.
- The MAPLe system is designed especially for the MAPLe probe. Use Novuqare probes only in combination with the MAPLe system.
- As a safety precaution, patients are not allowed to contact either the docking station and/or the iPad.
- Do not touch the patient and the iPad and/or docking station simultaneously.
- It is highly advised to only charge the handheld overnight. Battery conditions will rapidly deteriorate when charging the handheld in between short periods of use.
- Do not leave the handheld on the docking station when charging does not seem to work.
- The handheld may become warm during use. Do not hold the handheld during treatment.

3) Package contents

Package contents MAPLe system

1. Handheld
2. Docking station
3. Probe cable
4. Wall adapter
5. Reference cable
6. Keycord
7. O-Ring probe cable
8. Quick Guide

Detachable parts of MAPLe system

3. Probe cable
4. Wall adapter
5. Reference cable
9. Probe

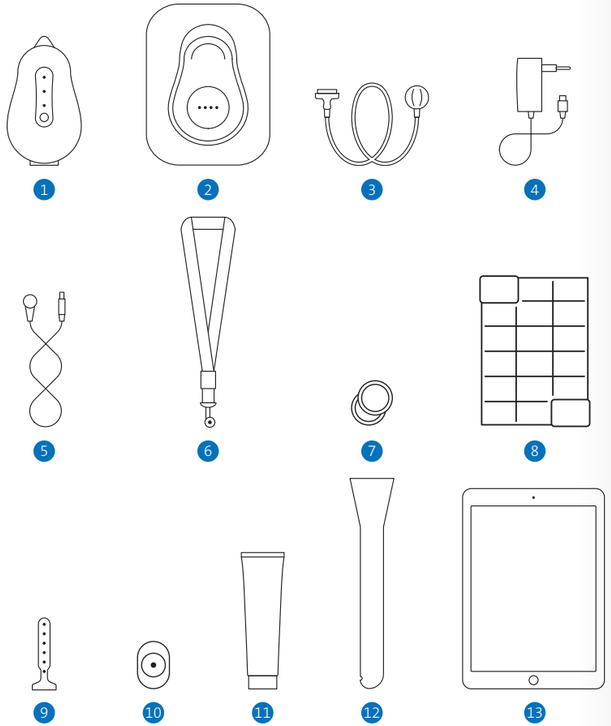
Consumables

9. Probe
10. Snap electrodes
11. Electrode gel
12. Cable sleeve

Required devices for operation of MAPLe system

13. iPad

NOTE
Please check the Novuqare webshop for the latest allowable consumables for use with the MAPLe system.



4) Intended use

Intended use

The MAPLe is a multiple channel device used for measuring or stimulating the pelvic floor muscles for diagnosis and treatment of Pelvic Floor Dysfunction in clinical environments by qualified personnel. It can be used for both men and women for transient use. It has two main functions:

1. Electromyography (EMG) measurement of muscle tissue
2. Electrical stimulation of nerves and/or muscle tissue

Qualified personnel can use this information along with clinical information of other methods for the diagnosis and treatment of patient conditions.

Intended user profile

The use of the medical device must be restricted to qualified medical personnel. Only qualified and experienced personnel will be able to make the right choices in treatment in order to achieve the desired effects.

a) Education:
- Qualified for treating Pelvic Floor Dysfunction, according to country regulations

b) Knowledge:
- Can distinguish differences between common Pelvic Floor Dysfunctions

c) Language understanding:
- Fluent in written and spoken system language

d) Experience:
- Experienced in working with patients
- Experienced in the use of invasive treatment (rectum/vagina)

Intended patient population

a) Age: 18 years and up after patient consent

b) Weight: not relevant

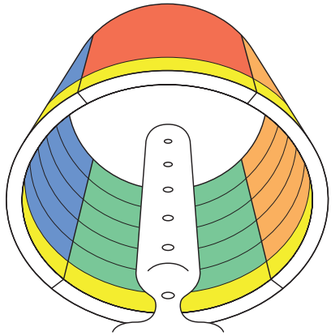
c) Patient state (user): patient is only the user when the probe is inserted and when interpreting the circular grid (biofeedback). Treatment is provided in sitting, standing, supine or side position. It is not required for the patient to set or change settings. Treatment may be provided for e.g. Urinary Incontinence, Faecal Incontinence, Constipation and Pelvic Pain.

5) Basic principles of the MAPLe system

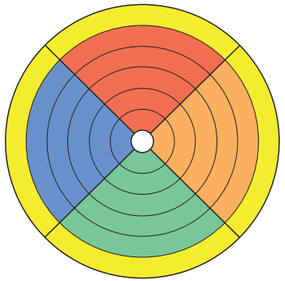
The grid explained

The MAPLe system uses two visualization principles;

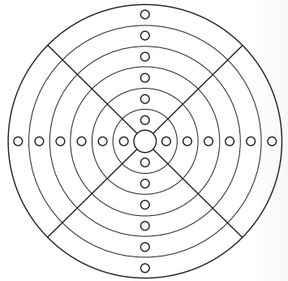
- A graph representation showing the averaged EMG signals of the electrodes that are switched 'on'. The values of the 'active' electrodes are added up and divided by the number of 'active' electrodes.
- A circular grid showing all 24 signals in one representation. This is a novel principle, which provides a clear overview of 24 signals at a single glance as a tunnel view. The center of the circle represents the top electrodes of the MAPLe probe. The outer ring represents the bottom electrodes of the MAPLe probe.



Tunnel view



Flat view



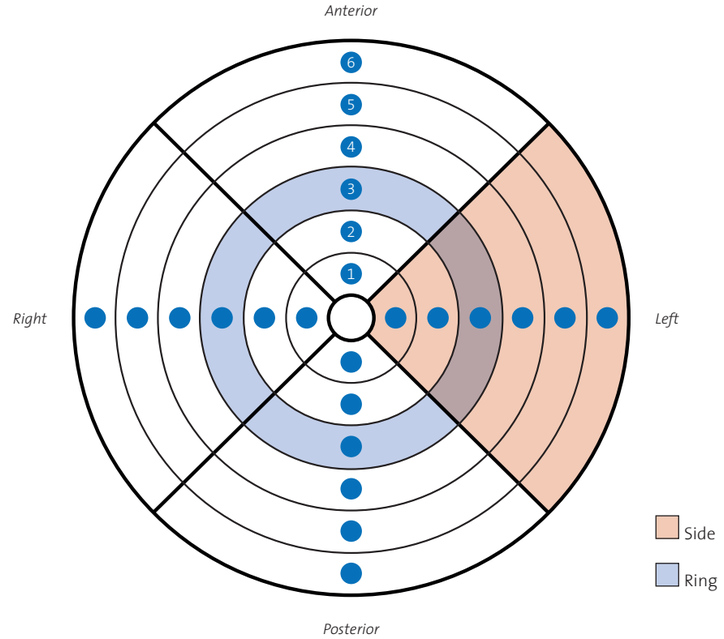
Grid + electrodes

Electrode numbering

The probe is divided into 4 sides and 6 rings. Each of these sides and rings can be switched on or off easily.

- A side corresponds to 6 electrodes on one side of the probe; Anterior, Left, Posterior or Right;
  E.g. the highlighted side is called 'Side Left'.

- A ring corresponds to 4 electrodes, one on each side of the probe;
  E.g. the highlighted ring is called 'Ring 3'.



Electrode numbering

Circular grid view modes

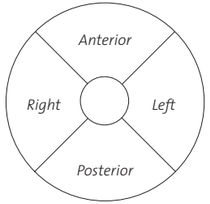
Two different view modes are provided for the circular grid. One can switch between these views at any given time during treatment:

The switch view button in the center of the grid.

Operator view

(Operator is looking at patient from feet up)

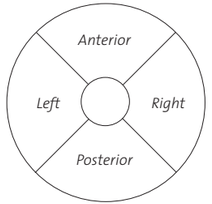
- The right side of the circular grid corresponds to the left side of the patient. The left side of the circular grid corresponds to the right side of the patient.



Patient view

(Patient is looking at iPad screen while being treated)

- The right side of the circular grid corresponds to the right side of the patient. The left side of the circular grid corresponds to the left side of the patient.



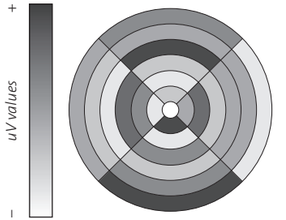
Absolute mode – Reference comparison mode

EMG measurements can be displayed in two different modes; absolute mode and reference comparison mode. One can switch between these visualisations at any given time during treatment by pushing the switch button near the Grid.

Absolute mode

Measurements are displayed in uV's (microvolts) in a grey scale.
The darker the color, the higher the uV value.

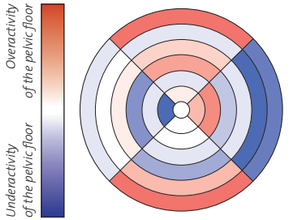
The switch to reference comparison mode button



Reference comparison mode

Measurements are compared to a healthy baseline of a reference group and are displayed in uV's in colors: overactivity (red), under-activity (blue) or same as reference group (white). More intense colors represent a larger deviation with the reference group.

The switch to absolute mode button



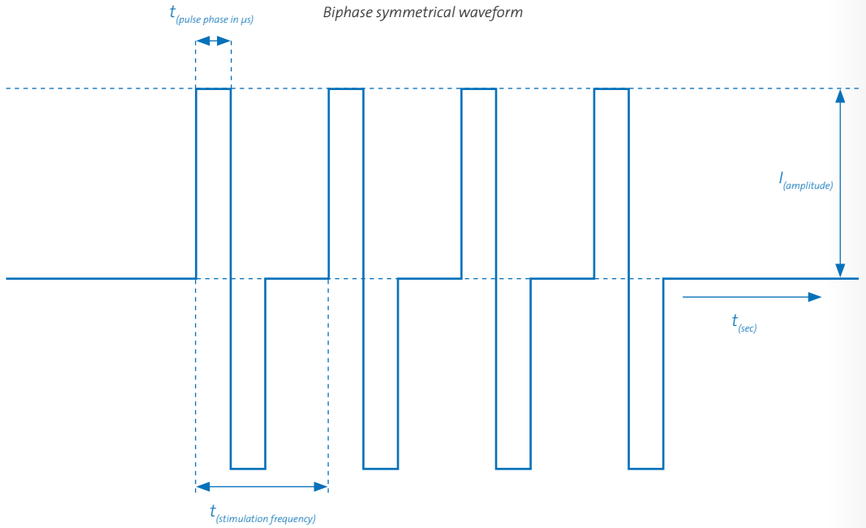
Stimulation current parameters

The MAPLe system uses a biphase symmetrical waveform which has mirror images above and below the baseline (a phase on each side), representing an equal net charge; no net positive or negative charge.

The amplitude used for stimulation depends on the load impedance of the patient's tissue; high tissue impedance will require higher stimulation amplitude than lower tissue impedance in order to feel the same. Tissue impedance differs inter patients, but also differs intra patients, due to hormone changes in the body.

Furthermore, the applicable height of the stimulation current depends on the individual patient threshold of pain/discomfort. This differs per patient.

Biphase symmetrical waveform



Electro stimulation output

The device outputs for electro stimulation are specified as follows; 2–150Hz with a pulse phase of 200–1000us, current output 0–29mA.

Please see chapter 9 (Technical description) for the full technical details.

Fade in/out

A fade in/out option will make sure the stimulation current will fade in/out, preventing abrupt changes in stimulation current for the patient. A rest period between stimulation sessions can also be introduced for patient ease.

Stimulation principles

Electrode configurations

There are four different electrode configurations. Colour indicates the polarity of the selected electrodes; green for negative and blue for positive. Since MAPLe uses a biphasic symmetrical waveform, halfway the stimulationpulse the polarity switches (negative becomes positive and vice versa).

Ring – Ring

You can select 2 rings (ring 1, 2, 3, 4, 5, 6). The 1st ring selected starts as negative (green), the 2nd ring as positive (blue).

Side – Side

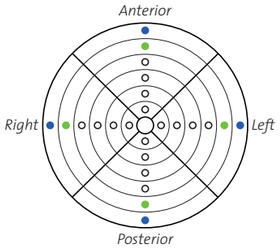
You can select 2 sides (Anterior, Left, Posterior, Right). The 1st side selected starts as negative, the 2nd side as positive.

Side 1–1

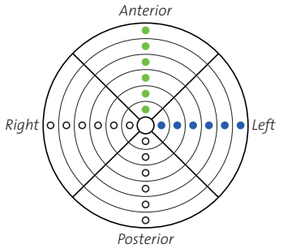
You can select 1 or 2 sides (Anterior, Left, Posterior, Right). Per selected side the 1st, 3rd and 5th start as negative, the 2nd, 4th and 6th as positive.

Side 3–3

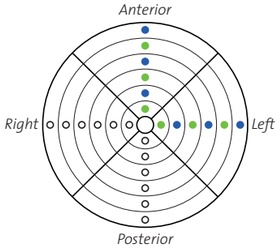
You can select 2 sides (Anterior, Left, Posterior, Right). Per selected side the 1st, 2nd and 3th start as negative, the 4th, 5th and 6th as positive.



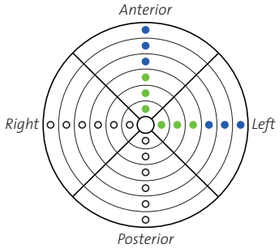
Ring - Ring



Side -Side



Side 1–1



Side 3–3

6) First installation

Charge the handheld

A Place the docking station at least 1.5 meters away from the treatment area. Plug the wall adapter into the docking station and into a wall socket.

B Place the handheld on the docking station. The docking station will blink blue, the handheld is charging.

Download the MAPLe App

1 Go to the App Store on your iPad and search for 'mapleapp'. Download and install the MAPLe App.

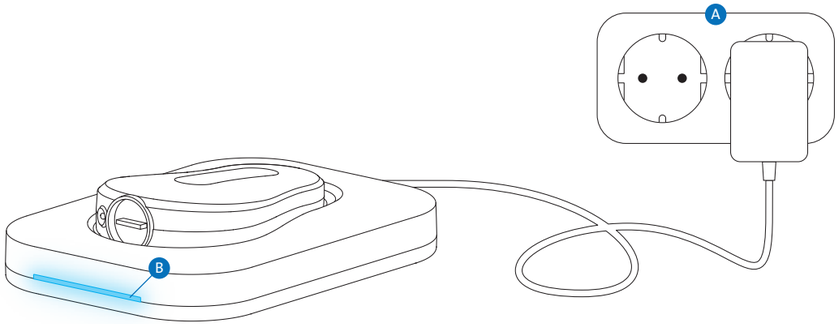
Available on the App Store

MAPLe App

2 Connect the iPad to the Wi-Fi network belonging to the MAPLe system. Go to your iPad's 'Settings', select 'Wi-Fi' and select the appropriate Wi-Fi network starting with MPFT. Enter the password supplied with your system (see label on box) and open the MAPLe App.

3 Create an administrator account and password. The first user created is automatically the administrator with accompanying username 'admin'. A system administrator is entitled to the following operations: add/remove users, assign administrator rights and reset user passwords. You are now set up to start using the MAPLe App.

4 When completed the previous steps, you will be guided to the Patients screen.



WARNING
Set the region code of the iPad to the country where the MAPLe System is used, for a correct use of the system.

NOTE
Make sure that you remember your administrator password.

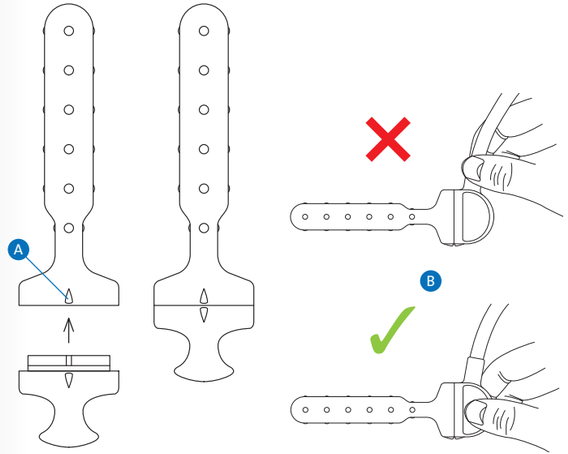
NOTE
An administrator can only see the patient data of his/her own patients.

7) MAPLe system 'getting started'

Connect probe cable and probe

A Align the probe cable and the probe at the alignment marks, connect the parts.

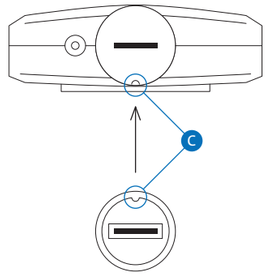
B Hold the probe at the appropriate grip. Do not touch the cable during treatment, this may influence the measurement.

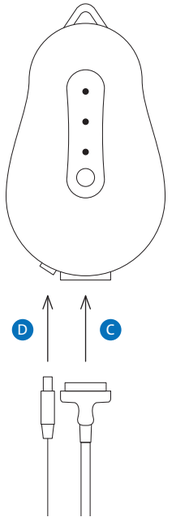


Connecting the probe cable to the handheld

C Align the probe cable with the handheld at the alignment marks, connect the parts.

D Connect the reference cable to the handheld.



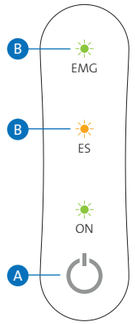


Switching on the MAPLe system

A Press the handheld on/off switch for 2 seconds until the 3 LEDs light up.

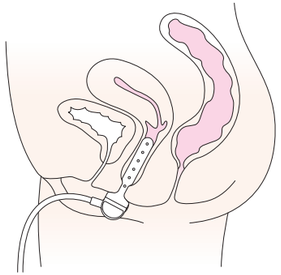
B The electromyography (EMG) LED will blink until the handheld is connected. Make sure the docking station is always powered. Only when powered, the handheld is able to connect.

C Open the MAPLe App when the LEDs have stopped blinking and the 'ON' LED is green.

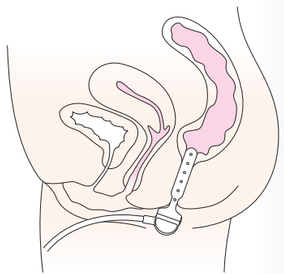


Probe placement

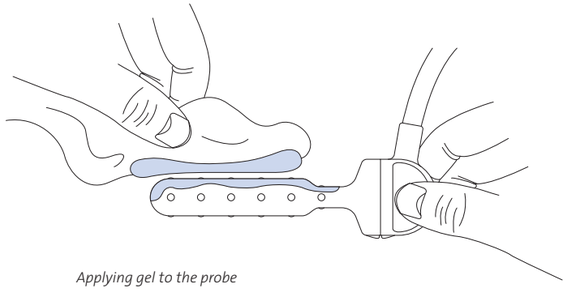
Apply electrode gel before placement of the probe. Apply the gel on a clean cloth. Gently wipe the cloth over the probe to apply the gel.
Insert the probe vaginally/anally until the bottom electrodes lay inside the body orifice. The cable shall point to the nose/belly of the patient.



Vaginal placement



Anal placement

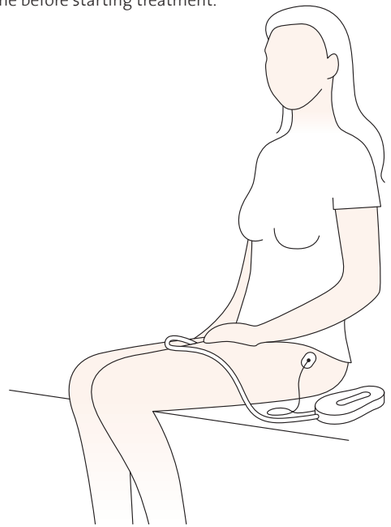


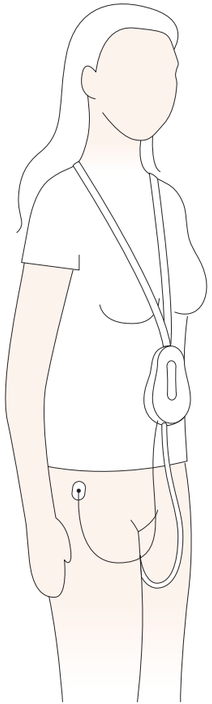
Applying gel to the probe

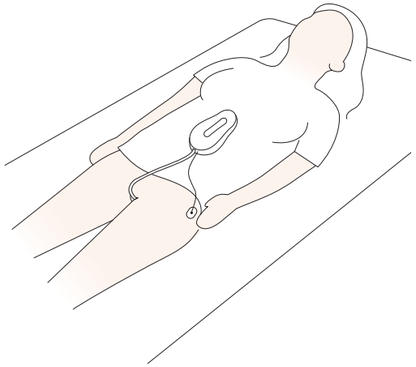
NOTE
The handheld will switch off automatically when there has been no activity for 15 minutes.

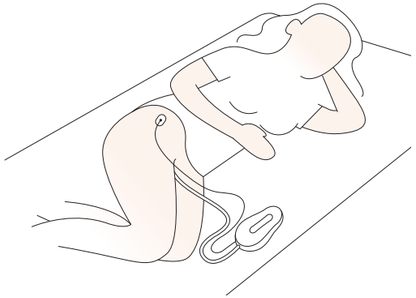
Patient position

Treatment may be provided in supine position, lying on one side, sitting or standing. The reference electrode shall be placed on the patient's hipbone before starting treatment.









8) The MAPLe app

When starting up the MAPLe App, one must log in as an existing administrator user or as a regular user. Once you have logged in, the App will proceed to the Patient screen as the first screen.

The MAPLe App is divided into 4 main menus:

8.1) Patient
8.2) Measurement
8.3) Stimulation
8.4) General settings

8.1) Patient

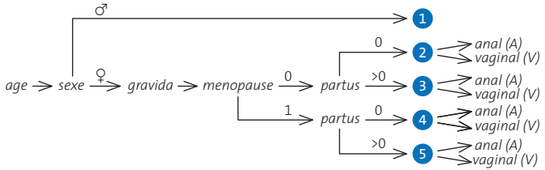
8.1.1) New/edit patient

Add patient, reference groups

When adding a patient to the MAPLe App, the patient will be automatically categorized into one of the five reference groups [1], according to sexe, gravida, menopause and partus. The reference groups contain the healthy baseline of the most important EMG values for rest, MVC and Endurance. This data is gathered from healthy volunteers and can be used to compare patient measurements to EMG values of the healthy baseline. (not available for reference group 4).

Edit patient details

Edit and save your patient's details. You can also delete a patient here.



Gravida & partus

Gravida indicates the number of times the woman has been pregnant, regardless of whether these pregnancies were carried to term. Partus indicates the number of >20-week births. Pregnancies consisting of multiples, count as one birth for the purpose of this notation.

Domain and Primary Indication

Selecting domain helps to categorise patient's indication under clinical specialities such as; Gynaecology, Orthopaedics, Proctology/ gastroenterology, Urology, Pain, Neurology and Sexology.

Selecting Primary Indication is based on the selected domain. For example, if gynaecology is selected, the indications provided are post-partum, (total)rupture, prolapse, pre/ post surgery and other.

Under treatment

Allows you to indicate whether the patient is under treatment / active or not.

History

View data from previous patient visits.
For more detailed information about the patient history section, please see page 24.

App-Handheld connection

App connected to Handheld

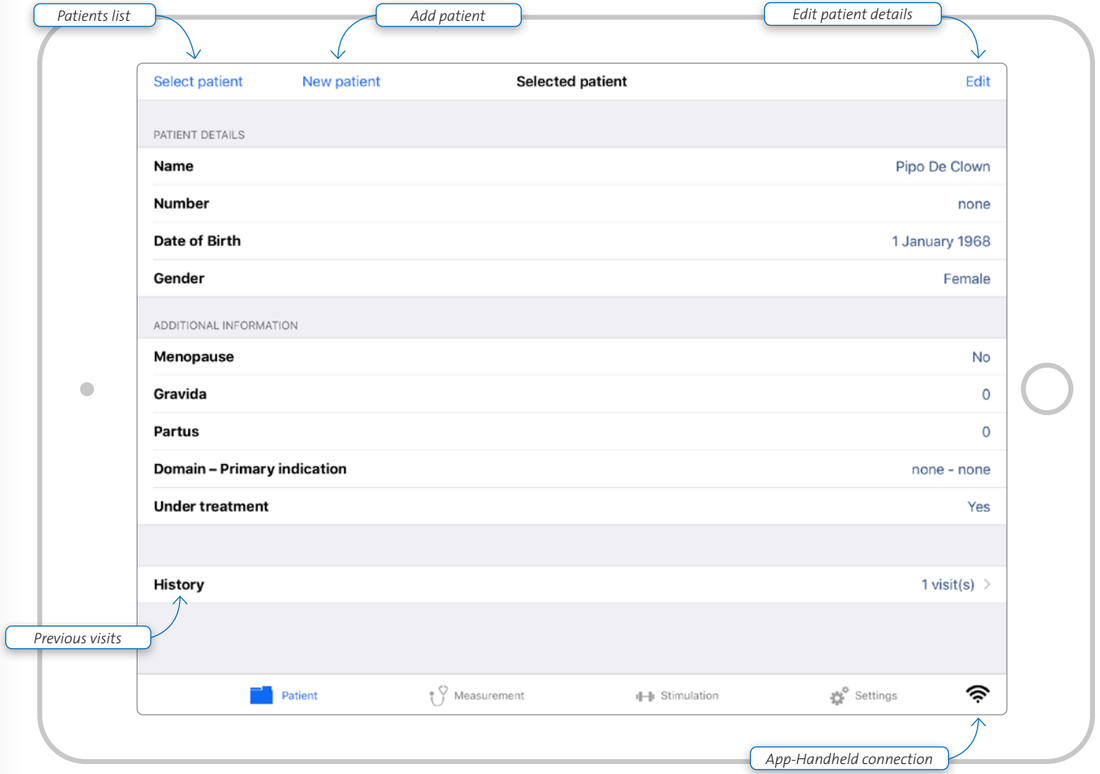
App not connected to Handheld

App connecting to Handheld

NOTE
Only when a patient is selected, one can proceed to the screen for Measurement or Stimulation.

NOTE
It is not able to compare to measurements to reference group 4.

(1.) Source *"Reliability and Differentation of Pelvic Floor Muscle Electromyography Measurements in Healthy Volunteers Using a New Device: The Multiple Array Probe Leiden (MAPLe)". The complete article was published in the peer reviewed "Neurourology and Urodynamics" journal. Author: dr. Petra J. Voorham- van der Zalm, PhD, Associate Professor, Pelvic Floor Physiotherapy, Leiden University Medical Center, Department of Urology.*

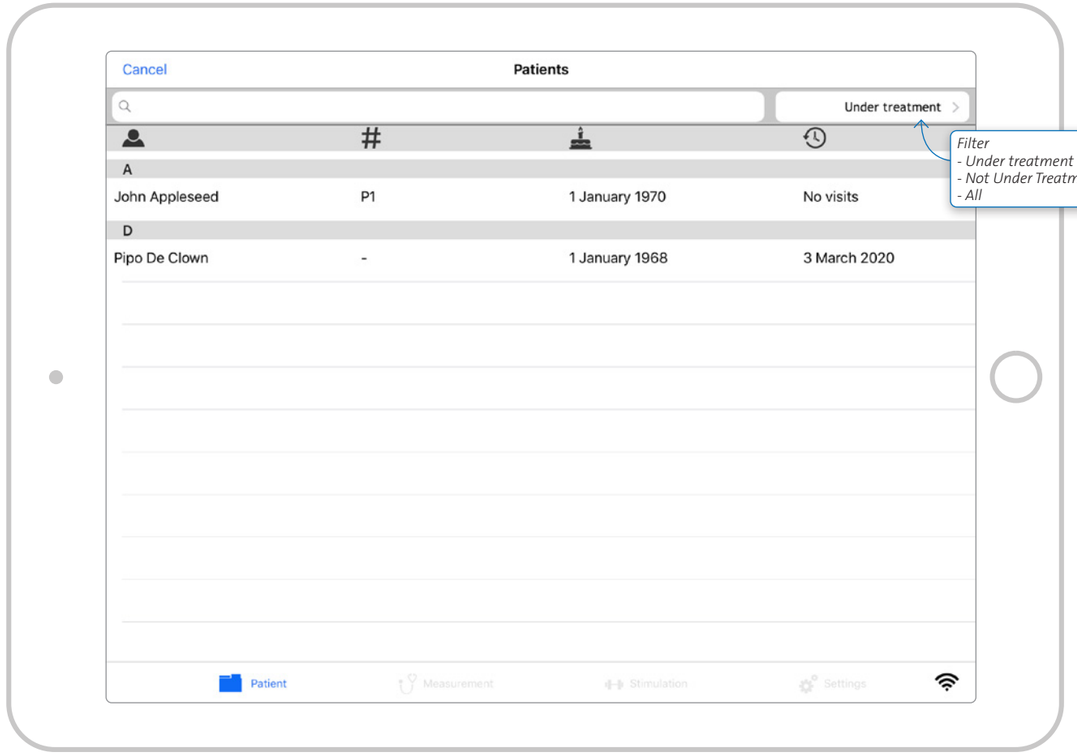


8.1.2) Patients list

Provides a list of existing patients in alphabetical order. It shows patient name, patient number, date of birth and date of last visit.

Filter

On the top right a filter can be set to sort your list with patients under treatment, not under treatment or all.



8.1.3) Patient - History

Switch between visits
One can flip through previous patient visits with the buttons in the top right.
Use the buttons 'Previous' and 'Next' to flip through each visit.

Views
There are two views: Grid (this page) and Graph (next page) where you can look through the details of all your saved measurements.

Grid view
Shows the differentiated measurement for Rest, MVC and Endurance. Switch between measurements on the same day with the stepper in the top right of each measurement type. Individual MVC and Endurance contractions can be assessed by flipping through them using the arrows for left and right.

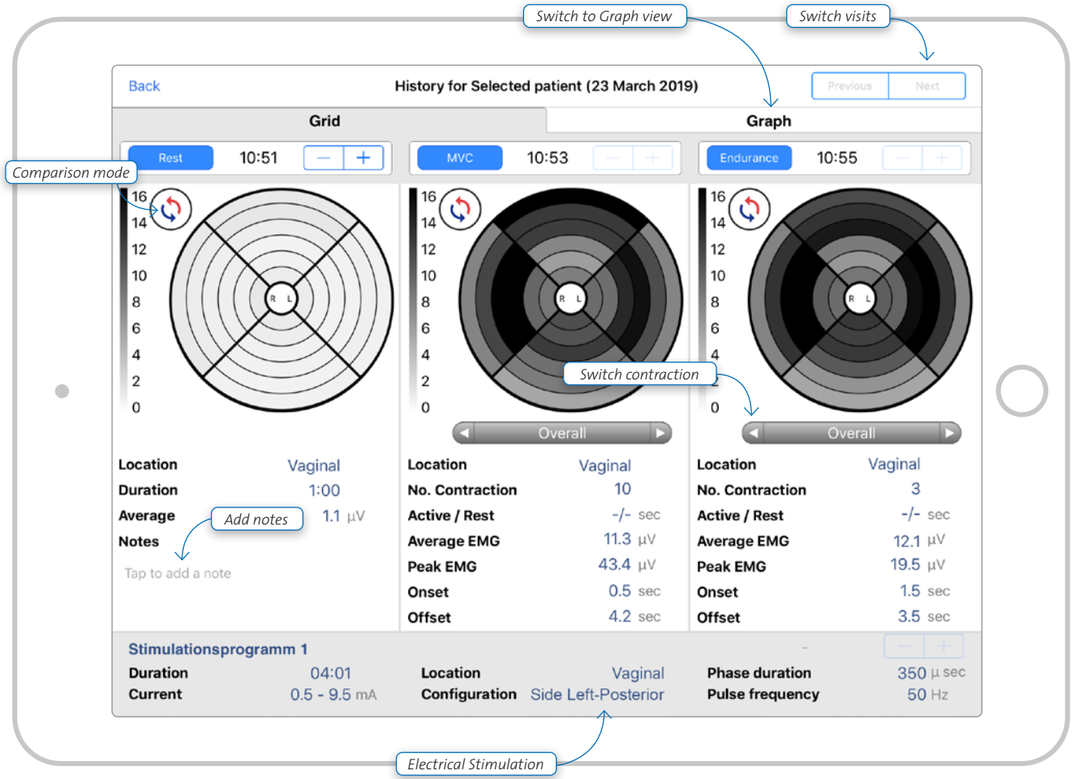
Below the Grid of each type details are displayed:
- Rest; Location, duration and average value µV.
- MVC and Endurance ; Location, number of contractions, Active/ Rest duration, Average EMG, Peak EMG, Onset and Offset.

Switch comparison mode
In Grid view there is the possibility to switch between the two comparison modes (absolute and reference comparison) by clicking the button next the the Grid of each measurement type.

Add notes
Notes can be added to the history screen per treatment day.
Tap in the 'Notes' section, the keyboard will appear and you can type a maximum of 250 characters.

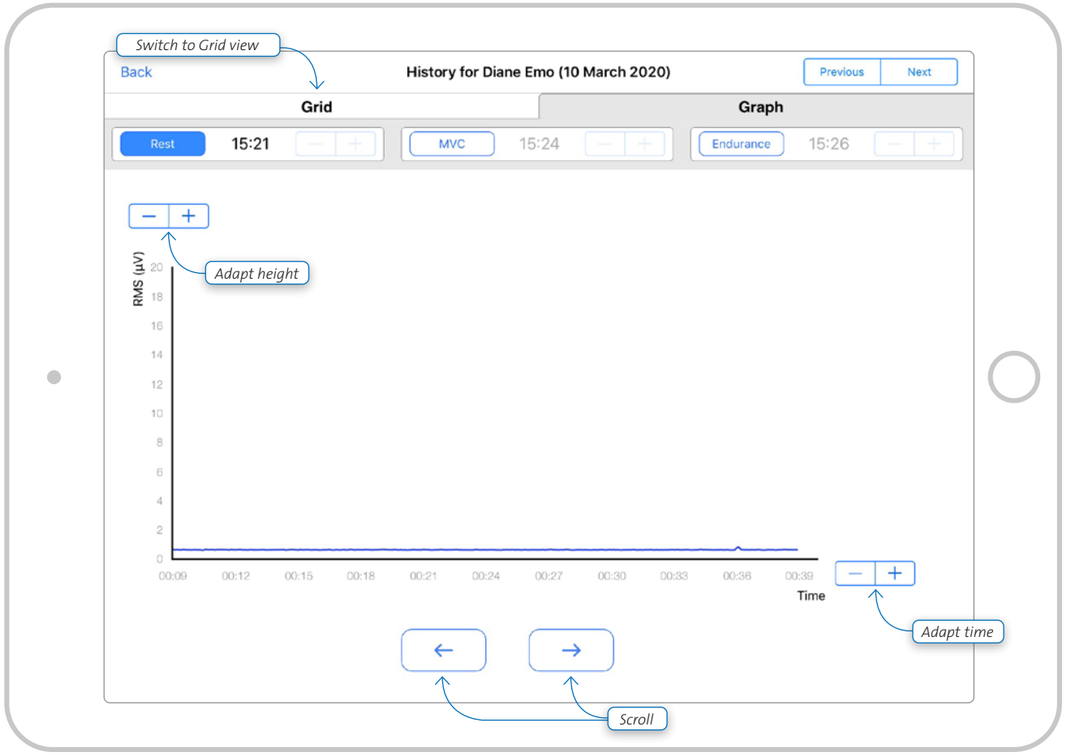
Stimulation data
The stimulation data shows the type of program that was set. Furthermore the Duration of the stimulation session is shown, the set stimulation Current levels from start of the session to finish, the Location of stimulation including the Configuration. The stimulation pattern is also shown; phase duration and pulse frequency. Multiple stimulation session can be saved per patient per visit.

NOTE
Rest, MVC and endurance history are always shown and saved in operator view.



Graph view

Shows the graph for the average EMG for every saved measurement. The blue color highlights the measurement shown in the Graph. Using the arrow buttons below the graph you can scroll through you can scroll through the graph. The stepper near to both axes allows you to decrease or increase the scale.



8.2) Measurement

8.2.1) Measurement Settings

1 Select location
For females the option for Vaginal or Anal is provided.

2 Select Measurement type
Choose from: Rest, MVC, Endurance or Training.

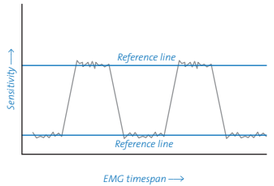
3 Set number of contractions for MVC/Endurance
Number of contractions can be set.

4 Set the contraction active period
For MVC the contraction active period can be set in steps of 1 second.
For Endurance the contraction active period can be set in steps of 1 second.

5 Set rest period between contractions
Set the duration of the rest period between contractions in steps of 1 second.

6 Edit Display settings
The display shows the average graph of the 'selected/active' electrodes
1. *Set EMG sensitivity*
   The EMG sensitivity can be set in steps of 5 µV.
2. *Set EMG Timespan*
   The EMG timespan can be set in steps of 5 seconds.
3. *Toggle EMG reference lines*

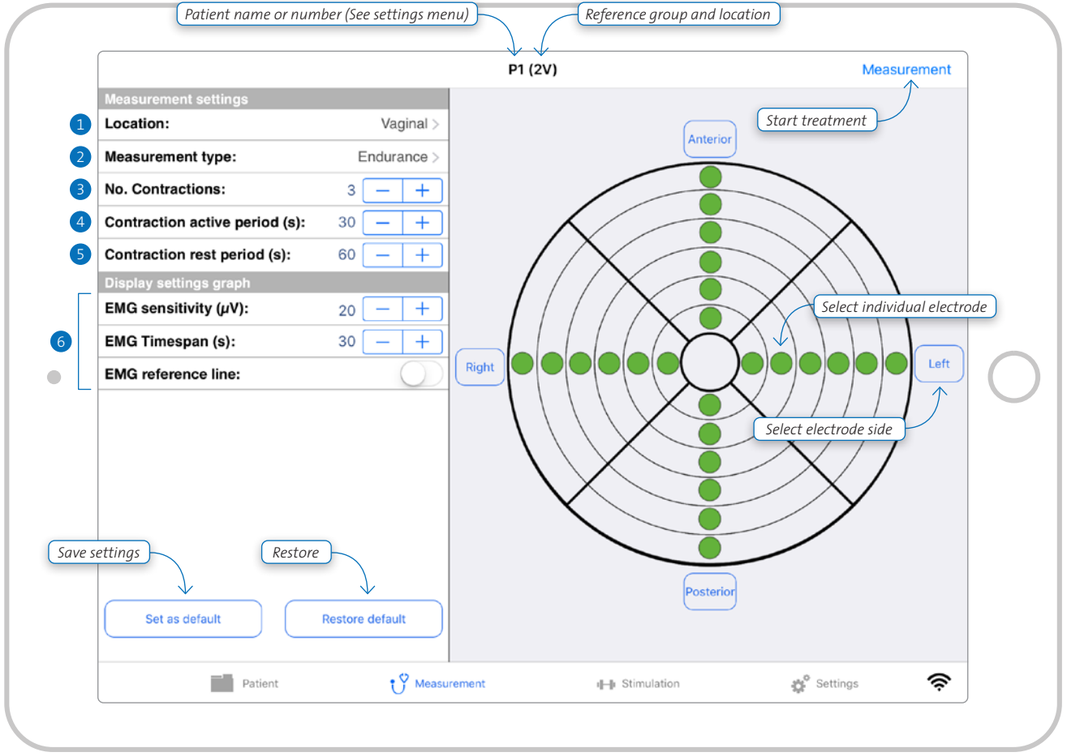
Two EMG reference lines can be chosen to serve as a reference for the patient. You can toggle them on or off. In the measurement screen you can set the height. The lines can be set at any level from 0 to the set EMG sensitivity per steps of 1 µV.



Personalize your settings
1. *Set as default*
   Frequently used settings can be set as default. Per diagnose type a default setting can be saved, the default applies for all patients.
2. *Restore default*
   Personalized default settings can be easily changed back to factory settings when 'Restore default' is selected.

Select electrodes
All 24 electrodes are 'active' per default
1. *Select/deselect individual electrodes*
   Individual electrodes can be selected/deselected when pressing each individual electrode.
2. *Select/deselect electrodes per side*
   Per plate the electrodes can be selected/deselected when pressing buttons 'Anterior', 'Left', 'Right' or 'Posterior'.

Select measurement button
Select the measurement button to proceed to the measurement screen.



8.2.2) Measurement screen

The measurement screen provides feedback for the measurement type, patient name or number, reference group and comparison type at the top of the display. Measurement time and the average value over the 'active' electrodes is also provided as feedback.

Start measurement

When selecting the 'play' button, the measurement starts.

Stop measurement

To stop the measurement session, select the 'stop' button. A new measurement can be started immediately by pressing the 'start' button again.

Save measurement

When a measurement has been stopped, the session can be either saved or discarded. When saving it, it will automatically be saved to the patient's history for the current visit/day.

Discard measurement

No measurement details are saved.

Circular grid modes

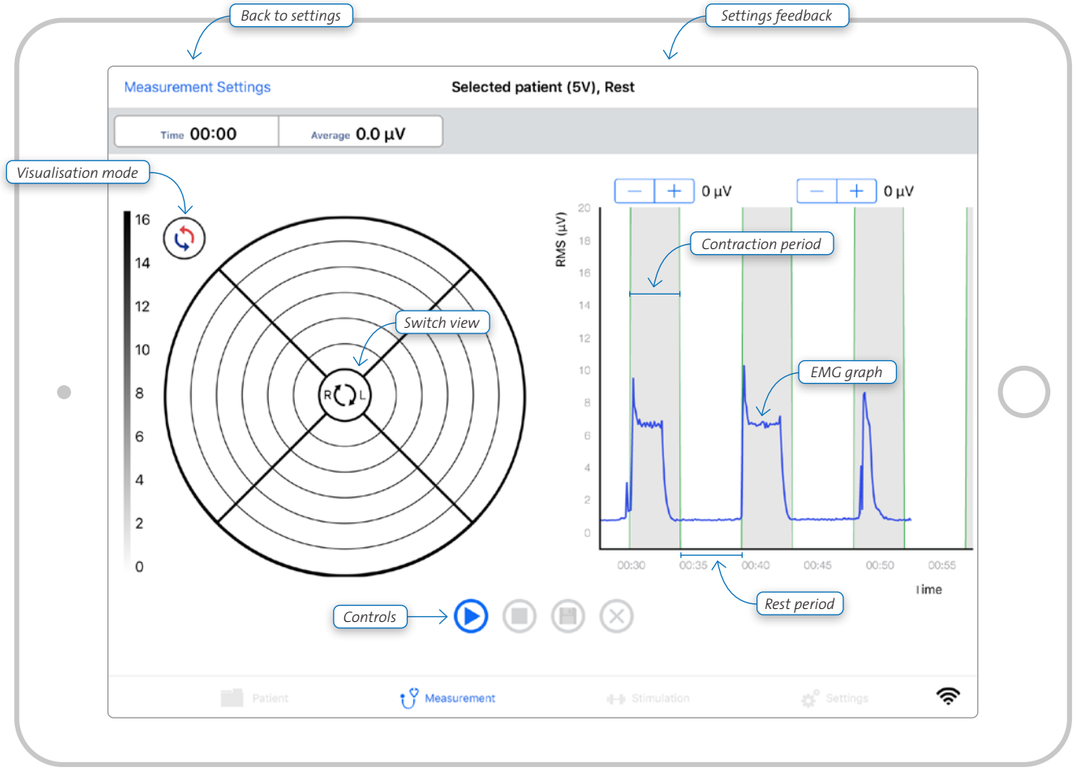
Two different view modes are provided for the circular grid: patient view and operator view. One can switch between these views at any given time during treatment:

The switch view button in the center of the grid.

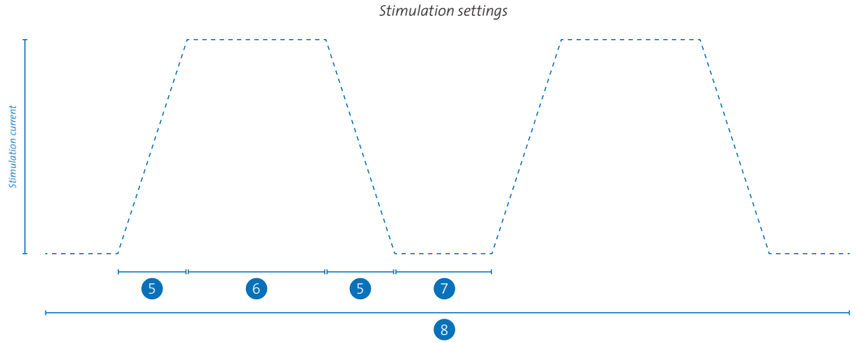
Two different display modes are provided for the grid: absolute and reference comparison mode. One can switch between these visualisations at any given time during treatment.

The switch to reference comparison mode button

The switch to absolute mode button



8.3) Stimulation



8.3.1) Stimulation settings

Edit Stimulation settings

Adjust the settings to patients' needs:

1. *Select location*
   For females the option for Vaginal or Anal is provided.
2. *Select Preset*
   Manufacturer presets (see 14) or user defined or last used

Edit Parameters

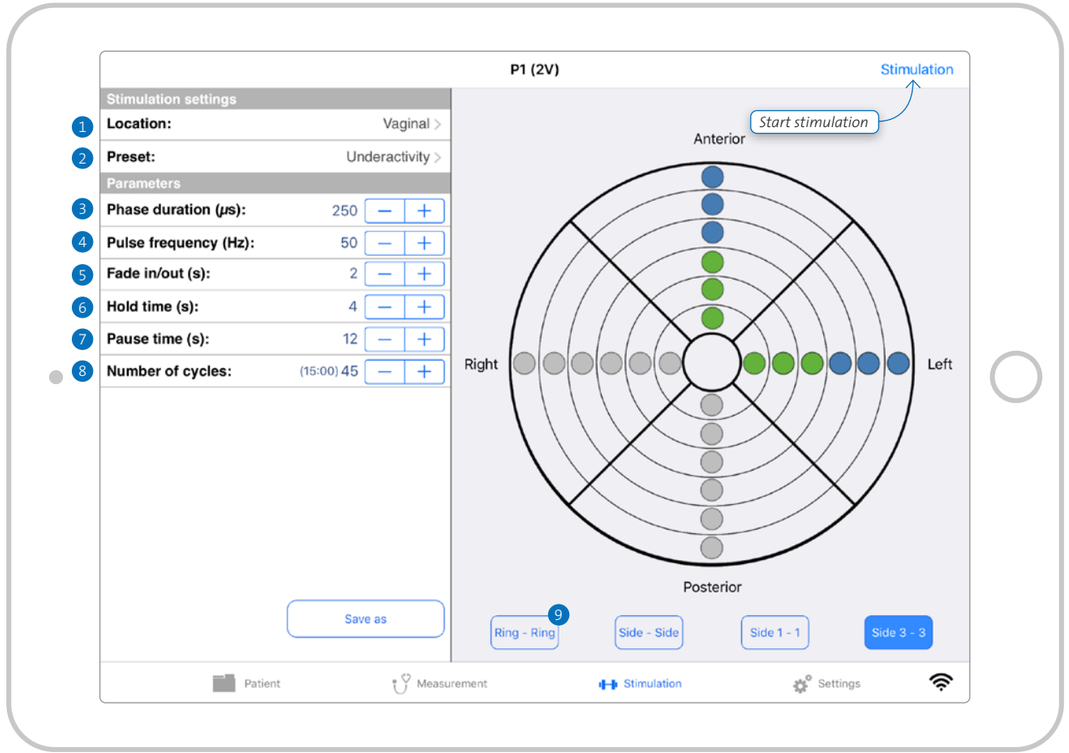
The stimulation program is adjustable, electro stimulation can be gradually faded in and out:

1. *Set Phase duration* 3
   The phase duration can be set in steps from 10µs.
2. *Set Pulse frequency* 4
   The pulse frequency can be set in steps of 1Hz
3. *Set Fade-in* 5 */ Fade-out* 5
   The fade in time is always equal to the fade out time and can be set in steps of 1 second.
4. *Set Hold time* 6
   The hold time can be set in steps of 1 second.
5. *Set Pause time* 7
   The pause time can be set in steps of 1 second.
6. *Set number of cycles* 8
   The number of cycles can be set in steps of 1.
7. *Select configuration* 9
   Choose from; ring-ring, side-side, side 1–1 & side 3–3.
8. *Select 'Stimulation' button*
   When all settings have been set, the 'Stimulation' button can be selected to proceed to the Stimulation screen.

WARNING
The MAPLe probe should be placed with care, making sure that electrodes contact the tissue. Please also note that high currents may cause irritations or burns.

WARNING
Always apply stimulation with care, increase current stepwise.

WARNING
Electrodes with current densities exceeding 2mA/cm2 may require the special attention of the user.



8.3.2) Stimulation screen

The Stimulation screen provides feedback with the selected patient or ref no, reference group, preset option and the selected stimulation location from either of the four options R-R or S-S or S1–1 or S3–3. Stimulation time is also provided as feedback

Set stimulation current

Per default the current level starts at 0.5mA. Current can be increased during active stimulation with '+' and decreased with '-'.

Start stimulation

When selecting the 'play' button, the stimulation starts.

Stop stimulation

To stop the stimulation session, select the 'stop' button. For safety features the 'stop' button is larger than the other buttons.

Save stimulation

When stimulation has been stopped, the session can be either saved or discarded. When saving it, it will automatically be saved to the patient's history for the current visit / day. One stimulation session can be saved per patient per visit. A previously saved session can be overridden with new session details after confirmation of the user.

Discard stimulation

No stimulation details are saved.

WARNING
Caution has to be taken when increasing the power, because overstimulation can result in discomfort or pain. It is advised that the power is turned up to maximum patient tolerances, however it should remain below the pain threshold of the patient, so that no pain or discomfort is experienced. The maximum amplitude used for stimulation depends on the individual threshold of pain/discomfort, which differs per patient.

WARNING
Possible side-effects that may occur are: pain and/or discomfort, unpleasant sensation, local skin irritation, vaginal bleeding, urinary tract infection, spasm of the bladder, diarrhea, fecal incontinence, exhaustion of stimulated muscle fibres (which could temporary increase specific pelvic floor dysfunction), tingling and/or leg tremor

8.4) General settings

Information about the MAPLe App and MAPLe system can be viewed in the settings menu, such as; handheld battery level, EULA, Privacy Policy and Application version.
The settings menu is also used for editing settings.

1 View handheld settings
1. *Handheld name and Firmware version.*
2. *Connection information*
   The connection status refers to whether the handheld and MAPLe App are connected or not. It shows the IP and the MAC address.

2 Change current user password
1. *Enter the current user's password.*
2. *Enter a new password.*
3. *Confirm the new password.*
4. *Press button 'Change password'.*

Press 'Logout' to log out the current user.

3 Manage users
1. *Press '+' in the top right to add user.*
2. *Add user details.*
3. *Confirm information with the Administrator password.*
4. *Finalize procedure by tapping the 'Create user' button.*

Reset user password
When a user forgot his/her password, the Administrator must assist in resetting this password.
1. *Log in as Administrator.*
2. *Go to 'Settings' menu.*
3. *Go to 'Manage users'.*
4. *Select the user in particular.*
5. *Type in new password and confirm this new password.*
6. *Type administrator password for verification.*
7. *Press button 'Reset password'.*

Manage users - Delete users
(Administrator-only feature)
1. *Users can be deleted when pressing 'Edit'.*
2. *Press the red icon in front of the user you wish to delete.*
3. *Confirm by pressing 'Delete'.*

4 Preferences
1. *Choose either Number or Name for patient reference.*
2. *Turn sound On / off*

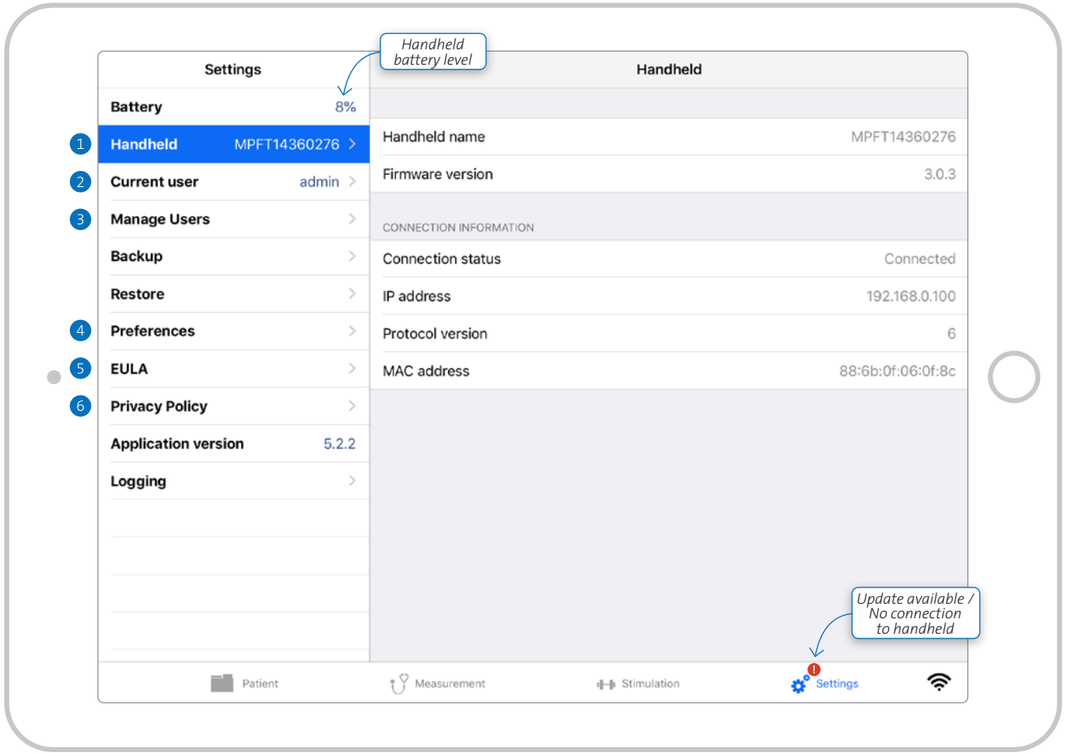
5 EULA
Shows the complete End User Licence Agreement.

6 Privacy policy
Our privacy commitment to the user.

Update firmware
When new firmware is available, this will be indicated in the Settings menu.
1. *Go to Settings menu.*
2. *Go to 'Firmware update available'.*
3. *Follow the procedures on the screen.*

WARNING
Deleting a user will also delete the patient data that is linked to this particular user.

PREPARATIONS FOR USE
All users and personnel shall have a good understanding of working in the right and safe way with the MAPLe device.



8.4.1) Backup & restoring backups

1 Create a backup and save it to your computer.

1. Open the MAPLe App and go to the Settings menu.
2. Go to 'Backup'.
3. Select 'Backup' button. The backup is encrypted and saved to your iPad.
4. Connect your iPad to your computer.
5. Open iTunes and follow the next steps in iTunes:
6. Select your iPad in iTunes: 
7. Create a backup of your iPad by selecting the 'Back Up Now' button, wait until finished.
8. Go to 'File sharing' in the iTunes Settings menu.and select the MAPLe App from there.
9. Select the latest backup file from the 'MAPLe App Documents' section and save it to your computer, using the button 'Save to'. The backup file is a zipfile. Select a personal location on your computer for saving your MAPLe App backups.

2 Restore a backup from your computer to the iPad

1. Connect your iPad to your computer.
2. Open iTunes and follow the next steps in iTunes:
3. Select your iPad in iTunes: 
4. Go to 'File sharing' in the iTunes Settings menu and select the MAPLe App from there.
5. Go to the 'MAPLe App Documents' section and select 'Add' to add the backup file (zipfile) you wish to transfer from your computer to your iPad, follow the procedure.
6. Sync your iPad in iTunes with the 'Synchronize' button.
7. Disconnect your iPad when the synchronization is finished.
8. Open the MAPLe App and go to the Settings menu.
9. Choose 'Restore backup'.
10. The backup which you retrieved from your computer will show.
11. Type in the administrator password for verification.
12. Press 'Restore backup' button and follow the procedure.

Restore a backup from your computer to a new iPad

1. Install the MAPLe App to a new iPad.
2. Connect your iPad to your computer.
3. Open iTunes and follow the next steps in iTunes:
4. Select your iPad in iTunes: 
5. Go to 'File sharing' in the iTunes Settings menu and select the MAPLe App from there.
6. Go to the 'MAPLe App Documents' section and select 'Add' to add the backup file (zipfile) you wish to transfer from your computer to your iPad, follow the procedure.
7. Sync your iPad in iTunes with the 'Synchronize' button.
8. Disconnect your iPad when the synchronization is finished.
9. Open the MAPLe App.
10. Read and accept the EULA if agreed upon, when opening the App the first time.
11. Select 'Next'.
12. Choose 'Restore backup'.
13. Type in the administrator password for verification.
14. Press 'Restore backup' button.

Lost administrator passwords and password recovery

1. When typed in the wrong password, press 'Reset Password'.
2. The Administrator must call Novuqare and provide the verification code. Novuqare will do a safety check for the request.
3. If safety check is OK, the administrator will receive an unlock code. Enter the unlock code to proceed.
4. Enter new password and confirm.
5. Press 'Reset Password'.
6. Log in with new password.

WARNING
Make sure that backups are regularly saved to your computer to prevent data loss.

WARNING
Before updating the MAPLe App via the App Store, you must create a backup of the MAPLe App and save it to your computer.

8.4.2) Logging

3 Create logfile & send

1. Go to Settings menu, make sure the handheld is connected.
2. Go to 'Logging'.
3. Select 'Save logging' button. The logfile is saved to your iPad.
4. Connect your iPad to your computer.
5. Open iTunes and follow the next steps in iTunes:
6. Select your iPad in iTunes:
7. Create a backup of your iPad by selecting the 'Back Up Now' button, wait until finished.
8. Go to 'File sharing' in the iTunes Settings menu and select the MAPLe App from there.
9. Select the folder 'Logging' from the 'MAPLe App Documents' section and save it to your computer, using the button 'Save to'. The logfile is a zipfile.
10. Email the zipfile to Novuqare.

9) Technical description

Product identification

Model	MAPLe MPFT
Serial no	MPFT1436xxxx
Version	V1
CE	0344 (Dekra Certification BV)
Safety class	IIa
Mains voltage	100 – 240V, 50 – 60Hz, 0.16 – 0.1A
IP class	IP25, Probe to Probe cable connection only

Manufacturer

Novuqare Pelvic Health BV
Kievitsven 42
5249 JJ Rosmalen
The Netherlands

iPad requirements for running the MAPLe App

Model	iPad Air and up
iOS version	iOS12 or iOS13 and up

Working conditions for use

A) Environment:
- Indoor use only
- In professional treatment room
- Temperature range: 0 – 25 (°C).
- Relative humidity range: 5 – 95%, non condensing

B) Frequency of use:
- Average treatment requires 10 sessions per patient. The average single patient will therefore use the MAPLe probe 10 times.
- Use of the MAPLe system is up to 14 sessions per day. Sessions regularly last 30 minutes, but can last up to 100 minutes.

C) Mobility:
- Handheld to be placed on the treatment couch when treating a patient.
- When handheld is not in use, it can be carried around with a keycord around the neck.

Applied parts

The MAPLe probe, probe cable, reference cable and handheld are type BF applied parts.

Technical product life

The expected product life of the MAPLe system is 7 years.

WARNING
No modification of this equipment is allowed.

WARNING
All equipment connected to the Ethernet port shall be reinforced insulated from mains.
Only connect IEC60950–1 compliant equipment to the docking station with a working voltage of <60Vdc.

WARNING
Do not update the Operating System of the iPad until Novuqare has communicated their approval.

Technical description MAPLe system

	MAPLe system
Type	Portable
Use	EMG and ES
Range	0 – 200 µV
Sensitivity	0,1 µV
Pulse type	Biphasic symmetrical rectangular
Phase duration	200 – 1000 µs
Pulse frequency	2 – 150 Hz
Amplitude	0 – 29 mA
Load impedance range	0 – 1 kOhm per electrode couple

EMG measurement settings

	Range settings
Measurement duration rest	1 – 55 (min), steps per 1 minute
Number of contractions MVC	1 – 40, steps per 1 second
Contraction active period MVC	1 - 15 (s), steps per 1 second
Contraction rest period MVC	3 - 30 (s), steps per 1 second
Number of contractions endurance	1-20, steps per 1 second
Contraction active period endurance	15 - 60 (s), steps per 1 second
Contraction rest period endurance	15 - 100 (s), steps per 1 second
EMG sensitivity	5 - 200 (µV), steps per 5 µV
EMG timespan	10 - 60 (s)
EMG reference line 1	Steps per 1 µV
EMG reference line 2	Steps per 1 µV

Electro stimulation settings

	Range settings
Phase duration	200 – 1000 (µs), steps per 10 µs
Pulse frequency	2 – 150 (Hz), steps per 1 Hz
Fade in/out	0 – 5 (s), steps per 1 second
Hold time	2 s – 30 m
Pause time	0 – 20 (s), steps per 1 second
Number of cycles	1 – 60, steps per 1

Technical description MAPLe probe

	MAPLe system
Shape	Cylindrical
Use	Vaginal and Anal
Number of electrodes	24
Active area of single electrode	0.05 cm^2

Third-party software and open source software

This product contains third-party software and open source software. In accordance with the applicable license terms we inform you on the license and the rights and obligations with regard to this software. This information applies only to the software as indicated and will not affect your rights or obligations under the license agreement between you and Novuqare.

- This product contains software developed by the OpenSSL Project for use in the OpenSSL Toolkit (http://www.openssl.org/).
- This product contains software written by Eric Young (eay@cryptsoft.com).
- This product contains software written by Tim Hudson (tjh@cryptsoft.com).

This product contains third-party software and open source GPL software. In accordance with the applicable license terms you may request a copy of the source code of the open source GPL software by sending a written request to Novuqare. Novuqare may charge a fee for this service.

Essential Performance

The MAPLe system is capable of EMG measurement and of providing electro stimulation. As measurement is a passive function, a loss or performance beyond the limits does not result in a risk of any kind. Therefore, EMG measurement is not an essential performance function.

Electro stimulation is maximized at 29mA; performance beyond this limit does result in risks that have been determined during Risk Management. Overstimulation results in unacceptable risks. Therefore, appropriate control measures have been taken in hardware and software, keeping stimulation at acceptable levels at all times. As performance beyond the specified limit is unacceptable, the electro stimulation function of the MAPLe system is defined as essential performance, it must stay under the specified maximum level at all times.

Information on materials

Electrodes - gold

The patient-contacting material of the electrodes is Gold. Gold is a noble metal and does not react with oxygen under ambient conditions. Therefore gold does not tarnish, leading to its use in jewelry and coinage. The same resistance to oxidation and other harsh chemical environments leads to its use in industrial applications such as labware and electrical contacts. Gold is known for its low-allergenic conditions to the human body; the top Gold layer is purposely chosen to minimize possible allergic reactions to the mucosa.

Plastics

The plastic which is used is a polyamide 12 compound. It is resistant to body fluids and is toxicologically safe. The grades are currently used in catheters and tubings and angioplasty balloon catheters. They also include housing parts, monitoring and imaging devices and durable medical equipment.

Conditions for transport / storage

Environment temperature:
–20 to +50°C
Relative humidity:
5 to 95%

Environmental information

The MAPLe system contains materials that can be recycled. Please consider disposing the MAPLe system at specialized companies that can take care of the dismantling and recycling of the system.

LED indications	Docking station	Handheld		
		EMG	ES	ON
Power on indication	●			●
Charging / Fully charged	☀ / ●			
Battery low	●			☀
Handheld is connecting	●	☀		●
EMG modus active	●	●		●
Stimulation modus active	●		●	●
Error Docking station	●			
Error Handheld			☀	●

10) Electromagnetic Compatibility (EMC)

The MAPLe system is designed to be used in professional treatment rooms and is approved according to the EMC safety standard of EN60601–1–2. Professional treatment rooms can be clinical environments such as a hospital, but can also be a dedicated treatment practice in a domestic environment.

Electromagnetic interference

- Simultaneous connection of a patient to the MAPLe system and high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation of the MAPLe system in close proximity (4 meters) to shortwave or microwave therapy equipment may produce instability to the stimulator output.
- It is highly recommended to maintain a distance of at least 4 meters between the MAPLe and any shortwave or microwave therapy equipment.
- Operation of the MAPLe system in close proximity to cellphones may produce instability to the MAPLe system. To achieve the best results it is highly adviced to switch off mobile phones when using the MAPLe system.
- Portable and mobile RF communications equipment can affect the MAPLe system.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The MAPLe system is intended for use in the electromagnetic environment specified on the next pages. It is the responsibility of the customer or user to ensure that the MAPLe system is used in such an environment.

Emissions Test	Compliance Level	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The MAPLe system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MAPLe system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000–3–2	NA	
Voltage fluctuations/flicker emissions IEC 61000–3–3	NA	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) to EN 61000–4–2	± 6 kV contact ± 8 kV	± 4 kV ± 8 kV	The compliance level for the ESD HCP is -4kV; Operators should wear a white coat when operating the MAPLe system. Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst to EN 61000–4–4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power should be that of a typical commercial or hospital environment.
Surge to EN 61000–4–5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000–4–11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT 40 % UT 70 % UT <5 % UT	Mains power should be that of a typical commercial or hospital environment. If the user of the MAPLe system requires continued operation during power mains interruptions, it is recommended that the MAPLe system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to EN 61000–4–8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the MAPLe system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF to EN 61000–4–6	3 Vrms 150 kHz to 80 MHz	3 V	Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2700 MHz
Radiated RF to EN 61000–4–3	3 V/m 80 MHz to 2700 MHz	3 V/m	Where P is the rated 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 (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MAPLe system is used exceeds the applicable RF compliance level above, the MAPLe system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MAPLe system.

(b) Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the MAPLe system

The MAPLe system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MAPLe system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MAPLe system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

11) Maintenance

Cleaning instructions

The probe and cable must be cleaned and disinfected immediately after use. according to the protocol mentioned below, or according to a country specific protocol if applicable. When the probe is connected to the probe cable, this connection is IP25.

Protocol probe and cable

- Rinse the probe and cable (still attached to each other) under lukewarm water from the tap. (A)
- Dry the material with a soft cloth or a soft, non-fluffy tissue.
- Disinfect probe and cable with a gauze which has been well wetted with alcohol 70 . Maintain a contact time of at least 30 seconds.
- Remove the probe from the cable with the gauze pad, put the probe aside to dry.
- With regard to the probe cable:
- Disinfect the rim, ring and inside of the connector at the side of the patient with a gauze pad well-moistened with alcohol 70 . Be sure no alcohol seeps into the connector.
- Maintain a contact time of at least 30 seconds. Air dry the cable.

Housing

The reference cable, handheld, dockingstation and iPad may be cleaned with a dry paper/cloth, or potentially with alcohol..

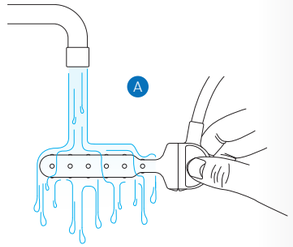
Preventive maintenance

Check the housing regularly for damage.Check the probe cable and reference cable regularly for damage. Calibration of the system can be provided upon request.

Battery

Battery changes are to be done by service personnel - expected after 3 years according to battery degradation.

Novuqare is not responsible for any repairs/maintenance carried out by unauthorized persons. Please check www.novuqare.com for our dealer network and authorized stations. Novuqare will make available on request circuit diagrams, component part lists, descriptions, or other information that will assist service personnel to repair those parts of the MAPLe system that are repairable by service personnel.



WARNING
The probe must be cleaned with the probe cable attached to the probe. The connectors must not become wet.

WARNING
Always use gloves during treatment and the cleaning procedure.

WARNING
Make sure the probe is dry before disinfecting it with alcohol, only then the alcohol will be effective.

12) Troubleshooting

WARNING
Do not attempt to open any part/component. Maintenance and/or repairs are to be carried out by authorized service personnel only.

WARNING
Only technical support personnel may intervene in the electronics.

WARNING
Replacement of batteries by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion).

WARNING
Do not service the MAPLe system or any part of the system when in use with a patient.

Having trouble? Many issues can be resolved by updating your MAPLe App and handheld firmware. Go to the App Store to find the most recent update.

If you are still having trouble with the most recent update, please check the troubleshooting.

12.1) Troubleshooting Docking station

Red LED

If the red LED lights up when the handheld is placed on the docking station, then proceed with the following steps:

- Check if the handheld is correctly placed on the docking station.
- Check if the handheld has become too warm to charge, wait 10 minutes before your proceed. If the red LED does not turn off, then an error has occurred.
- Turn off the MAPLe handheld.
- Reset the docking station by taking out its power cable and leave it out for 10 seconds.
- Connect the docking station to the power cable and wait 30 seconds.
- Check the indicator LEDs if the red LED is still illuminated.If the problem remains, please contact Novuqare

12.2) Troubleshooting Handheld

EMG LED blinks on handheld

When the EMG LED keeps on blinking on the handheld, no connection is found. Then proceed with the following steps:

- Turn off the MAPLe handheld.
- Reset the docking station by taking out its power cable and leave it out for 10 seconds.
- Connect the docking station to the power cable and wait 30 seconds.
- Switch on the MAPLe handheld and wait 30 seconds.
- Check the LEDs on the handheld.

If the problem remains, leave the handheld on the docking station to charge for at least 1 hour. Check if the same problem occurs by switching on the handheld.

ES LEDs blinks on handheld

When the ES LED keeps on blinking on the handheld, an error has occurred. Then proceed with the following steps:

- Turn off the MAPLe handheld.
- Reset the docking station by taking out its power cable and leave it out for 10 seconds.
- Connect the docking station to the power cable and wait 30 seconds.
- Switch on the MAPLe handheld and wait 30 seconds.
- Check the LEDs on the handheld

12.3) Troubleshooting iPad MAPLe App

Error message	Corrective Action
E01: Connection to the Maple Handheld is lost. Please reconnect.	Try to connect to MAPLe handheld; Settings/Handheld/'Connect' Make sure that the handheld is on. Make sure that you always turn on the handheld first, wait until it stops blinking, then start up your iPad App. Make sure the iPad is connected to the correct Wi-Fi network, corresponding to the serial number of the MAPLe system; check iPad settings. Make sure the docking station is powered and the green LED is on. If fail; turn off docking station by removing adapter and turn off handheld. Plug adapter back in docking station after 10 seconds. Start up the handheld after 30 seconds and consequently start up the App after the handheld is connected. Make sure the iPad, docking station and handheld are in the same room in order to have a stable connection with the wireless system.
E02: Probe is not connected	Probe/cable not connected. Connect a probe and cable to the MAPLe system.
E03: Unknown handheld error; restart handheld	Create logfile, send to Novuqare. Restart handheld. Recharge handheld.
E04: Handheld received invalid request; restart handheld	Create logfile, send to Novuqare. Restart handheld. Recharge handheld.
E05: Handheld battery level low	Charge battery. Place handheld on docking station.
E06: Handheld is connected to mains	Restart handheld. Create logfile, send to Novuqare. Restart handheld. Recharge handheld.
E07: Probe or reference electrode does not make contact with patient	Probe electrodes have no/bad contact with mucosa. Reposition probe or patient to improve probe-mucosa contact, or (re)apply electrode gel on probe electrodes. Reference electrode cable not connected or bad contact. Connect reference cable to handheld or check contact. Apply a little contact gel between reference electrode and the patient's skin.
E08: Invalid current increase	Restart handheld
E09: Max current reached	NA
E10: OVP/OCP error	Overstimulation or short circuit situation has occurred. Create logfile, send to Novuqare. Restart handheld.

Error message	Corrective Action
E11: Cannot update firmware with the same version	Repeat update procedure; use in-App guidelines to do so.
E12: Before the firmware can be updated, charge the battery of the handheld	Recharge handheld.
E13: Uploading firmware failed	Repeat update procedure; use in-App guidelines to do so.
E14: No firmware available for update	Repeat update procedure; use in-App guidelines to do so.
E15: Firmware flashing failed	Repeat update procedure; use in-App guidelines to do so.
E16: Firmware version is incorrect after update	Repeat update procedure; use in-App guidelines to do so.
E17: Firmware update has been aborted	Repeat update procedure; use in-App guidelines to do so.
E18: Unknown handheld error; restart handheld	Restart handheld.
E20: Connection to the Maple Handheld is lost. Please reconnect.	See E01.
E21: Connection to the Maple Handheld is lost. Please reconnect.	See E01.

Tips

When wanting to stimulate the Urethra, the probe can be turned 45 degrees to stimulate across the Urethra.

Did you know that the handheld turns itself off if there is 15 minutes of no activity? This saves the battery.

For the best results, make sure to use electrode gel recommended by Novuqare, do not use ultrasound gel.

When wanting to explain something to your patient, you can stop the treatment session with the 'stop' button. A new treatment session can be started directly by pressing 'play' again.

13) Background information

Electromyography (EMG) registration/Biofeedback

Among the technologies to study pelvic floor neural control, EMG registration of Pelvic Floor Musculature (PFM) has gained most attention and clinical relevance, while others have remained mainly research tools [1]. EMG is used clinically to evaluate the gross neuromuscular function of the PFM and to provide biofeedback during strength or coordination training.

Because the PFM lies deep to the skin surface and because the superficial and deep layers of PFM have distinct functions, it is not ideal to use surface electrodes adhered to the perineum to study the deep layer of the PFM, as unwanted activity (crosstalk) would inevitably be recorded from the superficial PFM and potentially from other nearby muscles including the anal sphincter, the gluteals, and the obturator hip musculature. Because the deep PFMs lie adjacent to the vaginal walls, electrodes positioned against the lateral vaginal walls or the anal canal is a convenient way to record their EMG activity. Electrodes mounted onto the solid surface of an intravaginal or -anal probe are typically used [2].

Nowadays, surface EMG with electrodes embedded on vaginal and anal probes is widely used to assess PFM function and to increase our understanding of pelvic floor function. Non-invasive recording of surface-EMG (S-EMG) from pelvic floor sphincter muscles usually adopts either longitudinal or ring-shaped pairs of electrodes or perianal electrodes [3].
The devices come in various shapes and sizes, and most comprise large plates or rings. Therefore, comparison of results from one device to another is not recommended. These devices have all been developed empirically and are not specifically designed with the pelvic floor anatomy in mind, most of them are not reliable and they are not validated. In several studies it already has been stated that the shape and size of the probes should be adapted to the local anatomy [2] [4].

In the latest reviews it is stated that there is evidence that EMG registration/biofeedback in the diagnosis and treatment of pelvic floor dysfunction is common practice. The reviews give a thorough overview of the clinical trials published on these subjects. All reviews regarding EMG registration with biofeedback state that biofeedback benefits in the treatment of pelvic floor dysfunctions. We know that EMG registration with biofeedback may be effective in the treatment of pelvic floor dysfunctions. However more randomized controlled trials are warranted with standardized treatment protocols and control groups and with the same equipment, in order to get more uniformity in diagnosis and treatment of pelvic floor dysfunctions.

Electro stimulation (ES)

In the context of conservative therapy, electrical stimulation can be applied using surface electrodes embedded on vaginal and anal probes. Electrical stimulation with non-implanted devices is used for patients with complaints of micturition, defecation, sexual function, pelvic pain and/or prolapse related to pelvic floor dysfunction. It involves stimulation of the PFM with an electric current using surface electrodes on a vaginal or anal probe. Electrical stimulation might lessen the contractions of the bladder muscle to ease the sense of urgency and allow the bladder to hold more urine.

Nowadays maximal electrical stimulation using a high-intensity stimulus (just below the pain threshold) is performed. In literature the frequencies used are 5–10 Hz, 20 Hz, and 35–50 Hz, with pulse durations of 200–1000 µsec. The pulse shape is generally rectangular and biphasic pulses are preferred [6] [7]. The power is turned up to maximum tolerances, however it remains below the pain threshold of the patient, i.e. the patient feels no pain or discomfort.

Also for electro stimulation there is a need for more randomized controlled trials that are warranted with standardized treatment protocols and control groups while using the same equipment, in order to get more uniformity in diagnosis and treatment of pelvic floor dysfunctions.

A clinical study was performed with the prototype of the MAPLe probe and a commercially available EMG acquisition device. The conclusions of this study were that the MAPLe is a reliable instrument to measure the different muscles on the different sides of the pelvic floor and that the probe is capable to differentiate between men and women, nulliparous, parous and pre- and post-menopausal. With the validation study of the MAPLe we hope to contribute to make pelvic floor physiotherapy more evidence-based [5].

The data retrieved from this clinical study is incorporated in the MAPLe system. It serves as reference data for patient measurements.

1 *Enck P, Vodusek DB.*
Electromyography of pelvic floor muscles. J Electromyogr Kinesiol 2006 December;16(6):568–77.

2 *Keshwani N, McLean L.*
State of the art review: Intravaginal probes for recording electromyography from the pelvic floor muscles. Neurourol Urodyn 2013 November 21.

3 *Voorham-van der Zalm PJ.*
Electromyographic registration of the pelvic floor musculature to measure pelvic floor muscle function. Dublin, Ireland: 2013; 2014. Report No.: 38th Annual meeting International urogynocological Association: Handout Workshop Digital Palpation to Imaging: How Do or Should Pelvic-Floor-Muscle Evaluation Tools Influence Physiotherapy Practice?

4 *Voorham-van der Zalm PJ, Pelger RCM, Van Heeswijk-Faase IC, Elzevier HW, Ouwerkerk TJ, Verhoef J, Nijeholt GABL.*
Placement of probes in electrostimulation and biofeedback training in pelvic floor dysfunction. Acta Obstetricia et Gynecologica Scandinavica 2006;85(7):850–5.

5 *Voorham-van der Zalm PJ, Voorham JC, van den Bos TW, Ouwerkerk TJ, Putter H, Wasser MN, Webb A, Deruiter MC, Pelger RC.*
Reliability and differentiation of pelvic floor muscle electromyography measurements in healthy volunteers using a new device: the Multiple Array Probe Leiden (MAPLe). Neurourol Urodyn 2013 April;32(4):341–8.

6 *Berghmans B, Hendriks E, Bernards A, de Bie R, Omar MI.*
Electrical stimulation with non-implanted electrodes for urinary incontinence in men. Cochrane Database Syst Rev 2013;6:CD001202.

7 *Jerez-Roig J, Souza DL, Espelt A, Costa-Marin M, Belda-Molina AM.*
Pelvic floor electrostimulation in women with urinary incontinence and/or overactive bladder syndrome: a systematic review. Actas Urol Esp 2013 July;37(7):429–44.

14) Electrostimulation recommendations

Electrostimulation recommendations (anal and vaginal) as preset in App

Dysfunction	Phase Duration	Pulse Frequency	Settings and treatment plan	Electrode configuration	Intensity	Remarks
Underactivity	250 µsec (250–600)	50 Hz (35–80)	Fade in/out: 2 s Hold time: 4 s (4–6) Pause time: 12 s (8–12) Number or cycles: 45	Based on EMG assessment: 1. ring 2–4, 3–5, 5–6 2. Side 3–3, L-R 3. Side 1–1, L-R 4. Side – Side, L-R	- Until noticeable contraction - Maximum tolerance - No pain	Hold time based on patient's ability. Let patient join stimulation until fatigued
Overactivity contractions	250 µsec (250–400)	35 Hz	Fade in/out: 2 s Hold time: 4 s (4–6) Pause time: 12s (10–16) Number or cycles: 45	Based on EMG assessment: At overactive or underactive area	- Until noticeable contraction - Maximum tolerance - No pain	Let patient join stimulation with accent on relaxation after contration/stimulation
Overactivity continuous	400 µsec	2 Hz	Continuous Fade in/out: 0 s Hold time: 20 m Pause time: 0 s Number or cycles: 1	Based on EMG assessment: At overactive area	- Sensible twitch - Maximum tolerance - No pain	
OAB (Urgency, frequency, Urge Urinary Incontinence)	1000 µsec (250–1000)	8 Hz (2–20)	Continuous Fade in/out: 0 s Hold time: 20 m Pause time: 0 s Number or cycles: 1	Based on EMG assessment: 1. Side 1–1 Anterior 2. Side - Side: Anterior - Left or - Right, turn probe 1/8 (45 degrees)	- Clearly sensible - No pain	2–8 session depending on (reduction of) symptoms
Pain high frequency	200 µsec (200–300)	80 Hz (80–100)	Continuous Fade in/out: 0 s Hold time: 20 m Pause time: 0 s Number or cycles: 1	On painful or overactive area	- Clearly sensible	
Pain low frequency	400 µsec	2 Hz (2–7)	Continuous Fade in/out: 0 s Hold time: 20 m Pause time: 0 s Number or cycles: 1	On painful or overactive area	- Sensible twitch - Maximum tolerance - No pain	

WARNING: *Expected and foreseeable side effects of Electrostimulation (ES) described in literature are: pain and/or discomfort, unpleasant sensation, local skin irritation, vaginal bleeding, urinary tract infection, spasm of the bladder, diarrhea, fecal incontinence, exhaustion of stimulated muscle fibres (which could temporary increase specific pelvic floor dysfunction), tingling and/or leg tremor*

Source *Pelvic floor electro stimulation in women with urinary incontinence and/or overactive bladder syndrome: A systematic review, J. Jerez-Roig et al., Actas Urol Esp. 2013;37(7): 429 - 444. Does vaginal electrical stimulation cause pelvic floor muscle contraction? A pilot study. Bø K, Maanum M., BMJ 1999;318:487-93 Neuromuscular Electrical Stimulation for Skeletal Muscle Function. Barbara M. Doucet, Amy Lam, and Lisa Griffin, Yale Journal of Biology and Medicine 85 (2012); Expert opinion*

General guidelines for using electrostimulation

Electrostimulation (ES) can be used for different therapies. It can generate an sensory (afferent) stimulus and an motor (efferent) stimulus. If ES does not provide a noticeable tingling sensation (sensory reaction) or cause a contraction (motor reaction), this could be because the current intensity is too low to feel or cause a contraction, the location of the stimulation (electrode configuration and selection), not the optimal stimulation settings, insufficient amount or wrong type of gel or nerve damage,

Possible Solutions

In case of digital palpation, it is advised to always use the same gel for ES and biofeedback. Remove too much gel or add a little more and re-insert/position probe. The gel will be better spread if the patient does a number of contractions prior to ES or when you move the probe a couple of times.

Change electrode configuration

If the ES is not felt (properly) or does not cause contraction, first change electrode configuration. The table lists suggested sequence. If you have selected ring-ring stimulation, we recommend not to skip more than 1 ring. Note: The best configuration may vary by location, patient and simulation setting. If the stimulation on underactive parts does not lead to a contraction (possibly due to denervation), then also stimulate active parts to reach less active parts.

Adjust phase duration and frequency

If the ES is too sensitive (sharp), you can shorten the phase duration and possibly increase it again in stages or increase the frequency. You could also move the probe a little. With muscle stimulation you can let the patient gently contract. This is possible during the fade-in, as soon as the patient feels something. If the ES cannot be felt clearly (the patient gets used to the stimulation) you can extend phase duration or change the frequency. For each change, the current intensity must be turned back.

Different electrode configurations

Configuration	Desciption
Ring – Ring	You can select 2 rings (ring 1, 2, 3, 4, 5, 6). The 1st ring selected starts as negative (green), the 2nd ring as positive (blue).*
Side – Side	You can select 2 sides (Anterior, Left, Posterior, Right). The 1st side selected starts as negative, the 2nd side as positive. *
Side 1–1	You can select 1 or 2 sides (Anterior, Left, Posterior, Right). Per selected side the 1st, 3rd and 5th start as negative, the 2nd, 4th and 6th as positive.*
Side 3–3	You can select 2 sides (Anterior, Left, Posterior, Right). Per selected side the 1st, 2nd and 3th start as negative, the 4th, 5th and 6th as positive.*

**Halfway the stimulation pulse polarity switches (negative becomes positive and vice versa, biphasic symmetrical).*

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