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KEFFORT

MC-100 / MC-100A

User Manual

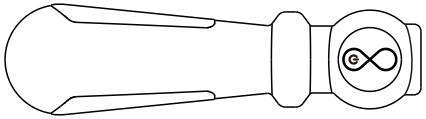

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TABLE OF CONTENTS

INTRODUCTION

Thank you for selecting Hee KEFFORT for treatment and rehabilitation of incontinence.

Read this User Manual carefully before using the KEFFORT. Pay particular attention to the Safety information in forthcoming sections and additional warnings throughout the manual.

The Essential Performance of the device is free from the production of unwanted or excessive stimulation output.

The KEFFORT is designed to be used for treatment and rehabilitation of urinary incontinence. KEFFORT is a multi-functional electrotherapy device that provides neuromuscular electrical stimulation (NMES) and vibration stimulation(MC-100 only). The device has been pre-installed with professional urinary incontinence treatment programs for female patients. To achieve optimal treatment success with your KEFFORT , you have to use the device according to the treatment instructions in this user manual.

Model	Features		
	Electrical Stimulation	Vibration Stimulation	Kegel Exercise
MC-100	✓	✓	✓
MC-100A	✓	– –	– –

PACKAGE CONTENTS

No.	DESCRIPTION	QUANTITY
A	Vaginal Probe	1PCS
B	Charging Case	1PCS
C	Charging Cable	1PCS
D	User Manual	1PCS

INTENDED USE

For Electrical Stimulation

The KEFFORT is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatments of stress, urge, mixed or overflow urinary incontinence for female patients.

For Vibration Stimulation (MC-100 only)

KEFFORT provides a set of auxiliary KEGEL exercise and vibration stimulation programs for independent use by female at home to strengthen pelvic floor muscles to treat stress and urge urinary incontinence.

CONTRAINDICATIONS

KEFFORT should not be used if the patient has any of the following conditions:

- Active urinary tract infection
- Pregnancy or attempting pregnancy
- Recent history of vaginal bleeding between menstrual periods
- Infections or lesions in the area of electrode placement
- Diminished sensory perception
- History of cardiac arrhythmia
- Demand type implanted pacemaker or defibrillator

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

It is important that you read all the warnings and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL

DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
NOTICE	Indicates a potentially hazardous situation which, if not avoided, may result in property damage and/or equipment damage.

DANGER

This device must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device.
- Electronic life support equipment, such as respirator,an artificial heart or lung.

Using this device with above mentioned medical devices will cause erroneous operation of those devices which could cause electric shock, burns, electrical interference, or death.

WARNING

DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:

- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- Electronic medical devices attached to the body, such as electrocardiographs.
- Stimulation should not take place while the user is connected to high-frequency surgical equipment. It may cause burn injuries on the tissue, as well as problems with the device.
- Do not use the device in the vicinity of shortwave or microwave therapy equipment, since this may produce instability in the stimulator output.
- In the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the device is in use.
- Urinary Incontinence may have many causes. You should try to identify your type of incontinence and the cause before using this device.
- If you have any urinary tract infections or any irritations within the vagina, it is recommended not to use the device.

- Care must be taken if you are not experiencing normal sensation or feeling in your vagina.
- People with extra-urethral incontinence (fistula, ectopic ureter), please consult with your physician before using this device.
- People with overflow incontinence due to outflow obstacle, please consult with your physician before using this device.
- People with serious retention of urine in the upper urinary tract , please consult with your physician before using this device.
- People with complete peripheral denervation of the pelvic floor, please consult with your physician before using this device.
- If you suspect or have any form of prolapse you MUST consult your medical advisor before using the device.
- Keep the device out of the reach of young children. The charging cable can cause strangulation.

DO NOT USE ON THESE INDIVIDUALS

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- Person incapable of expressing their thoughts or intentions.

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bathing or shower;
- While sleeping;
- While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.

PAIN MANAGEMENT WARNINGS

- If you have had medical or physical treatment for your pelvic pain, consult with your physician before using this device.
- If your pelvic pain does not relieve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician.

⚠ CAUTION

- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- This stimulation should not be applied over the menstruating or pregnant uterus.
- This stimulation should not be applied over areas of skin that lack normal sensation.
- Patients with urinary tract infections must be treated and clear of infection before starting treatment with KEFFORT. Consult your doctor.
- Turn off the device or make sure that the electrical stimulation output amplitude is turned to 0mA before removing the probe from vagina or touching the stainless steel electrodes of the probe.Getting electrical stimulation through the fingers is unpleasant but not harmful.
- If the vaginal probe is not functioning properly or you feel discomfort, immediately stop using the device.
- Do not use for any other purpose except for what the probe is intended for.

GENERAL PRECAUTIONS

- The long-term effects of electrical stimulation are unknown.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of patients.
- Do not service and maintain the device while the device is in use.

NOTICE

- Do not use the device while wearing electronic devices such as watches as this may damage the device.
- Do not drop because the device may not function properly. Place the vaginal probe into the sealed package and then store into the sealed package when not in use.
- Do not apply ointment or any solvent to the vaginal probe because it will disrupt the vaginal probe from functioning properly.
- Do not use the accessories which is not specified by manufacturer.
- No modification of this device is allowed.

POSSIBLE ADVERSE REACTIONS

- Do not use to treat one region for extended periods of time (more than 30 minutes a session, up to 3 times/day) or muscles in that region may become exhausted and sore.
- You should stop using the device and consult with your physician if you experience adverse reactions from the device.

MEDICAL BACKGROUND

Urinary Incontinence

Urinary incontinence is the loss of bladder control, resulting in the accidental loss of urine. Some women may lose urine while running or coughing, called stress incontinence. Others may feel a strong, sudden need, or urgency, to urinate just before losing urine, called urge incontinence. Many women experience both symptoms, called mixed incontinence, or have outside factors, such as difficulty getting to a standing position or only being able to walk slowly, that prevent them from getting to a toilet on time.

UI can be slightly bothersome or totally debilitating. For some women, the chance of embarrassment keeps them from enjoying many physical activities, including exercising. People who are inactive are more likely to be obese. Obesity increases a person's chances of developing diabetes and other related health problems. UI can also cause emotional distress. However, UI often can be controlled.

1. Stress Incontinence

Stress incontinence results from movements that put pressure on the bladder and cause urine leakage, such as coughing, sneezing, laughing, or physical activity. Physical changes from pregnancy and childbirth often cause stress incontinence. Weakening of pelvic floor muscles can cause the bladder to move downward, pushing the bladder slightly out of the bottom of the pelvis and making it difficult for the sphincters to squeeze tightly enough. As a result, urine can leak during moments of physical stress. Stress incontinence can also occur without the bladder moving downward if the urethra wall is weak. This type of incontinence is common in women, and a health care professional can treat the condition.

2. Urge Incontinence

Urge incontinence is the loss of urine when a woman has a strong desire, or urgency, to urinate. Involuntary bladder contractions are a common cause of urge incontinence. Abnormal nerve signals might cause these bladder contractions.

Triggers for women with urge incontinence include drinking a small amount of water, touching water, hearing running water, or being in a cold environment—even if for just a short while—such as reaching into the freezer at the grocery store. Anxiety or certain liquids, medications, or medical conditions can make urge incontinence worse.

Damage to the spinal cord or brain, the bladder nerves, or the bladder muscles may cause involuntary bladder contractions. Bladder nerves and muscles can be affected by

- Alzheimer's disease—a brain disorder that affects the parts of the brain that control thought, memory, and language
- injury
- Multiple sclerosis—a disease that damages the material that surrounds and protects nerve cells, which slows down or blocks messages between the brain and body
- Parkinson's disease—a disease in which cells that make a chemical that controls muscle movement are damaged or destroyed
- Stroke—a condition in which the blood supply to the brain is suddenly cut off, caused by a blockage or the bursting of a blood vessel in the brain or neck

Urge incontinence is a key sign of overactive bladder. Overactive bladder occurs when abnormal nerves send signals to the bladder at the wrong time, causing its muscles to squeeze without enough warning time to get to the toilet.

3. Mixed Incontinence
Mixed incontinence is when stress and urge incontinence occur together.

4. Overflow Incontinence
Overflow incontinence happens when the bladder doesn't empty properly, causing it to spill over. A health care professional can check for this problem. Weak bladder muscles or a blocked urethra can cause this type of incontinence. Nerve damage from diabetes or other diseases can lead to weak bladder muscles; tumors and urinary stones can block the urethra.

Urinary Incontinence Treatment

Treatment depends on the type of UI. Health care professionals may recommend behavioral and lifestyle changes, such as pelvic floor exercises, as a first-line therapy for most types of UI. If it turns out that you are not squeezing the right muscles, you may still be able to learn proper Kegel exercises by doing special training with biofeedback, electrical stimulation, or both.

1. Transvaginal Electrical Stimulation
Electrical nerve stimulation is a recognized treatment for urinary incontinence that involves altering bladder reflexes using pulses of electricity. Transvaginal electrical stimulation stimulates the pelvic floor muscles directly and the electrical energy discharged into the muscle can slowly desensitize the nerves in the area or even cause muscle contraction and then relaxation.

2. Kegel Exercise (MC-100 only)
Kegel Exercise, also known as pelvic floor muscles exercise, is first-line therapy to women with stress urinary incontinence or mixed urinary incontinence. Exercises of pelvic floor muscles can play an essential role in the prevention and treatment of urinary incontinence. These exercises are based on the assumption that the strong contractions of the pelvic floor muscles clamp the urinary tract, increase its pressure, and prevent the exit of urine in the event of a sudden increase in intra-abdominal pressure. Thus, pelvic floor muscle exercises can be recommended as a non-drug, non-invasive, and cost-effective way for controlling the urinary incontinence.

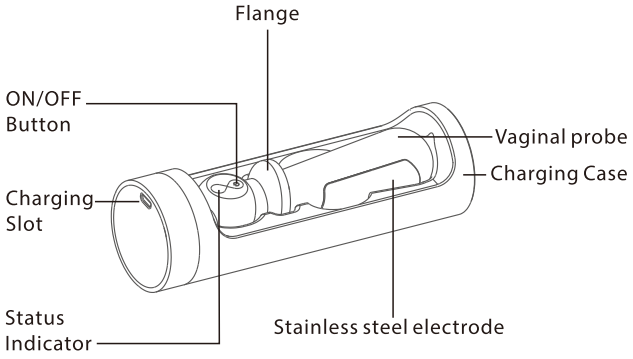
3. Vibration Therapy (MC-100 only)
Vibrations may stimulate the muscles of the pelvic floor to contract, this is done by opening neural pathways causing the nerves of the pelvis to be stimulated. This has dual effect, strengthening the pelvic floor muscles and retraining the bladder reducing the risk of urinary leaking.

Pelvic Pain

Pelvic pain occurs mostly in the lower abdomen area. The pain might be steady, or it might come and go. It can be a sharp and stabbing pain in a specific spot, or a dull pain that is spread out. If the pain is severe, it might get in the way of your daily activities.

You might feel pain during your period. It could also happen when you have sex. Pelvic pain can be a sign that there is a problem with one of the organs in your pelvic area, such as the uterus, ovaries, fallopian tubes, cervix, or vagina. It could be a symptom of infection, or a problem with the urinary tract, lower intestines, rectum, muscle, or bone. Some women have more than one cause of pelvic pain at the same time.

KNOW YOUR DEVICE



SET-UP AND TREATMENT PROCEDURES

Download the Free KEFFORT App

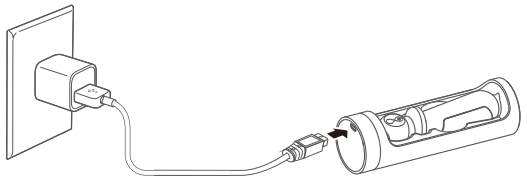
Prior to first use, download the free "KEFFORT" app from App Store or Google Play to your phone or tablet.

Charging the Vaginal Probe

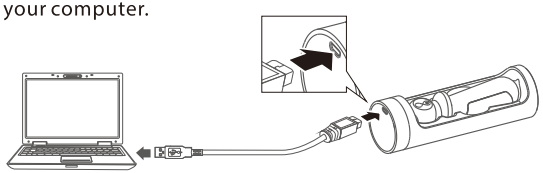
Prior to the first use, you have to fully charged the vaginal probe. It takes approx. 4 hours to fully charged up the vaginal probe under normal room temperature. The probe can continue operating for electrical stimulation treatment for approx. 8 hours under normal operating conditions.

Note: When charging the vaginal probe, no treatment should be performed.

1. Rotate to open the charging case.
2. Place the vaginal probe into the charging case firmly and correctly with the status indicator facing upwards.
3. Connect the charging case to a power outlet using the included charging cable. AC adaptor is not included in the package. The recommended AC adaptor should be a medical AC adaptor with an output of DC 5.0V, 1.0A or 500mA and complies with IEC60601-1/UL60601-1 and IEC60601-1-2/EN60601-1-2 is suitable for this device, such as UES06WNCPU-050100SPA (input 100-240V, 50/60Hz, 0.2A; output 5.0V, 1A). Please note that the KEFFORT jack size is USB Micro-B.
   The AC adaptor should incorporate a fuse link of 1A.



4. You can also charge the battery by connecting KEFFORT to your computer. You must connect the KEFFORT to a USB2.0 or 3.0 port on your computer.



Probe status	Status indicator
Charging	Steady Pink light
Fully charged	Steady Green light

Connect to the mobile device via Bluetooth

1. Turn on the Bluetooth connectivity of mobile device.
2. Open the KEFFORT App and follow the on-screen instructions to register and set-up your personal account at the first use.
3. Press and hold the ON/OFF Button of the vaginal probe for 3 seconds to switch on the probe.
4. Press the "SCAN" key on KEFFORT APP to wait until the model name printed on the probe (i.e. MC-100XXXX) appeared on the screen.
5. Select the device to complete the bluetooth connection.

Probe status	Status indicator
Power OFF	No Light
Power ON / Waiting Bluetooth Connection	Fast Flashing Blue Light
Bluetooth Connected	Steady Blue Light
Working	Low Breathing Blue Light

Note:

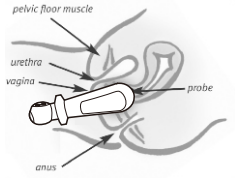
1. Vaginal Probe will automatically disconnected from mobile device if APP idol for 3 minutes.
2. Vaginal probe will automatically power off if idol under Bluetooth disconnected for 1 minutes.

Place the Vaginal Probe

⚠ CAUTION

- Clean the Vaginal probe before and after use with a soft, slightly moistened cloth and wipe gently with 70% alcohol.
- Do not use during pregnancy. Please refer to IMPORTANT SAFETY PRECAUTIONS AND WARNINGS Section for additional warning and important safety information.

1. Empty the bladder before inserting the vaginal probe into the body.
2. Connect the probe to your mobile device as per instructions mentioned in previous section.
3. Insert the probe into vagina in the same way as a tampon,until the flange get to the perineum. Please note that the indicator lamp should be upturned or faced upwards and the electrodes towards the legs.

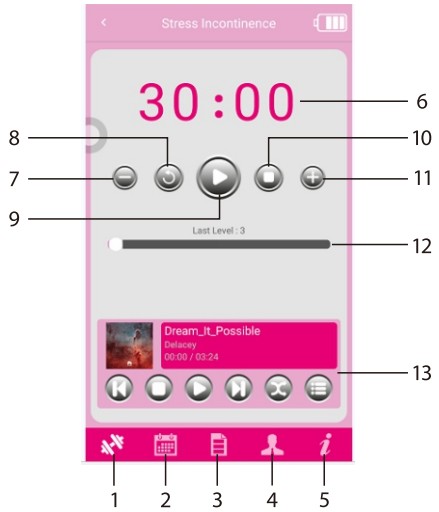


Note:

- It is important not to insert the rear portion (beyond the flange) of the vaginal probe into your body.
- If needed, use only silicone-safe or water-based lubricants.

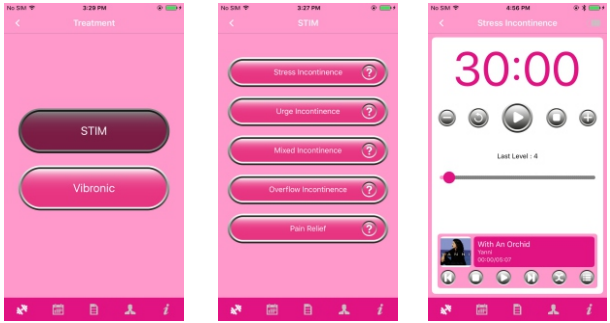
Simple illustration of KEFFORT APP

① Treatment
② Diary
③ Evaluation
④ e-Health
⑤ About
⑥ Treatment Timer
⑦ Intensity Adjustment: Decreasing
⑧ Restart
⑨ Start/Pause
⑩ Stop
⑪ Intensity Adjustment: Increasing
⑫ Intensity Level
⑬ Music Jukebox



Electrical Stimulation Treatment (STIM)

1. Check and ensure the probe is placed correctly into your vagina.
2. Follow the on-screen instructions to enter the TREATMENT page of KEFFORT APP.
3. Select "STIM" to enter electrical stimulation treatments.
4. Select the suitable procotol as per your need, e.g. Stress, Urge, Mixed or etc.
5. Start the treatment via tapping "START" button on screen.
6. Gradually increase or decrease the electrical stimulation output intensity via tapping "+" / "-" button on screen.



7. To restart the treatment from beginning, tap the "RESTART" button once.

Note: For MC-100A, the "Vibronic" features of Companion KEFFORT APP will be disabled automatically.

Vibronic Treatment (MC-100 only)

The HEE KEFFORT provides 2 kinds of vibronic treatments, i.e. active KEGEL exercise and auxiliary vibronic procotol, to help patients for strengthening their pelvic floor muscles.

KEGEL Exercise (MC-100 only)

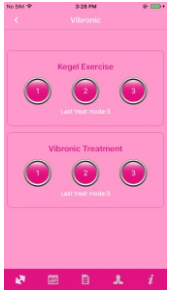
Kegel exercises were developed by Arnold Kegel in 1948 for improvement and correction of the loosening or atrophy of pelvic floor muscles. Kegel involves a series of exercises which aim to strengthen and establish a balance between the back and abdominal muscles and lower extremities muscles and also strengthen the pelvic floor muscles in order to keep the natural anatomic situation of pelvis. These exercises are based on the assumption that the strong contractions of the pelvic floor muscles clamp the urinary tract, increase its pressure, and prevent the exit of urine in the event of a sudden increase in intra-abdominal pressure.

1. Check and ensure the probe is placed correctly into your vagina.
2. Follow the on-screen instructions to enter the TREATMENT page of KEFFORT APP.
3. Select "VIBRONIC" to enter vibronic treatments.
4. Select the suitable procotol as per your need, e.g. BEGINNER (1), ADVANCE (3) or etc.
5. Start the treatment via tapping "START" button on screen. Contract the pelvic floor muscles while vaginal probe vibrate, and relax completely when the vibration stopped.
6. To restart the treatment from beginning, tap the "RESTART" button once.

Vibronic Treatment (MC-100 only)

The HEE KEFFORT utilises the symptoms of vibration on human body (adapted from Rasmussen 1982) to provide auxiliary vibronic procotol for strengthening pelvic floor muscles.

1. Check and ensure the probe is placed correctly into your vagina.
2. Follow the on-screen instructions to enter the TREATMENT page of KEFFORT APP.
3. Select "VIBRONIC" to enter vibronic treatments.
4. Select the suitable procotol as per your need.
5. Start the treatment via tapping "START" button on screen. Relax completely during the whole treatment process, i.e. 5 mins .
6. To restart the treatment from beginning, tap the "RESTART" button once.



CAUTION Make sure that you end the treatment by switching off the device or by setting the intensity to 0 mA in the app before you remove the vaginal probe. If you do not end the treatment, you may experience an unpleasant sensation. This sensation is not harmful, but can be unpleasant.

1. Switch off the vaginal probe by press and hold on the ON/OFF button for the 3 seconds.
2. Remove the probe. Clean the probe with water.
3. Recharge the vaginal probe to ensure it is ready for the next treatment.

CLEANING AND STORAGE

Cleaning the vaginal probe

1. Turn vaginal probe off.
2. Clean the device after use with a soft, slightly moistened cloth and wipe gently.

- Do not use chemicals (like thinner, benzene).
- Do not let water get into the internal area.

Note:

- This device and accessories do not require sterilization.

Storing the vaginal probe

- Place the vaginal probe back to charging case. Store the device in a cool, dry place, -10℃~55℃; 10% ~90% relative humidity.
- Do not keep at places that can be easily reached by children.

SPECIFICATIONS

- Battery type - vaginal probe: 3.7V DC, Li-Ion
- Electrical Stimulation Frequency: 3Hz~50Hz
- Electrical Pulse Width: 200us~300us
- Electrical Output Voltage: Adjustable, 0-40V, Max output 80V (peak to peak) into 1000ohm load.
- Vibration output frequency (MC-100 only): 10Hz~50Hz
- Treatment Time: around 30 minutes
- Operating Conditions: 5℃~40℃; 30%RH~75%RH, Atmospheric pressure: 700hPa~1060hPa
- Transport and Storage Conditions: -10℃~55℃; 10%RH~90%RH, Atmospheric pressure: 700hPa~1060hPa
- Size- vaginal probe: Ø31mm*118mm
- Weight: approx.69g (without charging case)
- The Essential Performance of the device is free from the production of unwanted or excessive stimulation output.
- Ingress Protection Rating: IP67

Wireless Communication:

- Bluetooth Version: V4.2 BLE
- Frequency Band: 2.402-2.480 GHz
- Bluetooth Range: 10m(Free space)

The service life of device: 2 years
The Service life of the battery: Charge at least 300 times.

PROGRAM LIST

Electrical stimulation

Program	Frequency (Hz)	Pulse width (us)	Up/down (sec)	Working (sec)	Rest (sec)	Treatment Duration
Stress incontinence	50	300	1	5	10	30 minutes, 3–5 times a week
Urge incontinence	10	200	1	5	10	30 minutes, 3–5 times a week
Mixed incontinence	20	250	1	5	10	30 minutes, 3–5 times a week
Overflow incontinence	35	250	1	3	6	30 minutes, 3–5 times a week
Pain Relief	3	200	Continuous			20 minutes, 3–5 times a week

Kegel Exercise (MC-100 only)

Program	Work (Sec)	Rest (Sec)	Treatment Duration
Kegel Exercise 1 (Beginner)	3	3	5 minutes, 3 times a day
Kegel Exercise 2 (Intermediate)	5	5	5 minutes, 3 times a day
Kegel Exercise 3 (Advance)	10	10	5 minutes, 3 times a day

Vibronic Treatment (MC-100 only)

Program	Work (Sec)	Rest (Sec)	Treatment Duration
Vibronic Treatment 1 (Beginner)	2	2	5 minutes, 3 times a day
Vibronic Treatment 2 (Intermediate)	2	2	5 minutes, 3 times a day
Vibronic Treatment 3 (Advance)	2	2	5 minutes, 3 times a day

TROUBLESHOOTING

If the unit does not work:
Are the battery exhausted? Recharge the battery.
Bluetooth connection failure :
if you fail to search for "KEFFORT" or cannot pair with this device, quit and re-launch KEFFORT APP. If problem keep occurring, restart your mobile device.
The stimulation feels unpleasant
Make sure that the probe is correctly placed with good contact. In case of irritation/inflammation in the vagina, please contact your health care provider.

DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.
Please dispose of the device in accordance with the legal obligation.

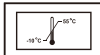
WARRANTY INFORMATION

The device is guaranteed for 1 year, subject to using in according with these instructions. Never dismantle or disassemble the device. Your warranty would be cancelled.
If any problem or would like further information, please visit website www.hee-beauty.co.kr or contact local agent

GLOSSARY OF SYMBOLS

	This symbol means: Disposal in accordance with Directive 2012/19/EU(WEEE)

	This symbol means: caution
	Type BF Applied Part (The applied part is probe)
	Class II Equipment
	Read the user manual before you start using the device.
IP67	The degree of protection against matter and water. The first number means dust-tight.The second number means that protected against the effects of temporary immersion in water
CE 0843	Complies with the European Medical Device Directive (93/42/EEC and amended Directive 2007/47/EC. Notified Body is UL International Ltd.
	Manufacturer information: The manufacturer is: Netop Industrial Company Limited
EC REP	Authorized representative in the European Community. The European representative is: Weikang ltd t/a welkangtech consulting
SN	Symbol for "SERIAL NUMBER"
LOT	Symbol for batch code, represent manufacturing date

	Symbol for “Temperature limits”
	Symbol for “Humidity limitation”
	Atmospheric pressure limitation

IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio / TV technician for help.

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.
Medical devices should also not interfere with other devices.
In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.
Medical devices manufactured by NETOP INDUSTRIAL CO.LTD. conform to this IEC60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.:

- Portable RF communications equipment(including peripherals such as antenna cable and external antennas) should be no closer than 30m(12 inches) to any part of the KEFFORT, including cables specified by the manufacturer. otherwise,degradation of the performance of this equipment could result .
- In rare circumstances, the normal function of the device may be disturbed by Strong Electro-Magnetic Interference. If so, please simply reset the device to resume normal operation by following the user manual. In case the function could not resume, please use the device in other location.

GUIDANCE AND MANUFACTURER'S DECLARATION–ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assures that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device 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. The device is suitable for used in domestic establishment and in establishment directly connected to Harmonic emissions a low voltage power supply network which supplies buildings used for domestic purposes.
Rfemissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration — electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kVair	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kVair	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 IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line (s) to line (s)	Not applicable	Not applicable
Voltage dips, shortinterruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95%dipin U_T) for 0.5 cycle 40% U_T (60%dipin U_T) for 5 cycles 70% U_T (30%dipin U_T) for 25 cycles <5% U_T (>95%dipin U_T) for 5 seconds	Not applicable	Not applicable
Powerfrequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

Guidance and- manufacturer's declaration. Electromagnetic immunity			
The device is intended for use in. the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MC100 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$, 80MHz to 800MHz
			$d = [\frac{7}{E_1}]\sqrt{P}$, 80MHz to 2,7GHz
			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)[b]. 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.[d] Interference may occur In the vicinity of equipment marked with the following symbol:
			(((•)))

NOTE 1 At 80 MHz ends 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 radios, amateur 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 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 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 DEVICE

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**80 MHz to 2,7 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

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