CODE-X

User Manual

Sections

[Model Name] CODE-X/CODE-XM

1. Introduction

1.1 Intended Use

CODE-X/CODE-XM is a Automated Microneedle System that creates micro-channels into the skin. Microneedle system is used as the collagen induction therapy for scars and stretch marks and as the transdermal delivery of active substances through epidermal barrier used by professional. CODE-X/CODE-XM has a function for puncturing the ingredients like lifting, rejuvenating, acne care and skin tightening.

CODE-X/CODE-XM improves skin condition and helps to deliver the effective ingredients so that can be used for skin-care including acne scar care, fine lines, wrinkles and stretch marks. It combinates with an alopecia treatment.

1.2 Usage Environments

CODE-X/CODE-XM should be used by professionals like physicians or estheticians. During the procedure, the user holds the CODE-X/CODE-XM in one hand and the other hand holds the skin-area to be treated.
CODE-X/CODE-XM requires to be used with the micro-needles which is sterilized. User should use CODE-X/CODE-XM according to the purpose and usage of Microneedle System.
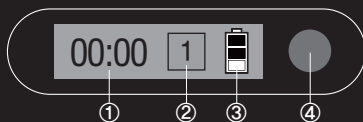
1.3 Features and Operation
1.3.1 Before you Begin

Before starting the procedure, it is important to check and read all information of CODE-X/CODE-XM and acknowledge of microneedle treatment.
To get started with the CODE-X/CODE-XM, new batteries will need to be charged for the first time.

-Display Status

① Displays the usage time.
② Displays the output level.
③ Displays the remaining battery capacity.
④ Control button.

  Display status when charging with power-on state

  Display status when charging in power off state

-Battery Status

Battery Status				
Using Time	2H	50Min	15Min	Need charging

-Charging the battery

Full charge needs 2hours. The battery life is approximately 2.5 to 3 hours at high speed and it is 2-3 standard treatments(1 to 1.5 hrs).

If the battery is no longer capable of supplying the power,

CODE-X/CODE-XM will show the battery status on a display.

Battery of CODE-X/CODE-XM is inserted inside of the product.

User should not attempt to dis-assemble the battery. For proper operation, it is recommended to use 1session for 30 minutes.

1.3.2 Getting Started

1. Press and hold the button to turn on the CODE-X/CODE-XM. Check the battery status first.

2. When the battery is sufficient prepare the disposable tips to assemble with CODE-X/CODE-XM. Disposable tips should be sterilized and packed without any damages.

3. Install the disposable tips into the CODE-X/CODE-XM. Turn the disposable tips clockwise to attach it to the CODE-X/CODE-XM.

4. Press the button shortly to start the CODE-X/CODE-XM. Speed is adjustable when the button is pressed. The speed is all 5 steps. Number of 1 to 5 is shown on a display and 5 is the fastest.

5. Turn the dial to adjust the depth of disposable tips up to 2.0mm.

6. On the treatment area, use the CODE-X/CODE-XM and doing the microneedle. There is a guideline of operation and treatment on 3.3.

7. When finished, press and hold the button to turn off the power.

1.3.3 After Use

• Keep the product out of the reach of children. Used disposable tips must be disposed of in a designated area. It must not be reuse.

• Do not dispose of broken and used products with household waste together.

2. Specification

2.1 Device Specification

Input : AC 100~ 240V, 50/60Hz, 0.32 - 0.19A

Output : DC 5V / 2.0A

Protection against electric shock: Class II, Type B applied part

Applied part: Disposable Tips

Battery: 3.7V 600mAh / Lithium-polymer rechargeable

It is a product that has a built-in battery and is used after charging. It is a 2 class device and an internal power type.

Disposable tips(surgical grade stainless steel) length: adjustable up to 2.0mm

• Battery and AC/DC adaptor

CODE-X/CODE-XM is a wireless and battery charge type. The battery is a built-in and plug it into a AC power outlet. New batteries need to be charged before they are used for the first time. To charge fully, it takes 2-2.5 hours.

• LCD display

CODE-X/CODE-XM shows the status of battery remaining on a display.
User can check when they need charge the CODE-X/CODE-XM.

• Speed levels

(Range -10%, +15%)

Speed	1	2	3	4	5
RPM	3500	4000	4500	5000	5500

• Handy and weight

CODE-X/CODE-XM is easy to carry and use compared to other products with a light weight of 65g.

• Various type of disposable tips

CODE-X/CODE-XM is compatible with various type of needles manufactured by Woorhi Mechatronics Co., Ltd.

More various types of disposable tips are Like below

Tip name	CODE-X	CODE-XM
	WTNR-03, WTNR-06, WTNR-09, WTNR-09F, WTNR-09S, WTNR-12S, WTNR-12F, WTNR-16S, WTNR-16F	WD-01, WD-01NN, WD-01EN, WD-03, WD-03EN, WD-04, WD-05, WD-06, WD-09, WD-MAGNUM

Please refer to detailed tips information : WM-UMN-004(Rev.0 / 10 JAN 2023)

2.2 Product Kit Components

CODE-X/CODE-XM consists of the following components:

- CODE-X/CODE-XM Device
- CODE-X/CODE-XM Desk Stand
- Disposable Tips sample
- Charging cord

2.3 Environmental Conditions

• Storage, Transportation and Operation condition
- Temperature: 5 ~ 40 ℃   - Humidity: 10-80%, non-condensing
- Air pressure : 700 hPa ~ 1,060 hPa

3. Maintenance and Using Guideline

3.1 Maintenance and Storage

• Recommend use the CODE-X/CODE-XM protection sleeve during the operation to avoid any contamination.
• After use the CODE-X/CODE-XM, user can clean it with the alcohol wipes.
• Never use the water or other cleaning fluids inside of the product.
• Store the product in a dry and well-ventilated place at room temperature.
• Keep the product out of the reach of children.

3.2 Trouble Shooting

Problem	Cause	Solution
CODE-X/CODE-XM is not working when a button pressed	Battery needs to be charged	Plug the charging cord and check the battery remaining status
	Motor or functional errors	Contact to the manufacturer or dealer
Broken the button or display	Damaged the parts	Contact to the manufacturer or dealer
Adjustment part of disposable tips is not working		
Product disassembly		

Abnormal noise	Wrong assemble the disposable tips	Check the status of assemblying of disposable tips and try again
	Broken inside of a product	Contact to the manufacturer or dealer

3.3 Order of procedure

Standard microneedle system with CODE-X/CODE-XM is follows below.

Step 1. Cleansing
Using the cleansing product, cleanse the skin being treated.
It is recommended the mild type of cleansing and ensure all traces of make-up are fully removed. Deep cleansing with steamed towel or any tools is available if it is not irritating.

Step 2. Preparation
Cover the poly-bag protection sleeve on the CODE-X/CODE-XM and check the battery status of CODE-X/CODE-XM.
Assemble the disposable tips into the CODE-X/CODE-XM and set the length of tips following the purpose of procedure.
Apply the anesthetic cream if it needs.

Skin condition	Treatments time	Duration	(mm)
Alopecia	10 times or more	Every 1 week	0.2~1.0
Scars	10 times or more	Every 2 weeks	1.5~2.0
Wrinkles	5 times or more	Every 1 week	0.5~1.2
Moisturizing	3 times or more	Every 1 week	0.2~0.6
Hyperpigmentation	10 times or more	Every 2 weeks	1.5~2.0
Brightening	3 times or more	Every 1 week	0.2~0.6
Dark circles	5 times or more	Every 1 week	0.2~0.6
Rejuvenating	5 times or more	Every 2 weeks	0.8~1.5
Stretch mark	10 times or more	Every 2 weeks	1.5~2.0
Cellulite Reduction	10 times or more	Every 2 weeks	1.5~2.0

Step 3. Applying the products
Apply the cosmetic or products, which is available for microneedle. To activate more the collagen
induction process, collagen products are recommended. For more information on cosmetics used with CODE-X/CODE-XM, please contact the manufacturer.

Step 4. Microneedle
User can use the CODE-X/CODE-XM for face, body skin and scalp area. In case of facial treatment, think of the face as divided into five parts: forehead, nose, cheeks, chin, lips, and around the eyes. Sensitive area as like lips and around the eyes, use the CODE-X/CODE-XM with lower speed and shorter length of tips than other parts. Use as if drawing a circle from the inside of the face to the outside. For body and scalp area, use like face, by drawing a circle with CODE-X/CODE-XM.

Step 5. Post care
After the microneedle, skin could have damages, so it is required the soothing procedure. Cooling the treatment area is helpful and use the soothing products as like facial mask. Recovery cream makes the skin rejuvenating.

4. Warning and Precautions
4.1 Warning
- The following person should be used under a doctor's
  prescription and guidance.
 • Pacemaker or other implanted medical device user.
 • Dermatosis patients.
 • Heart-lung machine or other types of life-sustaining medical devices user.
 • ECG equipment mounting medical device users.
 • Pregnant woman and infants.
- Use it with caution as it may cause malfunction due to
  electromagnetic waves from other medical devices. The results of the
  use of the medical device adverse events that may occur precautions
  for deadly side effects due to careless handling accidents and etc.

- Cause the following side effects, discontinue use and if used
  under a doctor's prescription and guidance.
- Irritation, itching and pain of skin.
- Inflammatory and allergic adverse reactions.
- Atopic dermatitis and skin disease.
- Skin rash

4.2 Contradictions
- This product should be performed by professional medical practitioners.
- DO NOT use other than intended use.
- DO NOT reuse Micro Needle.
- In the event of physical abnormalities, discontinue using immediately
  and consult a doctor.
- Check expiration date of the sterilized disposable needle before use.
- Do not install the device where it is difficult to remove the power plug
- Do not modify the product without the manufacturer's permission

4.3 Sterile Environment and lifetime
- Disposable tips using with CODE-X/CODE-XM is sterilized
  by EO gas and its expiry date is 3 years from the date of manufacture.
- Never use if there is a damage to the packaging of disposable tips.
- Never use by re-sterilization if there is a damage to the
  packaging or used disposable tips
- CODE-X/CODE-XM has 3 years life time. At the end of this lifetime,
  the warranty period for this product will expire.

5. EMC Information

Phenomenon	Basic EMC standard or test method	Phenomenon	Port tested	Enclosure	Test level/requirement
Mains terminal disturbance voltage	EN55011:2016+A1:2017 +A11:2020 CISPR 11:2015+A1:2016 +A2:2019	Continuous operation mode	AC Mains	100 V, 50 Hz 120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz 240 V, 50 Hz	Group 1, Class B

Phenomenon	Basic EMC standard or test method	Phenomenon	Port tested	Enclosure	Test level/requirement
Radiated disturbance	EN 55011:2016+A1:2017 +A11:2020 CISPR 11:2015+A1:2016 +A2:2019	Continuous operation mode	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	Group 1, Class B
Harmonic Current Emission	EN IEC 61000-3-2:2019 +A1:2021 IEC 61000-3-2:2018 +A1:2020	Continuous operation mode	AC Mains	230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013 +A1:2019+A2:2021 IEC 61000-3-3:2013 +A1:2017+A2:2021	Continuous operation mode	AC Mains	230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009 IEC 61000-4-2:2008	Continuous operation mode	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN IEC 61000-4-3:2020 IEC 61000-4-3:2020	Continuous operation mode	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communicatio	EN IEC 61000-4-3:2020 IEC 61000-4-3:2020	Continuous operation mode	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014 +A1:2020
Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	EN 61000-4-39:2017 IEC 61000-4-39:2017	Continuous operation mode	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	Table 11 in IEC 60601-1-2: 2014 +A1:2020
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012 IEC 61000-4-4:2014	Continuous operation mode	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	± 2 kV, 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014 +A1:2017 IEC 61000-4-5:2014 +A1:2017	Continuous operation mode	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV
Immunity to Conducted Disturbances Induced by RF fields	EN 61000-4-6:2014 IEC 61000-4-6:2013	Continuous operation mode	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	3 V 0.15 MHz - 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010 IEC 61000-4-8:2009	Continuous operation mode	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V, 50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN IEC 61000-4-11:2020 IEC 61000-4-11:2020	Continuous operation mode	AC Mains	100 V, 50 Hz 100 V, 60 Hz 220 V, 60 Hz 240 V, 50 Hz 240 V, 60 Hz	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 15°
					0 % UT: 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	EN IEC 61000-4-11:2020 IEC 61000-4-11:2020	Continuous operation mode	AC Mains	100 V, 50 Hz 100 V, 60 Hz 220 V, 60 Hz 240 V, 50 Hz 240 V, 60 Hz	EN IEC 61000-4-11:2020 IEC 61000-4-11:2020

6. Warranty Information

This product is manufactured under strict quality control and
inspection processes.
Standard warranty is 5years covered the lifetime of battery.
The manufacturer limits the warranty in below cases.

- User faults by lack of care and responsibility.
  (e.g. exposure to any liquid, damages by dropping)
- Faults caused by the user's own intention or unauthorized repair
- Unauthorised electric current connection faults
- Damages caused by natural disaster

Under the warranty period, the manufacturer will replace or repair free of charge
if the product goes out of order by normal customer use.

Any questions or request the warranty service, please contact to
Tel. +82-31-457-5032 or email to saleswrmc@gmail.com.

[SYMBOL DESCRIPTION]

Symbol	Description	Symbol	Description	Symbol	Description
	Class II Equipment		Do not use if sterlie package is compromised		Date of manufacture
	Manufacture	CE 0068	CE Marking		Expiry Date
	Keep away from sunlight	STERILE EO	EO gas Sterilization	LOT	LOT Number
	Do not sterilisation		Discharged separately from household waste		B Type
	Single use only	EC REP	Europe Representative		Operating instructions
	General prohibition sign		Refer to instruction manual/booklet	SN	Serial number
	General warning sign		Indicates a single sterile barrier system	UDI	UDI code
	Temperature limit		Humidity limitation		

| MANUFACTURER | Woorhi Mechatronics Co., Ltd.
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Republic of Korea(Zipcode: 15846)

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