Instructions for Use

ENT treatment unit

Company Address : (13Fl(1303~1306), b211~b214, 2804, 502, 905, A-Dong & b216~217, B-Dong) 17, Gosan-ro 148beon-gil, Gunpo-si, Gyeonggi-do 15850 REPUBLIC OF KOREA

Tel. +82-31-8068-1400 Fax. +82-31-8068-1430

Website : www.donga-chammed.com E-mail : chammed@donga.co.kr

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1. Description of the Product

The E.N.T. Treatment Unit is a compact all in one workstation with accessories for patient treatment in the otorhinolaryngology field.

1.1 Intended Use

The E.N.T. Treatment Unit is a combination of several devices which assist to diagnose and treat various diseases of the ear, nose and throat. The doctor selects the right accessories (sprayer, ear irrigation system, suction unit) according to the disease to be diagnosed and / or treated. This unit is used for conditions like infections, inflammations, blockages, and functional disorders. It is intended for use by trained medical professionals such as otolaryngologists, pediatricians, and family physicians, for both adult and pediatric patients.

1.2 Indications

The medical device is not used for a specific indication

1.3 Contraindications

There are no contraindications for the device.

1.4 Warnings

- Installation
  - Device must be connected to the ground.
  - Refrain from using power outlets that are not grounded, as they may cause electric shock.
  - Connect each hose to the indicated connector.
- Power Connection
  - Do not handle the device with wet hands.
  - Do not place the liquid container on the device.
  - Do not use flammable objects near the device.
  - In the event of thunder and lightning outside, please unplug the device.
  - To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth
- During operation
  - Anti-fog and pre-heating may generate temperatures above 35°C.
  - Please use the device only within the low pressure range, by adjusting the pressure knob to around 0.2Bar (=0.2kg/cm2).
  - It's important to note that specific medications and their applications may vary based on the individual patient's condition and the ENT practitioner's discretion. Always follow the instructions provided by the healthcare professional and the medication's package insert for proper usage and dosing.

1.5 Precautions

- General Precautions
  - The E.N.T. Treatment unit and its accessories are medical devices. They may only be used for their intended purposes.
  - Read the instructions for use carefully before installing or using the device.
  - This manual should be placed in a location where the user can easily access and read it whenever necessary.
  - The E.N.T. Treatment Unit should only be used by trained medical professionals, such as otolaryngologists, pediatricians and family physicians.
  - Every component of the device should be properly used.
  - The device should be switched off after work.
  - The service personnel and the installer must have sufficient experience in repairing or installing similar medical equipment.
  - Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are located.
- Installation
  - Do not place flammable objects near the device.
  - Do not install the device in a dusty location.
  - Do not install on a steep floor.
  - To secure the equipment use the locking device of the casters.
  - Do not install the device in places of extreme conditions. Recommended temperature is between 10°C and 40°C, pressure 70-106 kPa and humidity 30-75%.
  - Make sure all cable, wire and hoses are not damaged.
  - Avoid placing devices that are sensitive to electric or magnetic fields near the E.N.T. Treatment Unit.
  - Do not connect hose in the incorrect direction.
  - Ensure that the hose doesn't fold.
  - During installation, make sure there is a minimum distance of 10cm between the rear of this device and the wall.
  - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Moving
  - The equipment has small wheels that can get caught in holes and other floor irregularities.
  - For easier cleaning or making space the E.N.T. Treatment Unit may be moved with the installed casters.
  - When moving the E.N.T. Treatment Unit over door thresholds, elevator gaps, etc. use moving carts with large wheels.
- During Power Connection
  - Do not share the socket.
  - Do not pull the power cord.
  - Do not place heavy objects on the power cord.
  - Do not extend the power cord or cable.
- During Operation
  - When you notice a burning smell, immediately unplug the device.

- Do not disassemble or make alterations without permission.
- Non-continuous operation
    i. Spray and Vent can be used up to 2 minutes. After that the devices are automatically turned off for 2 minutes.
    ii. Spray can be used up to 15 minutes. After that the device is automatically turned off for 30 minutes.

- Devices that are sensitive to electric or magnetic fields should not be placed near this device.

- During Cleaning
    - Main power must be switched off for cleaning.
    - Ensure that all components and cables are not broken before cleaning (replace broken parts if necessary).
    - Clean with a soft cloth using cleanser or disinfectant.
    - Do not clean with flammable liquid.
    - The device is not waterproof. Do not pour water on the device.
    - The E.N.T. Treatment Unit should be cleaned and disinfected at least once a week.
    - Spray, Irrigator, Vent and Suction should be disinfected before each use according to the instructions for use.
    - The surfaces of other accessories should be cleaned (disinfected) at least once a day.
    - Spray tip, Irrigator tip, Vent tip, Suction tips and Suction tube catheter, must be sterilized before each use according to the instructions for use.
- During Servicing
    - The service personnel and the installer must have sufficient experience in repairing or installing similar medical equipment.
    - Service personnel must not repair the unit while it is connected to the power supply as this may result in electric shock.
    - Service personnel must take care not to damage the internal wiring during repair as this may result in electric shock to the operator or patients.
- Storage:
    - Ensure the following storage conditions: temperature between -20°C and 60°C, pressure 70-106 kPa and humidity 30-75%.

1.6 Alarms

Table 1 Overview processing prior each use

No	Alarm	Description	Occurrence Description	Restoration Procedure
1		Spray Motor Alarm	Triggered when the spray motor exceeds the set operating time, resulting in an alarm message and automatic motor cessation.	Cease the spray motor's operation signal (e.g., return the spray to its original position, deactivate the vent switch).

2		Suction Bottle Alarm	Activated when the water level sensor detects liquid, prompting an alarm message and initiating the Auto Drain routine.	Ensure the liquid level is below the sensor following the completion of the Auto Drain routine.

1.7 Accessories - Compatibility with other devices

The below listed devices can be used in combination with the E.N.T. Treatment Unit.

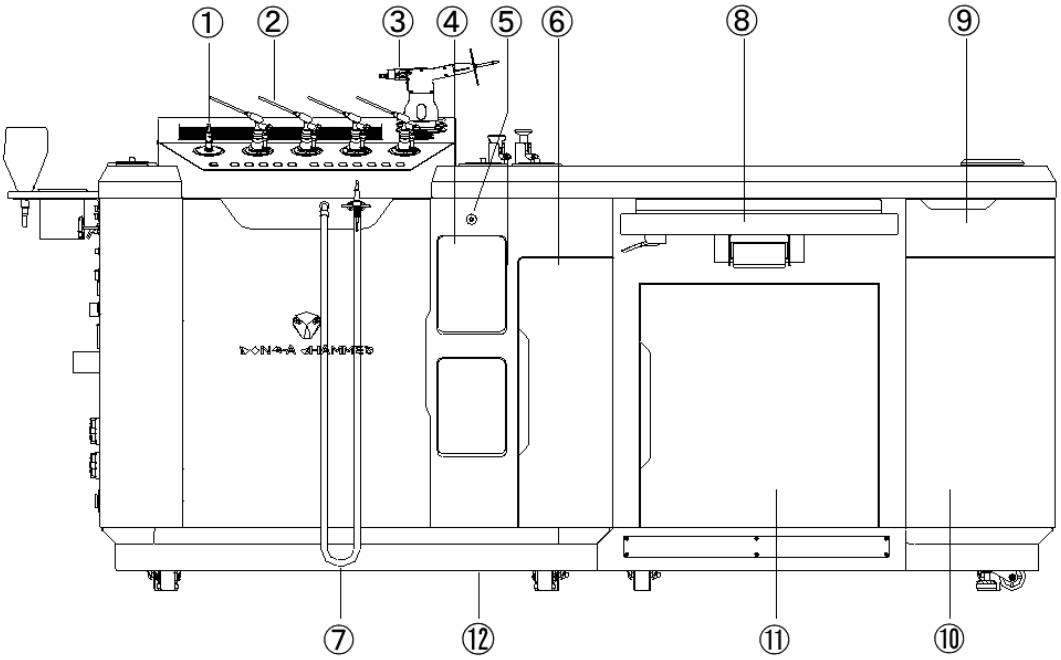
Table 2 Overview processing prior each use

Part	UDI-DI
E.N.T. Treatment Unit- DCU-8000	8800038903784
E.N.T. Treatment Unit- DCU-4000	8800038903777
Irrigator*	(01) 8800038903074
Vent*	N/A
Vent tip*	(01) 8800038903845
Spray*	(01) 8800038901414
Spray Tip*	(01) 8800038901605
Suction*	(01) 8800038901407
Suction Bottle*	(01) 8800038901391
Suction Tip (PC)*	(01) 8800038902961
Suction Tip (Silicone)*	(01) 8800038902992
Suction Tube Catheter (outer diameter Ø2mm±5%)*	(01) 8800038903166
Suction Tube Catheter (outer diameter Ø2.5mm±5%)*	(01) 8800038903173
Suction Tube Catheter (outer diameter Ø3.0mm±5%)*	(01) 8800038903180
Suction Tube Catheter (outer diameter Ø3.5mm±5%)*	(01) 8800038903197

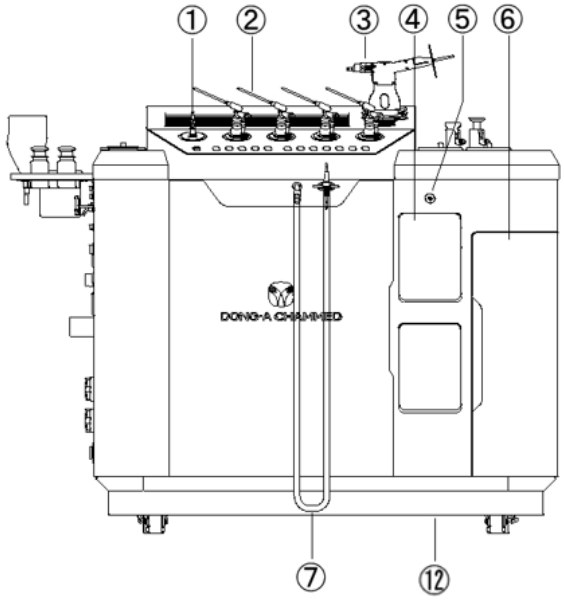
1.8 Appearance Description

1) Front View

(Model : DCU-8000)



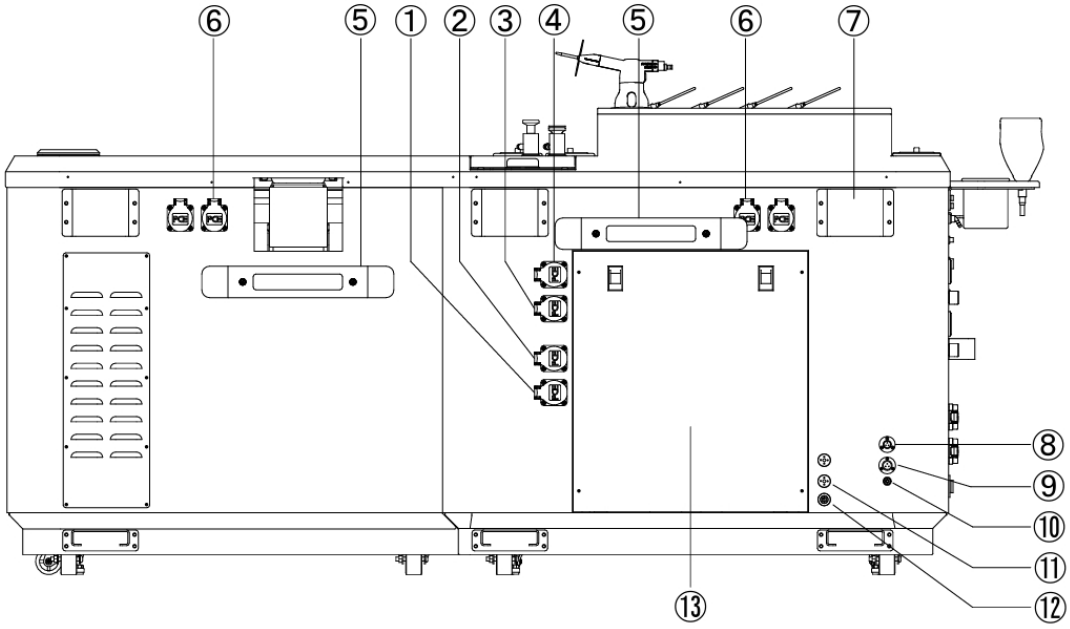
(Model : DCU-4000)



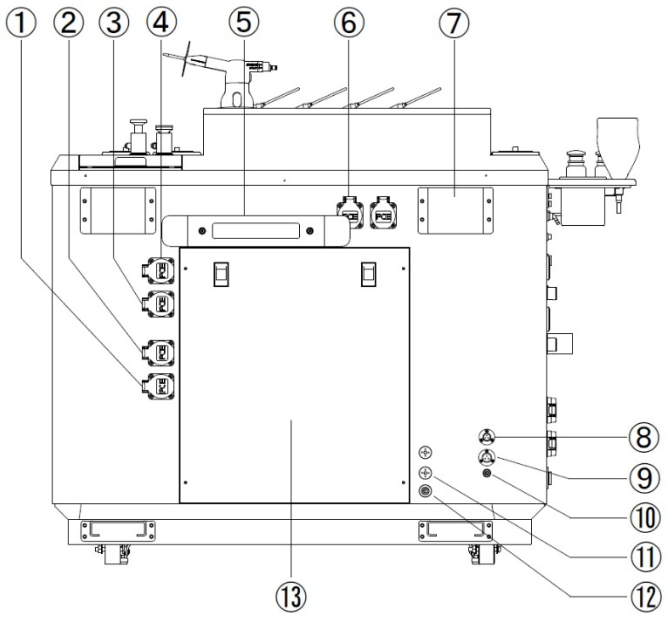
No.	Name	Functions
1	Sub Suction Adapter	Sub suction adapter used when inhaling foreign substances.
2	Spray	Spray saline solution through discharge pressure
3	IRRIGATOR	An injection mechanism that injects a cleaning liquid to clean the nose or ear.
4	Waste can DOOR	Install a can inside the door to contain gauze or other foreign substances generated during patient treatment.
5	Remote Controller	Infrared (IR) remote control receiver
6	SUCTION BOTTLE DOOR	A SUCTION BOTTLE is installed inside the door to open and close the door.
7	Main Suction Adapter	Main suction adapter used when inhaling foreign substances
8	Keyboard Tray	Stand to install the keyboard (model DCU-8000 only) The height of the slide & swing keyboard and mouse tray can be adjusted to accommodate the user.
9	Drawer	Drawers to store various items (model DCU-8000 only)
10	COMPUTER DOOR	Insert the COMPUTER body and open and close the door to use (model DCU-8000 only)
11	SUCTION MOTOR DOOR	Insert the SUCTION MOTOR and use it by opening and closing the door (model DCU-8000 only)
12	AMBIENT LIGHT	LIGHT illuminating the lower part (model DCU-8000, 4000)

2) Rear View

(Model : DCU-8000)



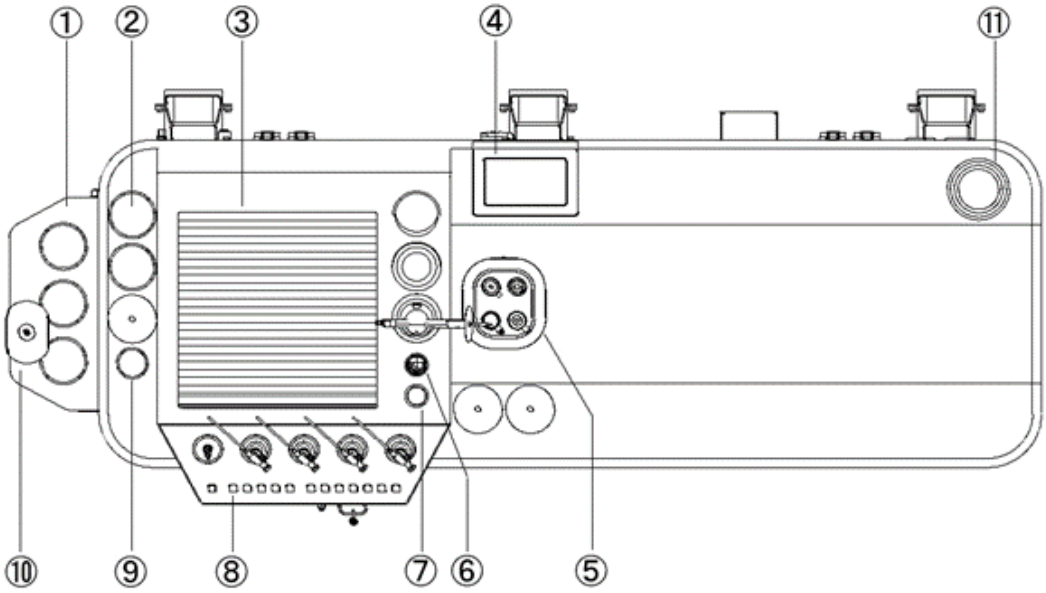
(Model : DCU-4000)



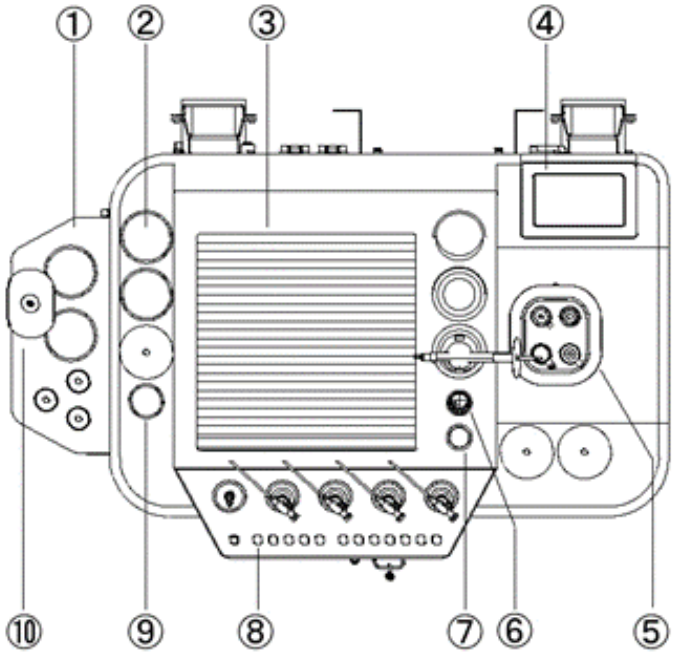
No.	Name	Functions
1	Service (LIGHT) Outlet (Option)	Power outlet for optional power supply and examination light
2	ETC Outlet	Optional power outlet
3	MICRO Outlet (Option)	Power outlet for microscope
4	VISUAL Outlet	Power outlet for light sources
5	Cable Organizer	A stand for organizing various cables
6	Monitor Connect Outlet	Power outlet for monitor
7	Post Pole Bracket	Bracket to fix the post pole
8	LIGHT Power Connector	Connector that supplies power to lights
9	Main Power Connector	Connector that supplies power to the device body
10	Earth terminal	Earth connection terminal between device and Earth
11	Silencer	Function to reduce the exhaust noise of the SUCTION motor
12	Filth Outlet (Option)	Outlet that connects filth the sewer after using SUCTION
13	SUCTION MOTOR DOOR	Use by inserting the SUCTION MOTOR and opening and closing the door. (model DCU-8000, 4000)

3) Top View

(Model : DCU-8000)



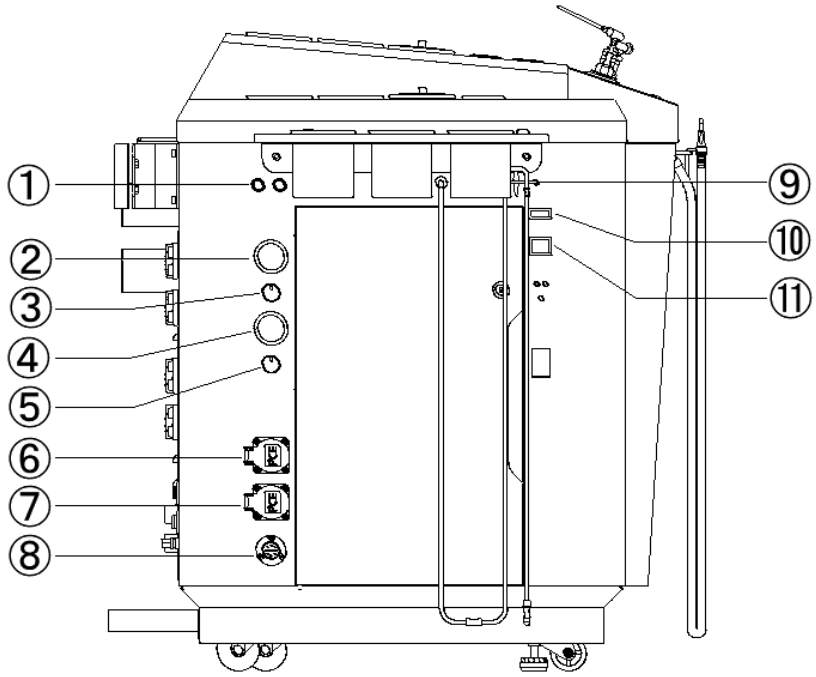
(Model : DCU-4000)



No.	Name	Functions
1	Sidecan Marble	Marble for use by adding cans
2	Multipurpose 83mm Can	83mm can that can hold the necessary surgical tools for patient care
3	Tool Box	A storage box that can contain various surgical tools during patient care Heat wire can be added as an option
4	LCD (option)	It displays various functional statuses of the main device and automatically displays error information to the user through self-monitoring to facilitate response when operating status information or abnormalities occur.
5	UV Storage (option)	A built-in mirror-type UV lamp allows for convenient storage and management of the endoscope.
6	Mirror Heater	Used to increase the temperature of medical tools and prevent frost due to human body temperature in winter
7	Mirror Heater Button	A switch that controls and turns on/off the power of the heater device
8	Control Switch Panel	A switch that controls the power of the device (ON/OFF) and controls various functions in the use of the device The stainless steel detachable control panel allows for hygienic management by removing and cleaning it.
9	Multipurpose 53mm Can	53mm can that can hold the necessary surgical tools for patient care
10	Cleaning water Pedestal (option)	A pedestal that supports the cleaning solution so that it does not drip when using the irrigator
11	220V Outlet (Option)	AC 220V outlet and USB charging available (model DCU-8000 only and USB is for charging)

4) Left Side View

(Model : DCU-8000, DCU-4000)



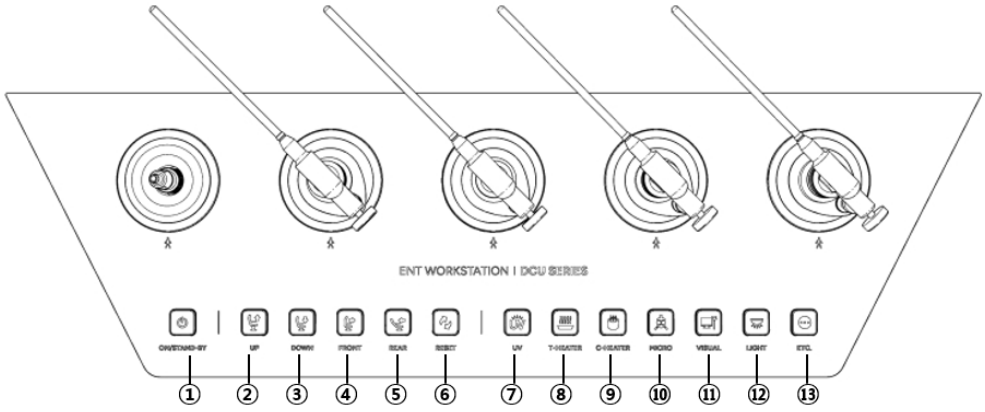
No.	Name	Functions
1	Power Fuse	Fuse for Electrical Safety
2	Spray Pressure Gauge	A gauge that displays positive pressure in the spray pipe
3	Spray Control knob	Knob to control spray pressure
4	Suction Pressure Gauge	A gauge that displays the negative pressure of the suction
5	Suction Control Knob	Knob to control the strength of the suction
6	Service outlet	Service power outlet (constant power)
7	Chair Outlet	Chair power outlet
8	Chair Connection Connector	Connectors used when connecting E.N.T chairs (limited to chairs supplied by the company)

9	Vent Adapter	It is connected to the compressor motor and when the operating switch is pressed, wind comes out and is used to unclog the Eustachian tube.
10	Vent Switch	It is connected to the compressor motor and when the operation switch is pressed, wind comes out and is used to unclog the Eustachian tube.
11	Main Power Switch	Power switch that turns ON/OFF the power of the entire device

5) Control Panel

▶ This is the control switch of the device. Be sure to read this before use to avoid injury to the human body due to malfunction.
▶ Never use this device for purposes other than medical use.

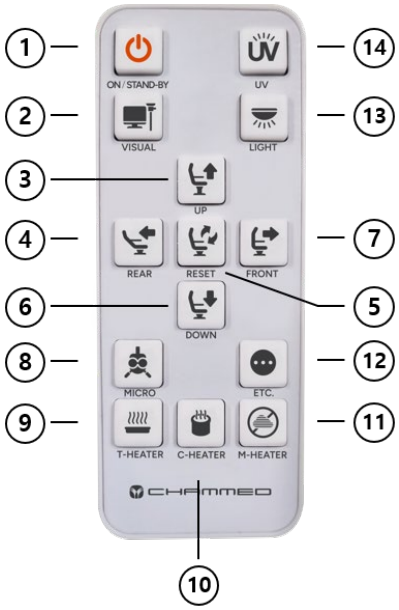
(Model : DCU-8000, DCU-4000)



No.	Name	Functions
1	ON / Stand-by Switch	Switch to control the power of the main unit (ON/STAND-BY) (The on state is 'green or blue ON', the off state is 'white STAND-BY')
2	Up Switch	As a switch used when connecting a E.N.T chair to a E.N.T units, it raises the chair
3	Down Switch	As a switch used when connecting a E.N.T chair to a E.N.T units, it lowers the chair
4	Front Switch	As a switch used when connecting a E.N.T chair to a E.N.T units, it pulls the chair
5	Rear Switch	As a switch used when connecting a E.N.T chair to a E.N.T units, it tilts the chair back

6	Reset Switch	As a switch used when connecting a E.N.T chair to a E.N.T units, it returns the chair to its initial state
7	UV Switch (Option)	Switch to turn ON/OFF the power of the UV lamp
8	T-Heater Switch (Option)	A control switch that controls (ON/OFF) the power of the heater wire installed in the toolbox.
9	C-Heater Switch (Option)	A control switch (Option) that controls (ON/OFF) the power of the heater wire installed in the can.
10	Micro Switch (Option)	A control switch used when connecting a microscope to the body of the device, it controls the power of the microscope
11	Visual Switch (Option)	A control switch used when connecting a monitor to the main body of the device, it controls the power of the monitor
12	Light Switch	Switch to turn on/off the power of medical treatment lights
13	ETC Switch	A switch that turns ON/OFF power supplies such as examination light

6) Control Panel



No.	Name	Functions

1	ON/STAND-BY	Switch to control the power of the main unit (ON/STAND-BY) (The on state is 'green or blue ON', the off state is 'white STAND-BY')
2	VISUAL	This is a control switch used when connecting a monitor and medical imaging equipment to the main body and controls the power of the monitor and imaging equipment. (Option)
3	UP	This switch is used when connecting a treatment chair to a treatment device and raises the chair.
4	Rear	This switch is used when connecting a treatment chair to a treatment device and tilts the chair back.
5	Reset	This switch is used when connecting a treatment chair to a treatment device and returns the treatment chair to its initial state.
6	DOWN	This switch is used when connecting a treatment chair to a treatment device and lowers the chair.
7	Front	This switch is used when connecting a treatment chair to a treatment device and pulls the chair forward.
8	Micro	This is a control switch used when connecting a microscope to the main body of the device and controls the power of the microscope. (Option)
9	T-Heater	Switch (Option) that controls (ON/OFF) the power of the heating Wire installed in the toolbox.
10	C-Heater	Switch (Option) that controls (ON/OFF) the power of the heating Wire installed in the can.
11	M-Heater	Switch to control (ON/OFF) the power of the Mirror Heater installed on the top plate
12	ETC	This is a control switch used when connecting other equipment to the main unit and controls the power of other equipment.
13	LIGHT	A switch that turns the power of medical treatment lights on/off.
14	UV	A switch to turn on/off the UV lamp (Option)

1.9 Clinical Benefits

For the E.N.T. Treatment Unit no specific clinical benefit exist for the patient. Increased comfort and optimized use for the professional user are based on the technical performance of the workstation. For clinical benefits of the accessories please see the referring Instructions for Use.

1.10 Performance Characteristics

Table 3 Performance Characteristics

No.	Specification Item		Specifications	
			DCU-8000	DCU-4000
1	Power Voltage & Frequency		220/230 V~, 50/60Hz	
2	Power Consumption		2,000VA	
3	Spray	Spray pressure	0.215 ± 0.068MPa (Adjustable)	
		Spray volume (general)	Spray 3㎖ within 1 min.	
4	Suction device	Suction power	-0.066MPa below within 30 sec. (Adjustable) " High Vaccum"	
		Maximum suction flux	Suck 200㎖ water within 20 sec "High Flow"	
		Suction bottle	3,000 cc	
		Auto drain emission	Drain 100 ㎖ within 15 sec (Option)	
5	Irrigator	Cleaning water irrigation fluid	Over 150㎖ within 1 min. (Option)	
		Irrigator Temperature Range	34~39℃(Option)	
6	Vent	Spray pressure	0.215 ± 0.068MPa (Adjustable)	
7	Instrument tray, Can Heating Temperature		Be over 35˚C within 15 min from start. And not over 50˚C. (Option)	
8	Switching panel		7" LCD control panel and Front Panel	
9	UV generating capacity		253.7nm ± 5% (Option)	
10	Brightness of examination light		Over 45,000 Lux	
11	Main Fuses		2 X AC250V, 10A	2 X AC250V, 10A
12	Protection Against Electric Shock Hazards		Class 1	Class 1
13	Dimension		1800㎜(W) × 797㎜(D) × 798㎜(H) ± 10%	970㎜(W) × 797㎜(D) × 798㎜(H) ± 10%
14	Weight		200㎏± 10%	120㎏± 10%

1.11 Adverse Reactions

No adverse reactions were observed.

1.12 MRI Safety Information

Not applicable for the E.N.T. Treatment Unit.

2. Instructions for Use

Prior to powering on the device, ensure the unit is installed in accordance with the guidelines outlined in the Installation and Maintenance Manual.

2.1 HOW TO USE

A. Preparation before use

1) Installation of the device
2) Connection of power cable
3) When the power switch is connected, there should be no unwanted operation.
4) Remove unnecessary devices around the device and remove elements that may cause electrical hazards such as moisture.
5) Secure the stable location of the device.

B. Operating sequence or method of use

1) Connect the power cable of the device.
2) Press the green main power switch on the left side of the main body to supply power to the device.
3) When the spray is lifted, the driving motor operates, and at this time, press the spray button to spray the saline. If you put it back in place after use, the motor will automatically stop.
4) When the suction adapter is lifted, the motor automatically operates and inhalation starts.
5) Suction pressure and injection pressure can be adjusted with a control knob mounted on the left side of the exterior.
6) Operate by selecting the operation panel on the top part of the main body and the directly used part.
7) The vent adapter does not work automatically even if it is lifted up. If you press the "VENT" switch on the left side of the outside, the lamp lights up and the operation starts.

8) Examination lights are also turned ON/OFF by pressing the "SERVICE" switch on the operation panel.

9) The warm air blows out immediately when the "HEATER2" switch on the control panel is pressed, and the mirror heater is automatically turned off after 10 seconds for the user's convenience.

10) The chair control switch can directly adjust the height/lowness of the chair and the angle of the chair back when the treatment chair is connected.

11) Use tool boxes and multi-purpose can while paying attention to cleanliness according to the user's purpose.

12) For the UV lamp, press the "UV" switch on the control panel, and the external LED is displayed in blue, and the power of the UV lamp is turned on.
In that state, if you press the "UV" switch on the control panel again, the external LED is displayed in white and the power of the UV lamp is turned off.

13) Operator can directly control "UV/Spray/Suction display LED brightness", "LCD sound On/Off", "Ambient Light On/Off" through the menu on the LCD panel.

14) IRRIGATOR separates the spray connection coupler, assembles it to the irrigator connection connector, and connects the suction adapter part to the pedestal to operate.

15) Use the remote control to wirelessly operate the operations available on the control switch.

C. How to store and maintenance after use

1) Install and store in a place where water does not reach.

2) Pay attention to atmospheric pressure, temperature, humidity, ventilation, and sunlight, and install and store in a place that is not adversely affected by air containing dust, salt, or ions.

3) As a device installed on the wall, there should be no severe vibration or contaminants on the wall.

4) Do not install or store in a place where chemicals are stored or where gas is generated.

5) Check that the device is operating correctly and stably.

6) Check that the connection of the Earth wire and connector is correct and safe.

7) Be sure to clean the spray with medical alcohol after use.

8) After using the Main Suction and Sub Suction, be sure to inhale clear water for 30

seconds and saline solution for 10 seconds to keep them clean, and clean the exterior with medical alcohol.

9) After removing various multi-purpose cans from the device and wiping them clean with clear water, be sure to use medical alcohol to keep them clean.

10) After using the Suction Bottle inside the device, be sure to empty the foreign substances and clean it with clean water to keep it clean.

11) Clean the exterior of the device with medical alcohol and keep it clean at all times.

* Related Caution

a. Use after fully understanding the handling and operation of the device.

b. Use while paying attention to other electrical safety.

c. Follow the prescribed sequence and turn off the power switch.

d. When unplugging the cord, wait exactly before pulling it out.

e. The use of the device should never be operated by anyone other than an expert.

f. In case of failure, mark appropriately and contact the manufacturer.

g. Never modify this device arbitrarily.

2.2 Mirror heater

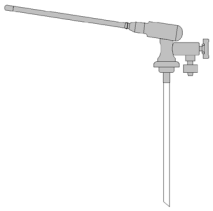
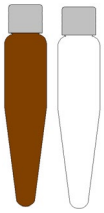
① To use the mirror heater, press the "M-HEATER" button in the upper figure.

② For user's convenience, the power supply is automatically cut off 10 seconds after using the mirror heater, adding convenience.

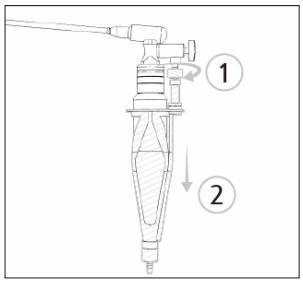
▶ Be careful not to let foreign substances enter the heater.

2.3 SPRAY

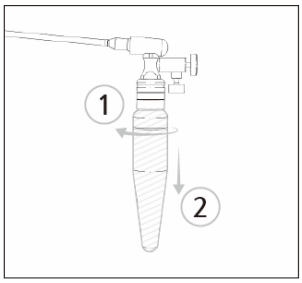
① Spary composition

		
Spray Head	Spray BOTTLE	Spray Holder

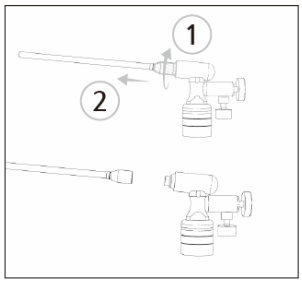
② Separation of spray components



- Remove the spray holder -

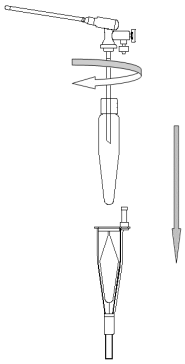


- Separation of saline bottle -



- Remove the spray tip -

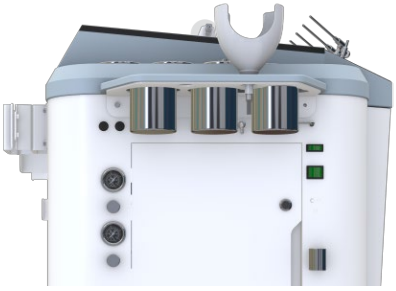
③ How to replace and operate spray saline



- After turning the bottle to separate it, put saline in it and turn it again to lock it.
- Put the bottle in the holder and turn the screw under the switch to lock it.
- When you raises the spray, the spray starts working automatically.
- Press the spray button with your finger to spray the saline solution.
- After using the spray, if you return it to its original position, it will automatically turn off.

Do not drip the spray onto the floor. It becomes a factor of deterioration of spray performance.

Spray pressure control knob

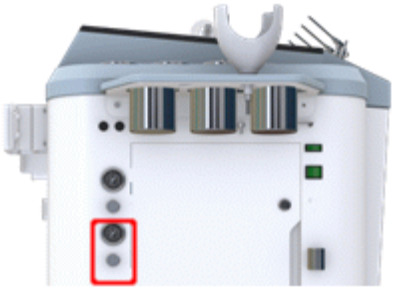


▶ Control the strength of the spray by turning the control knob located on the left side of the product.

※ Set and use the pressure control according to the user's convenience.

NOTE ▶ There is a spray pressure control knob in item 3 on page 8 of the manual.

Suction pressure control knob

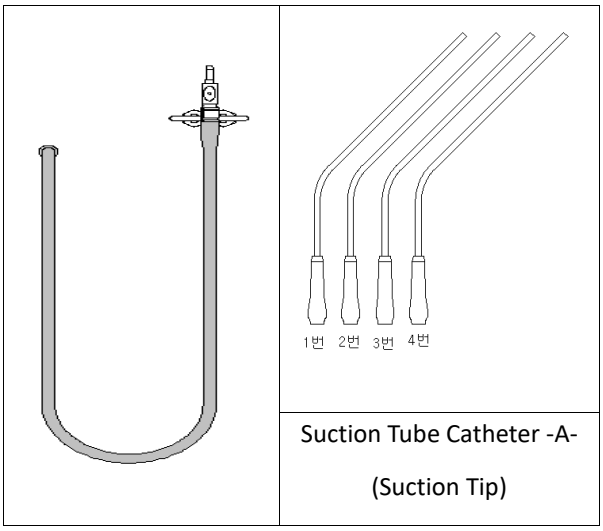


▶ Control the strength of the suction by turning the control knob located on the left side of the product.

※ Set and use the pressure control according to the user's convenience.

NOTE ▶ There is a spray pressure control knob in item 3 on page 8 of the manual.

2.4 SUCTION ADAPTER



Suction Tube Catheter -A-

(Suction Tip)

▶ There are 4 types of Suction Tube Catheter -A-.

▶ Material : Stainless Steel(STS)

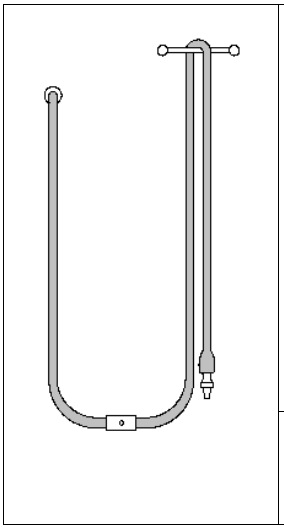
Size : 150mm

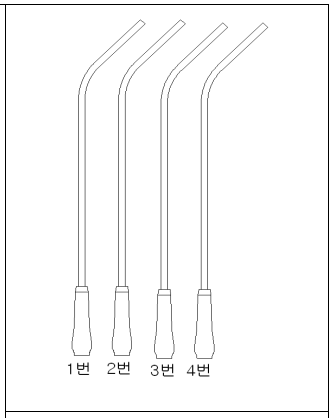
▶ Suction Tube Catheter -A- is divided into Ø1,2,3,4.

Use it according to your purpose.

▶ Suck alcohol or saline solution for about 1-2 seconds after using suction. This is to prevent the inside of the suction hose from being blocked by foreign substances.

2.5 VENT ADAPTER





Suction Tube Catheter -B- (VENT Tip) (option)

▶ There are 4 types of Suction Tube Catheter -B- (Vent Tip).

▶ Material : Stainless Steel(STS)

Size : 150mm

▶ Suction Tube Catheter -B- is divided into Ø1,2,3,4.

Use it according to your purpose.

2.6 IRRIGATOR

IRRIGATOR	Cleaning Water Pedestal

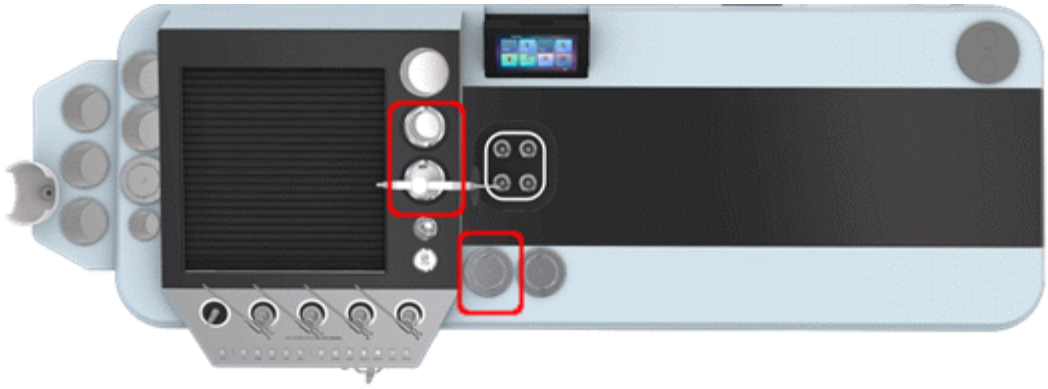
① When using Spray

▶ After separating the tube connected to the one-touch spray, connect it to the irrigator part and connect it to the irrigator set to spray, and adjust the hole part of the blue display by opening or blocking.

② When using Suction

▶ After connecting the suction to the irrigator set to suction, adjust the pressure by opening or closing the hole part of the suction.

2.7 Heater CAN (Optional)



▶ The two cans on top of the unit are for heating saline or water in the irrigator.

▶ Fill the top of one can with about 1/3 of the water and add the reagent bottle (Antifon solution).

▶ Pay attention to the temperature inside the can.

2.8 220/230V outlet and USB charging (Optional) DCU-8000 only

▶Press the device's center button located on the top right of the product and rotate the circular plate 90 degrees to use it as a 220/230V outlet and USB charging port.

▶The USB port is for charging only

2.9 LCD control screen

A. Unit Menu(STATUS A)

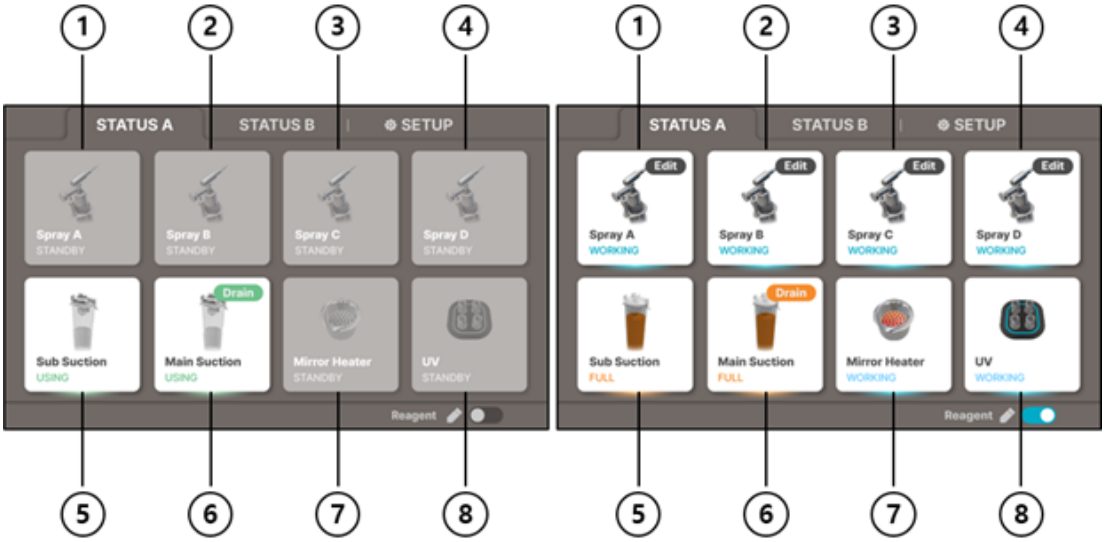
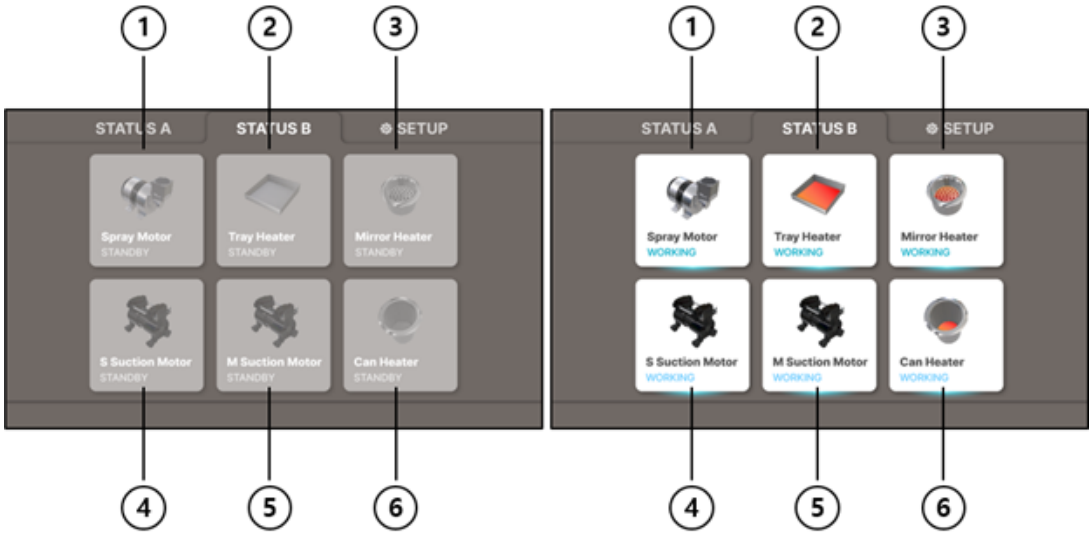


Figure 1 Unit Menu

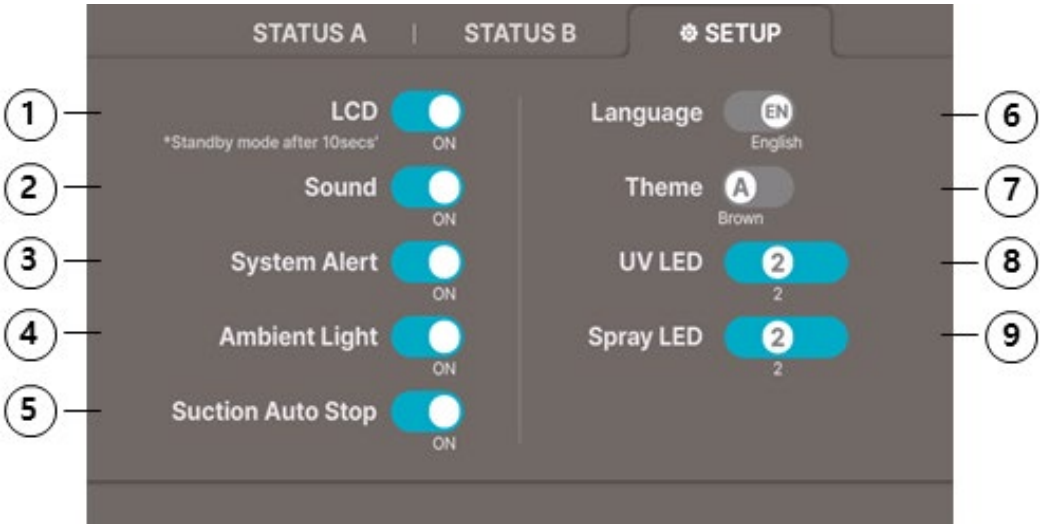
No.	Name	Functions
1	Spray A	When SPRAY A is operated, it is activated and converts from 'STANDBY' to 'WORKING'
2	Spray B	When SPRAY B is operated, it is activated and converted from 'STANDBY' to 'WORKING'
3	Spray C	When SPRAY C is operated, it is activated and converted from 'STANDBY' to 'WORKING'
4	Spray D	When SPRAY D is operated, it is activated and converts from 'STANDBY' to 'WORKING'
5	Sub Suction	Displayed as 'LOW', 'HALF FULL,' or 'FULL' according to the amount of filth in the sub suction bottle
6	Main Suction	Displayed as 'LOW', 'HALF FULL' or 'FULL' according to the amount of filth in the main suction bottle
7	Mirror Heater	When the M-Heater switch on the control panel is turned 'ON', it is activated and converted from 'STANDBY' to 'WORKING'
8	UV	When the UV switch on the operation panel is turned 'ON', it is activated and converted from 'STANDBY' to 'WORKING'

B. Unit Menu(STATUS B)



No.	Name	Functions
1	Spray Motor	When the SPRAY MOTOR is operated, it is activated and changes from 'STANDBY' to 'WORKING'
2	Tray Heater	When the T-Heater switch on the control panel is turned 'ON', it is activated and converted from 'STANDBY' to 'WORKING'
3	Mirror Heater	When the M-HEATER switch on the top panel is turned 'ON', it is activated and converted from 'STANDBY' to 'WORKING'
4	S Suction Motor	When the Sub Suction Motor is operated, it is activated and changes from 'STANDBY' to 'WORKING'
5	M Suction Motor	When the Main Suction Motor is operated, it is activated and changes from 'STANDBY' to 'WORKING'
6	Can Heater	When the C-Heater switch on the control panel is turned 'ON', it is activated and converted from 'STANDBY' to 'WORKING'

C. Unit Menu (SETUP)



No.	Name	Functions
1	LCD	Switch to control ON/OFF of LCD
2	Sound	Switch that controls sound ON/OFF
3	System Alert	Switch to turn on/off the display function of system notification messages
4	Ambient Light	Switch to control ON/OFF of Ambient Light
5	Suction Auto Stop	Switch that turns on/off the automatic suction stop function when the suction amount of waste is full.
6	Language	Language can be adjusted to 'English' or 'Korean'
7	Theme	The theme can be adjusted to 'brown' and 'blue'
8	UV LED	Switch that controls ON/OFF and brightness of UV LED from level 0 to level 5
9	SPRAY LED	Switch to control ON/OFF and brightness of SPRAY LED from level 0 to level 5

2.10 Maintenance Schedule

Table 4 Trouble Shooting

Maintenance Task	**Minimum Frequency**
Daily Operation Check	Daily
Using the LCD Control or Foot Control, ensure the proper functioning of the equipment.	
Motor Operation Check	Weekly
Verify the proper operation of all motors within the system.	
Suction Bottle Inspection	Daily
Daily examination to ensure the correct functioning of all suction bottles.	
Cleaning and Disinfection	Daily
Perform daily cleaning and disinfection procedures as specified in the device's cleaning instructions.	
Connectors and Plugs Inspection	Every 6 months
Semi-annual inspection to confirm the tightness of all circuit board connectors and cable plugs.	
Cable Condition Check	Every 6 months
Examine all cables for signs of damage or fraying during the semi-annual inspection.	
Electrical Cord Inspection	Every 6 months
Conduct a thorough inspection of the electrical cord every six months. Ensure there are no signs of wear or damage.	

2.11 Trouble Shooting

Table 5 Trouble Shooting

Issue	**Solutions/Checks**
Treatment Unit Malfunction	Ensure the power cable is securely plugged in. Check and replace the fuse if necessary. Inspect the cable for any signs of damage.
Weak Spray	Confirm that all connection points are securely sealed. Improve spray performance by disassembling and soaking it in warm water for 20 mins. Utilize the enclosed needle to enhance spray functionality.
Weak Suction	Adjust the suction intensity knob located on the front. Ensure the suction bottle cover is tightly sealed. Enhance suction by placing the suction hose in warm water for 20 mins.
Insufficient Brightness	Adjust the brightness settings using the control panel. Verify that the light guide cable is free from damage.
Camera Not Operational	Confirm the proper connection of the camera cable. Check the camera power status on the control panel. Inspect the camera cable for any signs of damage.
Unclear Image	Examine the endoscope for potential damage. Ensure the light guide cable is free from damage. Improve image clarity by removing any dust from the lens.

3. Recommended Environmental Conditions

3.1 Temperature - Humidity - Atmospheric Pressure

During Transport

Temperature range (short term): -20°C~+60°C

Relative Humidity: below 95%

Atmospheric pressure: 70-106 kPa

During Storage and Use

Temperature range: +10°C~+40°C

Relative Humidity: below 95%

Atmospheric pressure: 70-106 kPa

4. Disposal

Dispose of the E.N.T. Treatment Unit in accordance with valid local regulations.

5. Maintenance

The main parts of the workstation are maintenance-free. Motors and pumps are critical components: It is recommended to inspect or replace these components every five years. Please ask our service technicians.

6. Cleaning, Disinfection, Sterilization (CDS)

6.1 General Principles

Set the main switch of the ENT workstation to OFF prior to any cleaning and disinfection steps.

The following instructions are in compliance with the recommendations (guidelines) of the German Robert-Koch-Institute (RKI) and the EN ISO 17664-1:2021. The following instructions are valid and released, if not stated otherwise, for all offered devices which can be attached to the ENT Workstation. Please find specific information in the individual instructions for use of the Medication sprayer, Ear irrigation system, Vent Adapter and the Suction unit.

Due to their shape, curves within the tips and narrow tubes, all devices which are indicated as to be sterilized in the below table are classified as semi-critical B according to the above-mentioned regulations. The exception is the suction bottle and the suction tube catheters which have to be cleaned, disinfected and sterilized due to the high number of infectious materials.

If prion disease / Creutzfeldt-Jakob disease is suspected, special reprocessing requirements must be followed. These procedures have not been described within the scope of these reprocessing instructions. Please refer to Annex 7 of recommendation "Hygiene requirements for the reprocessing of medical devices" by RKI and BfArM.)

Cleaning Agent Information: Contact DONG-A CHAMMED Co., Ltd

The recommendations provided above have been validated by DONG-A CHAMMED Co., Ltd

All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hygienic policies and procedures along with current applicable guidelines and standards.

Users should utilize appropriate personal protective equipment (PPE) when processing devices

Unsuitable disinfectants and unsuitable concentrations of disinfectants may lead to material damage and to inadequate disinfection performance.

6.2 Planning of actions for Cleaning, Disinfection and Sterilisation

All actions have to be performed by qualified and trained staff who are familiar with reprocessing.

Table 6 Overview processing prior each use

Parts	UDI-DI	Material	to be cleaned	to be disinfected	to be sterilized	Daily
Surfaces (housing of the E.N.T. Treatment Unit, drawers, instrument deposit, mirror anti-fog heater, instrument trays)[1]	8800038903784	divers	x	x	-	x
Surfaces (housing of the E.N.T. Treatment Unit, drawers, instrument deposit, mirror anti-fog heater, instrument trays) [1]	8800038903777	divers	x	x	-	x
Irrigator[2][3]	(01) 8800038903074	Poly(oxy-1,2-ethanediyloxycarbonyl-1,4-phenylenecarbonyl)	x	x	-	

[1] Wipe cleaning and disinfection:
All surfaces of the ENT Workstation have to be wiped with a clean (disposable) wipe which is damped with disinfectant solution. The entire surface has to be wiped thoroughly and may not be dried afterwards.
Please also consider that visible stains have to be removed and disinfected immediately with the same detergent and cleaning procedure as specified below.
[2] optional accessory, depending on the configuration of the E.N.T. Treatment Unit

[3] Immerse instruments into cleaning solution immediately and completely. Complete wetting is required, and dirt must be removed from any cavities. Prior to rinsing, it is necessary to brush the instruments thoroughly with suitable brushes to eliminate all residues. Use brushes that are appropriate for the specific instruments to reach all surfaces

Parts	UDI-DI	Material	to be cleaned	to be disinfected	to be sterilized	Daily
Irrigator tip	(01) 8800038903814	Silicone	x	x	x	
Vent tube tip	(01) 8800038903845	Polyacetal	x	x	x	
Spray [23]	(01) 8800038901414	C3604	x	x	-	
Spray Tip [23]	(01) 8800038901605	Copper alloy, Stainless steel 304	x	x	x	
Suction[23]	(01) 8800038901407	C3604	x	x	-	
Suction Bottle[23]	(01) 8800038901391	ABS	x	x	-	x

and cavities without damaging the material. After the soaking time, instruments must be rinsed 5 times at the beginning and at the end of the soaking time with water, using a single-use syringe (minimum volume 50 ml). Then, they have to be dried and sterilized afterwards as indicated. Please also observe the instructions for use for the single devices.

Parts	UDI-DI	Material	to be cleaned	to be disinfected	to be sterilized	Daily
Suction Tip (PC) [23]	(01) 8800038901483	Carbonic acid diphenyl ester polymer with 4,4'-(1-methylethylidene)bis[phenol]	x	x	x	
Suction Tip (Silicone) [23]	(01) 8800038903203	Silicone	x	x	x	
Suction Tube Catheter (outer diameter Ø2mm±5%)[23]	(01) 8800038903197	Copper alloy, Stainless steel 304, Stainless steel 300	x	x	x	
Suction Tube Catheter (outer diameter Ø2.5mm±5%)[23]	(01) 8800038903173	Copper alloy, Stainless steel 304, Stainless steel 300	x	x	x	
Suction Tube Catheter (outer diameter Ø3.0mm±5%)[23]	(01) 8800038903180	Copper alloy, Stainless steel 304, Stainless steel 300	x	x	x	
Suction Tube Catheter (outer diameter Ø3.5mm±5%))[23]	(01) 8800038903197	Copper alloy, Stainless steel 304, Stainless steel 300	x	x	x	

6.3 Cleaning and Disinfecting Agents

General Notes:

Do not use disinfectants that contain organic or inorganic acids or bases, as they could cause corrosion damage. Do not use disinfectants containing chloramide or phenol derivatives, since these may cause stress cracks in the plastic material used.

ENT Workstation:

- For disinfection, you may use all surface and instrument disinfectants listed in the following subchapter "Recommended Disinfectants".
- Please ensure that no wet surfaces are left behind after cleaning. Use a disposable cloth to absorb any liquid. If any disinfectant is spilled, make sure to wipe the surface dry immediately in order to prevent the liquid from penetrating into gaps and edges.
- All applied parts that are exposed to direct contact with the patient during treatment must be exchanged or cleaned and disinfected immediately for hygienic reasons.
- Only deposit clean instruments on the shelves!
- Clean and disinfect the instruments regularly.

Instruments:

Vent Tip, Irrigators tip, Spray Tips and Suction Tips have to be cleaned, disinfected and sterilized according to the instructions below.

Recommended Detergents: Enzymatic cleansers

Recommended Disinfectants: High-level disinfectants

ENT workstation:

Please clean at least once at the end of the day, according to the hygiene plan in your office.

Spray:

After treatment of each patient please immediately exchange the tubes for the spray. Disassemble the medication sprayer by unscrewing the sprayer nozzle and pull it from the sprayer head. Thoroughly rinse all parts under running water. A dishwashing liquid or a cleaning agent may also be used if required. Thoroughly rinse to eliminate all residues of these substances. Make sure that the air opening is not closed!

Disinfect all components using the disinfectants listed in the chapter above or according to the recommendation of the manufacturer of the detergent.

Suction:

After treatment of each patient please immediately exchange the tubes for the suction. Disassemble the suction device including the tips, the bottle and the catheters. Thoroughly rinse all parts under running water. A dishwashing liquid or a cleaning agent may also be used if required. Thoroughly rinse to eliminate all residues of these substances. Make sure that the air opening is not closed!

Disinfect all components using the disinfectants listed in the chapter above or according to the recommendation of the manufacturer of the detergent.

Drying the bottle may take longer as there may not be sufficient air flow. Compressed air can speed up the process.

Vent:

After treatment of each patient please immediately exchange the tubes for the tip. Thoroughly rinse all parts under running water. A dishwashing liquid or a cleaning agent may also be used if required. Thoroughly rinse to eliminate all residues of these substances. Make sure that the air opening is not closed!

Disinfect all components using the disinfectants listed in the chapter above or according to the recommendation of the manufacturer of the detergent.

Irrigator:

After treatment of each patient please immediately exchange the tubes for the irrigation system. Disassemble Irrigator and the irrigation tips. Thoroughly rinse all parts under running water. A dishwashing liquid or a cleaning agent may also be used if required. Thoroughly rinse to eliminate all residues of these substances. Make sure that the air opening is not closed!

Disinfect all components using the disinfectants listed in the chapter above or according to the recommendation of the manufacturer of the detergent.

6.4 Manual Cleaning and Disinfection

Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner and neutral detergent with a pH between 7 and 9.

- Prepare a new enzymatic or pH neutral (pH 7-9) detergent cleaning solution in accordance to the manufacturer's instructions.
- Fully immerse the instrument in freshly prepared enzymatic or cleaning detergent solution to avoid aerosol generation.
- Use a minimum suitable, tight fitting, soft lumen brush (e.g. nylon) to thoroughly scrub the lumen or the cannula of each device.
- Push the brush through the entire length of the lumen using a twisting motion to remove debris.
- Clean the brush in the cleaning solution between each pass of the brush through the lumen by manually immersing the brush in the cleaning solution until no sign of debris can be seen.
- Pass the brush through the lumen as described above several times for 1 minute from both ends, cleaning the bristles before retracting until brush comes out clean.
- Use a 50ml syringe, or equivalent, filled to capacity with cleaning solution to flush the lumen of each device.
- Rinse the device with tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
- Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with tap water.
- Rinse the device components with tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
- Perform a final rinse using critical water (high purity water generated by processes such as RO, deionization or distillation).
- Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.

6.5 Automated Cleaning and Disinfection (Washer-Disinfector) only for the Instruments

Alternative to the Manual Cleaning in the chapter above the below steps should be followed for Automated Cleaning

- Observe standards DIN EN ISO 15883-1 and DIN EN ISO 15883-2.
- Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions.
- Using a brush (nylon brush) under running water, wipe the entire surface for at least 1 minute until there are no visible residues.
- Check the disinfectant concentration before filling the washer-disinfector (WD) with disinfectant: Check that it is 1,000 ppm or more with a stirrup.
- After inserting the tube into the connection part of the object to be cleaned, insert the other side of the tube into the washer-disinfector channel study.
- Close the door of the washer and sterilizer and enter the parameters as follows as the operation mode is A MODE.
- Load the devices into the washer-disinfector in such a manner that the o that the lumens can drain. Clean, using the "INSTRUMENTS" cycle in a validated washer disinfector and a pH neutral cleaning agent intended for use in automated cleaning using the full cycle parameter set points below:

Table 7 Full Cycle Parameter set points

Phase	Time (Minutes = min., Seconds = sec.)	Cleaning methods	Detergent Type
Wash 1	1 min 30 sec.	Constant	
Detergent	1 min.	Constant	Enzyme detergent
Wash 2	1 min.	Constant	-
Disinfection	10 min.	Immersion	Disinfectant
Rinse 1	30 sec.	Constant	-
Rinse 2	30 sec.	Sterile distilled water	-
Dry	30 min.		-

6.6 Cleaning Inspection

Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes, and moveable parts. If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments for a minimum of 1 minute with tap water after using hydrogen peroxide solution. If soil is still present, re-clean the instrument. Carefully inspect instruments between uses to verify proper functioning.

6.7 Sterilization

Use a validated, properly maintained and calibrated steam sterilizer. Effective steam sterilization can be achieved using the following cycles

Ensure that the device is wrapped in a sterilization wrap before placing it in the sterilizer to maintain its sterility during the process.

Table 8 Sterilization in the United States

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time
Pre-Vacuum	132°C (270°F)	4 minutes / 30 minutes dry time

For further guidance to sterilization refer to ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."

Table 9 Sterilization outside the United States

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time
Pre-Vacuum	134°C (273°F)	3 minutes / 30 minutes dry time

6.8 Storage of sterilized Instruments

Store sterile packaged instruments protected from dust, moisture, insects, vermin, and extremes of temperature and humidity. For temperature ranges please see chapter "During Storage and Use"

6.9 UDI Label Maintenance : Post-Reprocessing Inspection

After each reprocessing cycle, verify that the UDI label remains readable and scannable to ensure proper identification. If necessary, perform a re-inspection to confirm that the UDI label retains its integrity and functionality following reprocessing procedures.

7. Installation and Maintenance

Please see separate installation and maintenance manual.

8. Additional Information for EU Customers

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are located

9. Trademarks

The device is not sold under any trade names.

10. Policy and Warranty

DONG-A CHAMMED Co., Ltd guarantees a 1-year warranty on all new products from the date of shipment, covering faults in materials. This warranty specifically addresses faulty components manufactured by DONG-A CHAMMED Co., Ltd

DONG-A CHAMMED Co., Ltd will charge a service fee in the following cases:

1. If the product malfunctions after the warranty period expires.
2. If the product malfunctions due to natural disasters.
3. If the product malfunctions due to improper transportation after installation and careless use.
4. If the product malfunctions due to improper repair or renovation.

DONG-A CHAMMED Co., Ltd will not be responsible for any loss, damage, or injury resulting from delays in service under this warranty.

DONG-A CHAMMED Co., Ltd will not be liable for incidental or consequential damages of any kind arising from or connected with the use of its equipment.

DONG-A CHAMMED Co., Ltd does not provide a warranty for endoscopes, as they can be damaged by careless handling.

DONG-A CHAMMED Co., Ltd is not responsible for the use of the product, when it is used by/on patients with Creutzfeldt Jacob disease (CJD) or its variants.

After-sales service issues arising in foreign countries, including the EU, will be handled through the respective regional agency. The regional agency will assume responsibility for supplying necessary components and support.

In the event of medical accidents or recalls resulting from device inadequacies, DONG-A CHAMMED Co., Ltd will assume complete responsibility.

Other than the mentioned conditions, free after-sales services can be determined based on the contract with the customer.

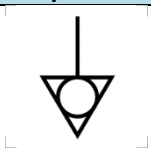
11. Explanation of Symbols

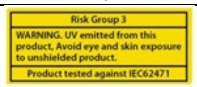
Table 10 Symbols

Symbol	Explanation
 Figure 2 Manufacturer	The name of the company that manufactured this medical device.
 Figure 3 Authorized representative	Information about the authorized representative in the European Community or Union.
 Figure 4 Medical device	Indicates that this is a medical device.
 Figure 5 Catalogue number	Indicates the catalogue number of the device.
 Figure 6 Model number	Indicates the model number of the device.
 Figure 7 Serial number	Indicates the serial number of the device.

Symbol	Explanation
Figure 8 Unique device	The unique identifier assigned to this specific device.
Figure 9 Date of manufacture	Indicates the date of manufacture.
Figure 10 Caution	Serves as a caution symbol for important notes or warnings.
Figure 11 Humidity limitation	Indicates a humidity limitation.
Figure 12 Keep dry	Advises the user to keep the device dry.
Figure 13 Temperature limit	Indicates a temperature limitation.
Figure 14 Keep away from sunlight / heat	Indicates that the user needs to keep the device away from sunlight/heat.

Symbol	Explanation
Figure 15 Handle with care	Indicates that the user needs to handle the device with care.
CE 0123 *Figure 16 CE-Marking of Conformity*	Indicates that the device conforms to Annex V, CE-Marking of Conformity.
Figure 17 Distributor	Represents the Distributor.
Figure 18 Importer	Represents the Importer.
Figure 19 Type B applied part	Identifies a type B applied part complying with IEC 60601-1 standards.
Figure 20 Read the instruction manual/booklet	Advises to read the instruction manual/booklet.
Figure 21 Vacuum low-high	Turn the knob to increase/decrease the vacuum for proper device operation.

Symbol	Explanation
 *Figure 22 Equipotentiality*	Refer to the instruction manual/booklet for details on equipotentiality.
Figure 23 Important notice	Important notices; read the instruction manual/booklet for additional information. Failure to follow the instructions could result in personal injury to the user or property damage.
Figure 24 Packing direction	Information about the correct packing direction.
Figure 25 No hook	Indicates that hooks should not be used with this device.
Figure 26 Notice	An indication of important content that is required for installation, use, and maintenance.

Symbol	Explanation
 Figure 27 Waste Electrical and Electronic Equipment (WEEE)	Indicates that separate collection for Waste Electrical and Electronic Equipment (WEEE) is required.
 Figure 70 Safe Working Load	Information related to drawers on the device. Specifies the maximum safe working load capacity of the device.
 Figure 71 Care against pinch Rotation bar	Caution against pinching related to rotation bars.
 Figure 72 Care against pinch Drawer, Door	Caution against pinching related to drawers and doors.
 *Figure 73 Warning*	Caution against exposure to unshielded UV emissions from the product.