

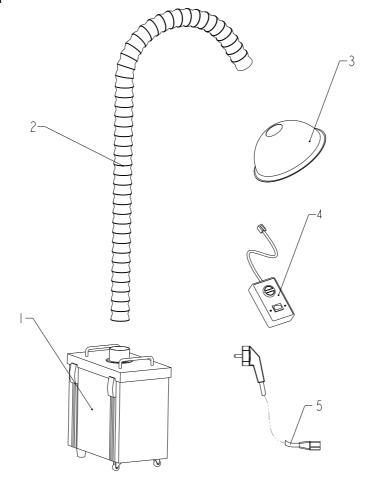
# Extraoral Dental Vacuum System USER MANUAL

### Content

1. Scope of VacStation	1
•	
2. Symbols	
3. Introduction	6
3.1 Scope of application	6
3.2 Safety instructions	6
4. Installing VacStation	8
4.1 Remove transportation protective foam	8
4.2 Installing VacStation	9
5. User Interface	. 11
6. Operating instructions	. 12
6.1 Air volume setting	. 12
6.2 Connect volume controller for air volume adjustment	. 12
6.3 Power off	. 13
7. Maintenance	. 14
7.1 Cleaning and disinfection	. 14
7.1.1 Forward	. 14
7.1.2 General recommendations	. 15
7.2 Filter replacement	. 16
7.2.1 The frequency of filter replacement	. 16
7.2.2 How to replace filters	. 16
8. Trouble shooting	. 17
9. Technical Data	. 18
10. EMC Tables	. 19
11. Statement	. 24

# 1. Scope of VacStation

- 1. Main Engine Box
- 2. Directional Duct
- 3. Suction Nozzle
- 4. Volume Controller
- 5. Power cord



# 2. Symbols

WARNING	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
ΝΟΤΕ	Additional information, explanation of operation and performance.
SN	Serial number
REF	Catalogue number
$\sim$	Date of manufacture
LOT	Lot of manufacture
	Protective earth(ground)
Ŕ	Type B applied part
	Fuse
×.	WEEE directive marking
Ť	Keep dry
-20°C	Temperature limitation
20%	Humidity limitation
70kPa	Atmospheric pressure limitation
	Manufacturer's LOGO
CE	CE mariking
ECREP	Authorized Representative in the European Community
<b>E</b>	Consult instructions for use

## 3. Introduction

#### 3.1 Scope of application

VacStation is used to reduce drill aerosols, abrasion powder, and mercury vapour during dental procedures before they spread.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

#### 3.2 Safety instructions

1. Please read this manual before use.

2. The VacStation must be placed upright when being used. Laying on the side or upside down is prohibited, because these will cause damage to the machine or shorten its service life.

3. When replacing the filter, pay attention to whether the rubber frame is flat, otherwise air leakage will occur and the suction power will be reduced.

4. When using the buckle button, make sure to press the top cover part firmly, and then fix the buckle button, otherwise the buckle button will be damaged.

5. The main filter is heavy, so be careful when replacing it. VacStation is heavy, so be careful when moving it.

6. When replacing the primary effect filter, it should be noted that the dense side faces the filter, and the sparse side faces the air inlet.

# 

1. The device can capture the virus and bacteria in the air sucked into the device. Please note that the device cannot be used to prevent the spread of virus and bacteria in the air that doesn't go through the filters.

2. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.

3. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.

4. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near the active

#### 3 Introduction

HF Surgical Equipment in the hospital. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VacStation, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Do not operate or store at high temperatures. Comply with the specified operating and storage conditions.

5. If irregularities occur in the device during treatment, switch it off. contact the agency.

6. Never open or repair the device yourself, otherwise, void the warranty.

# 4. Installing VacStation

#### 4.1 Remove transportation protective foam

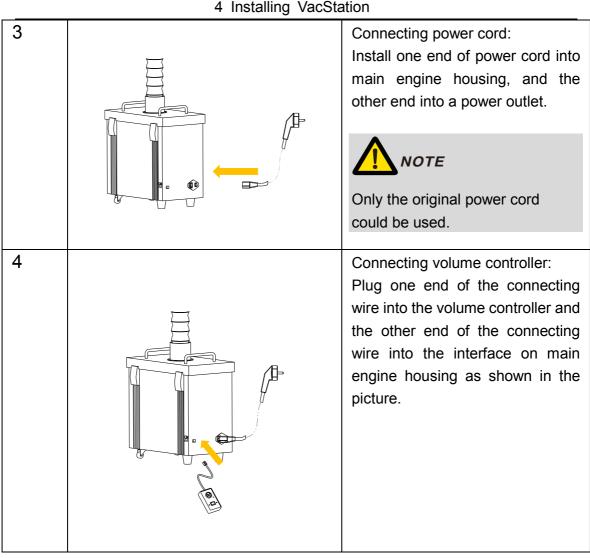
Before using the machine for the first time, please take out the foam for transportation protection at the bottom of the main filter assembly, otherwise the machine won't work normally. Please refer to the following steps to remove the foam.

Step	Diagrammatic Sketch	Description
1		Remove the top cover: Open four buckles (marked by blue arrows) and remove the top cover.
2.		Take out main filter assembly: Take out the sealing strip and filter elements in sequence. Then take out the main filter assembly enclosed by the dotted line.
3		Remove the foam: Take out the foam installed at the bottom of the main filter element. The foam can be discarded according to the local law and regulations

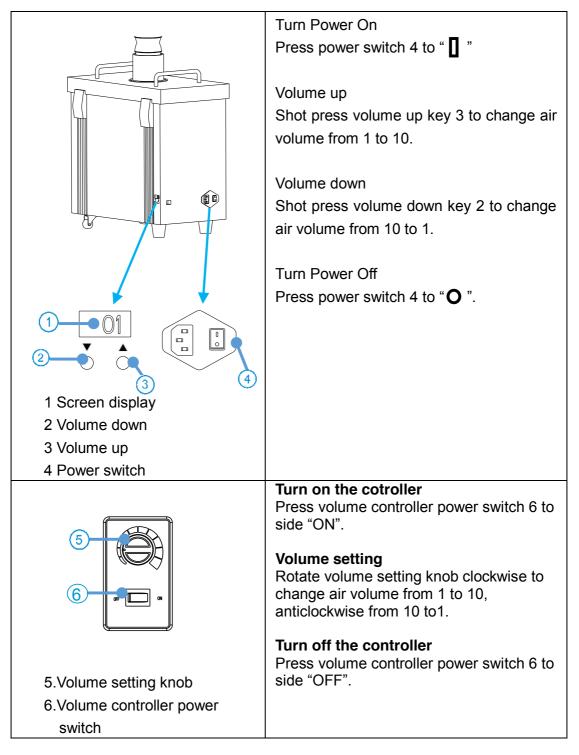
# 4 Installing VacStation 4 Install the main engine box: Install the parts in order and fix four buckles.

### 4.2 Installing VacStation

Installation of suction nozzle: Screw the nut, fix suction nozzle to the directional duct.
Installation of directional duct: Plug the directional duct to the top cover.
ΝΟΤΕ
Directional duct should be installed vertically and in place on top cover, otherwise the suction ability will be degraded.



# 5. User Interface



## 6. Operating instructions

# 

Do not block the air inlet artificially to avoid damage to the motor. After the filter is blocked, please replace the filter immediately to avoid damage to the motor.

# ΝΟΤΕ

Before first use, be sure to remove the foam placed under the main filter.

When using the buckle button, be sure to press the top cover part firmly, and then fix the buckle button, otherwise the buckle button will be damaged. Fix the directional air duct, adjust the direction of the directional air duct according to different occasions, connect the power supply, turn on the power switch (without inserting an external keyboard to adjust the air volume), the value displayed at this time is the air volume gear at the last shutdown.

When starting up, the display shows two-digit value, indicating the air volume range: 01-10, if there is no operation within 3 minutes (including the key box and the machine  $\blacktriangle$  or  $\checkmark$  key), the cumulative flow value is displayed, and the flow value is a three-digit value (flow The value is that when the fan rotates 5.76 million revolutions, the cumulative value is 001, which is accumulated in multiples of 5.76 million revolutions.)

#### 6.1 Air volume setting

A total of  $01 \sim 10$  ten-speed air volume can be set. Click the  $\blacktriangle$  or  $\blacktriangledown$  key to set the air volume. When 01 is displayed, the air volume is the smallest; when 10 is displayed, the air volume is the largest.

#### 6.2 Connect volume controller for air volume adjustment

When the volume controller for air volume regulation is connected, the  $\blacktriangle$  or  $\checkmark$  key on the machine fails, and the air volume can only be adjusted by the knob on the controller. When the air volume is large, the suction capacity of the machine is strong. It is recommended to work under the condition of large air volume.

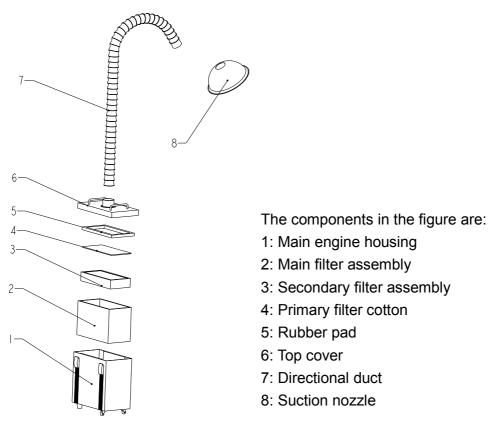
#### 6.3 Power off

Turn off the device by pressing volume controller power switch to side "OFF", and the window will display "OFF". To disconnect the power supply, please press the power switch on main engine box to " $\mathbf{O}$ ".



In some cases such as the temperature of suction nozzle is much lower than water, condensate water may appear on suction nozzle. In such case, keep the device working for 15~30 minutes without any treatment involved to make sure there is no water or vapour exist in directional duct and suction nozzle.

#### 7. Maintenance



#### 7.1 Cleaning and disinfection

#### 7.1.1 Forward

For hygiene and sanitary safety purpose, the components (suction nozzle) must be cleaned and disinfected before each usage to prevent any contamination. This concerns the first use as well use the subsequent uses. The components (directional duct, main engine box, power cord and volume controller) should be cleaned and disinfected regularly according to the usage. Comply with your national guidelines, standards and requirements for cleaning and disinfection.

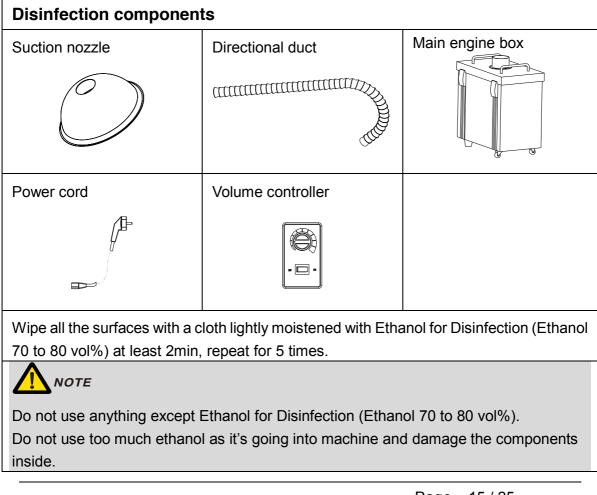
Reprocessing procedures have only limited implications to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation. In case of damage, the device

#### 7 Maintenance

should be reprocessed before sending back to the manufacturer for repair.

#### 7.1.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHMlisting, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Do not use bleach or chloride disinfectant materials.



#### 7.2 Filter replacement

#### 7.2.1 The frequency of filter replacement

Componente	Frequency		
Components	Durability	Accumulative flow	
Primary filter cotton	1Month	Display 010 and its multiples	
Secondary filter assembly	3~6Month	Display 030 and its multiples	
Main filter assembly	6~12Month	Display 060 and its multiples	
Replace relevant filter as long as required usage time or accumulative flow occurs. When the LED window displays "  " circularly, the filter must be replaced.			

#### 7.2.2 How to replace filters

Release the four buckle buttons on the edge of the upper cover of the machine, and pick up the top cover part, primary filter cotton, secondary filter assembly and main filter successively. Replace the main filter with a new one. Make sure the new main filter is placed correctly and the fan outlet connected to the bottom of the filter is conductive.



When replacing filter, turn off the power switch first.

# 8. Trouble shooting

When a problem or malfunction occurs, please check the machine with the table below before contacting the dealer to quickly eliminate common problems or malfunctions. If the problem or malfunction is not solved, please contact the dealer.

Problem or malfunction	Reasons	Solutions	
The window flashes "OFF" and clockwise "□" alternately, alarms, the fan stops working.	The air inlet is completely blocked	Turn off the power, check whether the direction air duct and suction nozzle are blocked by foreign matters, and if so, clean them up. If the problem is not solved, open the upper cover and check whether there is foreign matter blocking the air inlet inside the machine, and if so, clean them up. After these steps, restart the machine and observe after one minute whether it still alarms, if so, replace the filter	
LED window displays "ERR", alarms, the fan and motor stop working.	The fan or line control part is abnormal	Turn off the power and restart the machine to check whether it is working properly, and if not, check the fan.	

# 9. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd
Model	VacStation
Dimensions	53cm x 46 cm x 60 cm±1 cm(Package)
Duct	Φ75mm×1500 mm
Weight	21kg±10%
Input	220-240V AC for European Standard/100-120V AC for American Standard
Frequency	50/60Hz
Power	250W Max
Filter efficiency (0.3um)	99.97%
Static pressure	3000Pa
Blowing rate	14m/s
Volume(Filter included)	3.7m <sup>3</sup> /min
Electrical safety class	Class I
Applied part	В
Operating conditions	Use: in enclosed spaces Ambient temperature: 5°C ~ 40 °C Relative humidity: <80% Operating altitude < 3000m above sea level
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa~106kPa

# 10. EMC Tables

#### Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The <b>VacStation</b> uses RF energy only f its internal function. Therefore, its F emissions are very low and are not like to cause any interference in nearl electronic equipment.	
RF emissions CISPR 11	Class B	The VacStation is suitable for use in all	
Harmonic emissions IEC61000-3-2	Class A	establishments, including domestic establishments and those directly	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

Guidance and manufacturer's declaration – electromagnetic immunity			
The <b>VacStation</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>VacStation</b> should assure that it is used in such an			
environment.  Immunity test IEC 60601 Compliance Electromagnetic environment -			
		level	guidance

10 EMC Tables				
Electrostatic discharge	+/- 8 kV	+/- 8 kV	Floors should be wood,	
(ESD) IEC 61000-4-2	contact	contact	concrete or ceramic tile.	
			If floors are covered with	
	+/- 2 kV, +/- 4	+/- 2 kV, +/- 4	synthetic material, the	
	kV, +/- 8 kV,	kV, +/- 8 kV,	relative humidity should	
	+/- 15 kV air	+/- 15 kV air	be at least 30 %.	
Electrical fast	±2kV	±2kV	Mains power quality	
transients/bursts	100kHz	100kHz	should be that of a	
IEC 61000-4-4	repetition	repetition	typical commercial or	
	frequency	frequency	hospital environment.	
Surge	Line to line:	Line to line:	Mains power quality	
IEC 61000-4-5	±0.5kV, ±1kV	±0.5kV, ±1kV	should be that of a	
			typical commercial or	
	Line to earth:	Line to earth:	hospital environment.	
	±0.5kV, ±1kV,	±0.5kV, ±1kV,		
	±2kV	±2kV		
Voltage dips	0% UT; 0.5	0% UT; 0.5	Mains power quality	
IEC 61000-4-11	cycle	cycle	should be that of a	
	at 0°, 45°, 90°,	at 0°, 45°,	typical commercial or	
	135°, 180°,	90°, 135°,	hospital environment. If	
	225°, 270°,	180°, 225°,	the user of devices	
	and 315°	270°, and	require continued	
		315°	operation during power	
	0% UT; 1		mains interruptions, it is	
	cycle and 70%	0% UT; 1	recommended that	
	UT; 25/30	cycle and	devices be powered	
	cycles	70% UT;	form an uninterruptible	
	sine phase at	25/30 cycles	power supply or a	
	0°	sine phase at	battery	
		0°		
Voltage interruptions	0% UT;	0% UT;		
IEC 61000-4-11	250/300 cycle	250/300 cycle		

Page 20 / 25

#### 10 EMC Tables

Rated Power frequency magnetic field IEC 61000- 4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer's declaration – electromagnetic immunity			
The VacStation is intended for use in the electromagnetic environment specified below.			
The customer or the user of the VacStation should assure that it is used in such an			
environment.			
Immunity testIEC 60601 test levelCompliance levelElectromagnetic environment - guidance			
Conducted dis-turbances	3 V	3 V	Portable and mobile RF

Conducted dis-turbances	3 V	3 V	Portable and mobile RF
induced by RF fields	0.15 MHz – 80		communications
IEC 61000-4-6	MHz, 6 V in		equipment should be
	ISM bands be-		used no closer to any part
	tween 0.15		of the VacStation,
	MHz and 80		including cables, than the
	MHz, 80 % AM		recommended separation
	at 1 kHz		distance calculated from
			the equation applicable to
			the frequency of the
			transmitter.
Radiated RF EM fields		3V/m	<b>_</b>
IEC 61000-4-3	3 V/m, 80 MHz	0 1 111	Recommended
120 01000-4-3	– 2,7 GHz,		minimum separation
	80 % AM at 1		distances
	kHz		See the RF wireless
			communication equipment

#### 10 EMC Tables

			table in "Recommended minimum separation distances"
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	

#### **Recommended minimum separation distances**

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **VacStation** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **VacStation** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787 LT 13	LTE Band	Pulse		0.3	9
745		7 13, 17	modulation	odulation 0.2		
780			13, 17	217Hz		
810		GSM				
870	800/900, 800-960 iDEN 820, CDMA 850, LTE Band 5		Pulse modulation 18Hz	2	0.3	28
930		iDEN 820, CDMA 850,				

1720		GSM 1800;				
1845		CDMA 1900;				
1970	1700- 1990	GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240		14/1 A NI	Dedaa			
5500	5100- 5800	WLAN 802.11	Pulse modulation	0.2	0.3	9
5785	5500	a/n	217Hz			

10 EMC Tables



1. Use of accessories and cables other than those specified or provided by the manufacturer of **VacStation** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **VacStation** and result in improper operation.

#### Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter	1.8	No	/

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

# 11. Statement

#### Service Life

The service life of VacStation series products is 3 years.

#### Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

#### Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Please deal with them according to the local environmental protection laws and regulation.

#### Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.

# Changzhou Sifary Medcial Technology Co., Ltd

Add: NO.99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, 213000 Jiangsu, China
Tel: +86-0519-85962691
Fax: +86-0519-85962691
Email: ivy@sifary.com
Web: www.eighteeth.com



Llins Service & Consulting GmbH Tel: +49 175 4870819 Add: Obere Seegasse 34/2, 69124, Heidelberg, Germany Email: Llins.Service@gmail.com

Version: 01 IFU-6835001 Issued: 2020.04.10 All rights reserved.