

INSTRUCTION MANUAL

Read Before Installation & Use

This product must be operated by a dentist or professional skilled
personnel

Surgy Star & AIC SURGERY









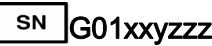

dmotec

CONTENTS

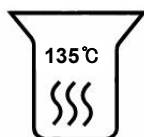
| | | |
|---|-------|-------|
| 1. Symbols | ----- | 3 |
| 2. Consisting | ----- | 4~5 |
| 3. Instruction for Use | ----- | 6~13 |
| 4. Clearning & Maintenance | ----- | 14~16 |
| 5. Technical Specification | ----- | 17~18 |
| 6. Guidance and manufacturer's declaration | ----- | 19~21 |
| 7. Troubleshooting guide | ----- | 22~24 |

1. Symbols

Symbols used on Unit

| | | | |
|---|--|---|---|
|  | <p>Attention! Consult the manual before use</p> |  | <p>Direct current</p> |
|  | <p>Applied part type BF (To IEC-60601-1 Standard)</p> |  | <p>Alternating current</p> |
|  | <p>"ON" (only for a part of equipment)</p> |  | <p>OFF" (only for a part of equipment)</p> |
|  | <p>Correspond to EC directive 93/42/EEC Including IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-4</p> |  | <p>Date of manufacture</p> |
|  | <p>G01 : Surgystar model xy : Manufactured year/month zzzz : Number</p> |  | <p>Manufacturere</p> |

Symbols used on Handpiece



Autoclavable at 135°C

2. Consisting

Main unit



Handpiece Tubing



Foot Switch



AC/DC Adaptor



Autoclave Tray



Torque Wrench



Hanger for Handpiece



hanger for Saline



Peristaltic pump tubing



Instruction Manual



Surgery Instruction DVD



Tip (A TYPE)



Tip (B TYPE)



Surgy Star

| Part name | Q'ty | |
|----------------------------|------|-------------------|
| 1. Main Unit | 1 | |
| 2. Handpiece Tubing | 1 | |
| 3. Foot Switch | 1 | |
| 4. AC/DC Adaptor | 1 | |
| 5. Autoclave Tray | 1 | |
| 6. Torque Wrench | 1 | |
| 7. Hanger for handpiece | 1 | |
| 8. Hanger for saline | 1 | |
| 9. Peristaltic pump tubing | 1 | |
| 10. Instruction Manual | 1 | |
| 11.Surgery Insturction DVD | 1 | |
| 12. Tip | 10 | Each for 10 types |

3. Instruction for use

3.1 Note before use

- 1) Use only the own tip.
- 2) To prevent bio-contamination, Tips & Handpiece must be sterilized in autoclave for 3minutes at 135°C before use or reuse.
- 3) We recommend to use 1 tip for 10 cases surgery. Please discard the used tip after 10 cases.
- 4) Check the tip`s abrasion or rust before using. In the case, Please discard it.

3.2 Caution when use

- 1) This machine should be used by the dentist only.
- 2) Do not use for the face-making purpose.
- 3) This device must be used for intended purpose.
- 4) Must use standard, certified AC power supply code.
- 5) Before use, check the tips whether there is water spray(flow), if no water flow, it causes burning.
- 6) Must use a standard adaptor supplied by manufacturer.
- 7) Must use grounded power supply.
- 8) Avoid water or dust from "Surgy-Star"
- 9) Do not use nearby inflammability gas.
- 10) Must put at a even place.
- 11) Do not assemble or disassemble by dentist or other unqualified person.
- 12) Do not put the heavy thing on the power supply connection line, and avoid the heat.
- 13) Remove the power supply code when working abnormally.
- 14) As the tips are so sharp (made of stainless steel) and by mistake, it can be hurted, it is strongly required many training before operation.
- 15) After every using, keep the handpiece, cable, tip after sterilization.

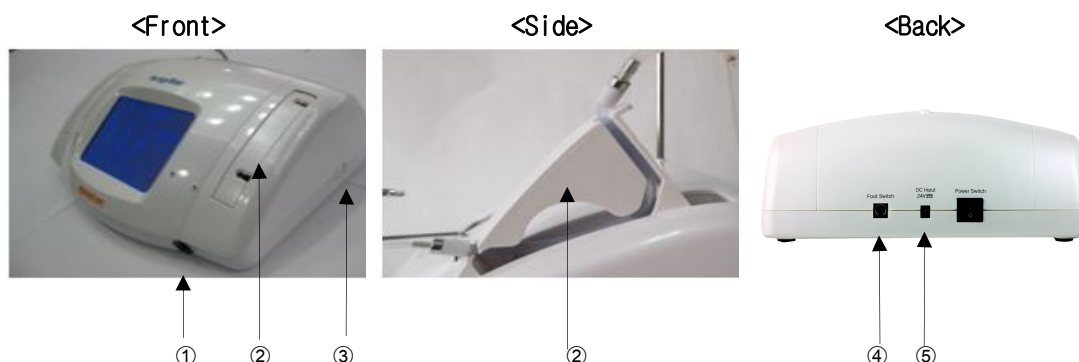
* Caution

- Working without water flow, handpiece and tip would be overheated.
- The handpiece itself has not a heating effect.
- Water spray is sufficient to cool the point of friction between the tip and the tooth.
- Please be careful, if the tip contacts non-intended surgical spot, there are the probabilities of burn or abrasions.

3.3 How to install

In order to install Surgystar, the following connection is needed.

- Water supply : distilled water or saline solution
- Electrical supply of DC 24V, 2.7A (with transformer output)



Connection of the handpiece

- Screw a selected tip onto the handpiece.
- Tighten the tip with Torque-wrench.
- Connect the handpiece-cable to connector(①) and place it on holder.

Connection to water supply

- Connect the water hose to a water package(bottle).
- Open Pump-cover(②) with push button(③) on the right-side of unit.
- Put water hose into pump and close pump-cover.

Connection of Foot switch

- Connection the footswitch cable to the socket on the back of unit. (See mark ④)

Connection to electricity supply

****WARNING: Always the specified electric power must be supplied.**

- Connect the transformer to socket on the backside of unit. (See mark ⑤)
- Transformer input: AC 100-240V , 50/60Hz
- Transformer output: DC 24V, 2.7A

3.4 How to use

- 1) Select a suitable tip and mount onto the handpiece with torque wrench.

***Caution: There is the possibility of hurt by the sharp edge of tip.**

***Tips and handpiece must be sterilized before use.**

- 2) Connect the handpiece cable to connector of main unit.
- 3) Connect water-hose to distilled water or saline solution.

*** Must supply distilled water or saline solution**

4) Open pump-cover, and put water-hose into cover hole like the photo. Push to close pump-cover.



5) Switch on main unit.

6) Select SURGERY MODE menu on the right side of screen.

7) Select the level of vibration power(ultrasonic intensity)

using ▲▼button on POWER tab. SurgyStar has 10 degree of ultrasonic intensity level.

8) Regulate the flow of water using ▲/▼button on the WATER tab.

9) Control the boost level by using ▲/▼button on the Boost tab

10) Step on foot switch to operate.

- FOOT FREE: Operating during step on foot switch.

- FOOT LOCK: Operating with one press foot switch.

11) List of setting mode

| NO | Tip | Power | Water | Boost | Surgical applications |
|----|------------------------|-------|-------|-------|---|
| 1 | BS01/BS1S BS2R/BS2L | 100 | 70 | 100 | Window opening/Block bone graft/Ridge split/Corticotomy |
| 2 | CA00 | 100 | 50 | 100 | Crestal approach technique |
| 3 | EX01 | 80 | 70 | 80 | Apicoectomy/Periotome tooth extraction |
| 4 | HB01/HB02 | 100 | 30 | 100 | Bone Harvesting |
| 5 | EX02/EX03 | 100 | 50 | 100 | Apicoectomy |
| 6 | SL01 | 50 | 30 | 0 | Sinus graft |

12) Power and Boost specification

1.Powerlevel 1(10%) to level 10(100%) by increasing one level , Water level 1(10%), Boost level 0(0%).

- The vibration length of tip is increasing by level up the power.

※ Please set the tip and power referring to “11) List of setting mode”

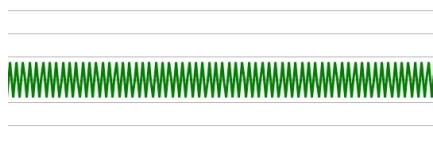
2.Power level 1(10%), Water level 1(10%), Boost level 1(10%) to 10(100%) by increasing one level

- Change of vibration distance of tip by increase of boost is not too much. However, using Boost makes about two times of tip vibration distance rather than one of the reverse.

※ When boost on, please set the tip and boost referring to” 11) List of setting mode”

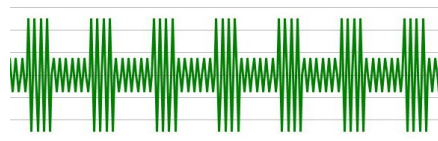
3. Power mode & Boost mode

1) Power mode



Vibration and frequency is same


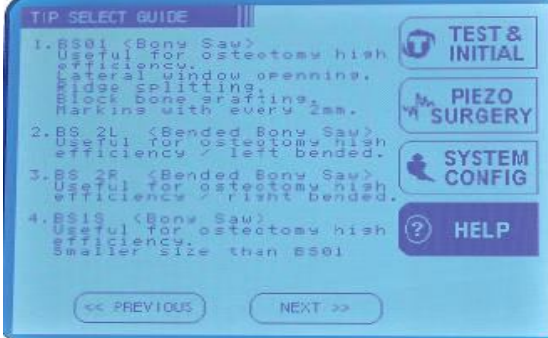
2) Boost mode



vibration and frequency is not same

Good performance for cutting and sawing

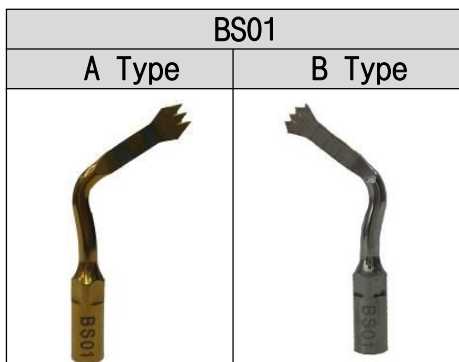
| | | |
|----------|---|--|
| <p>1</p> | <p>•TEST & INITIAL MODE</p> <ul style="list-style-type: none"> -Selection system check -Ready for Operation: Set Stand-by status, user can operate justly. -Auto-diagnosis when turn on : When boot, tested by automatic system. | |
| <p>2</p> | <p>•PIEZO SURGERY</p> <ul style="list-style-type: none"> -User Program: Load the saved user setting. -Foot Free: Lock/Unlock Foot switch. -▲▼ Regulate Power, Water and boost -Save : Save current user setting | |
| <p>3</p> | <p>•USER PROGRAM</p> <ul style="list-style-type: none"> -Load the saved user setting. | |
| <p>4</p> | <p>•SYSTEM CONFIG</p> <ul style="list-style-type: none"> -BEEP LEVEL : Beep adjusting -CONTRAST LEVEL : Contrast adjusting -BACKLIGHT LEVEL : Backlight adjusting -DEFAULT : Initial setting status -TOUCH SETUP : User setting | |

| | | |
|---|---|--|
| 5 | <p>•HELP</p> <ul style="list-style-type: none"> - Introduction of Piezo Surgery - Tip Selection Guide - Maintenance - Warnings - Program information |  |
| 6 | <p>•TIP SELECT GUIDE</p> <ul style="list-style-type: none"> - Explanation of each tips - Previous: Previous Information - Next: Next Information |  |

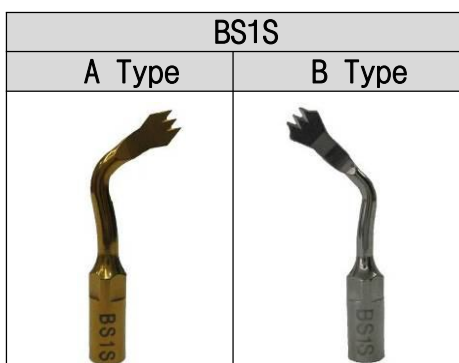
3.5 Tip information

A TYPE - Plating Tip (Titanium) / B TYPE - Non-Plating Tip

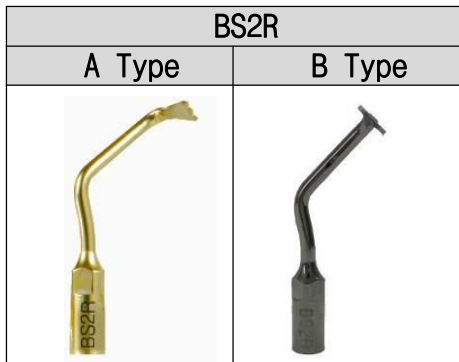
- The only difference between plating and non-plating is the titanium plating.



<Bony Saw>
 Useful for osteotomy high efficiency.
 Lateral window opening
 Ridge splitting
 Block bone grafting
 Marking with every 2mm

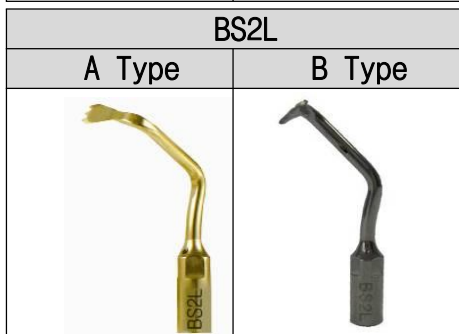


<Bony Saw>
 Useful for osteotomy high efficiency.
 The length is shorter than the BS01 tip.



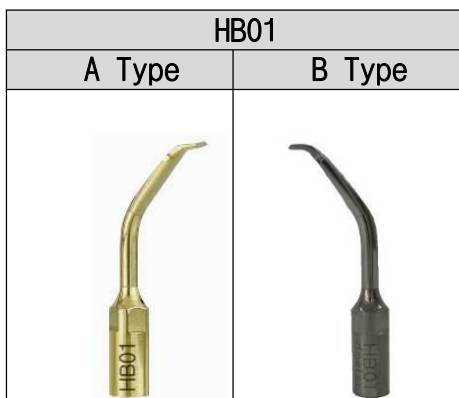
<Bended Bony Saw>

Useful for osteotomy high efficiency / right bended



<Bended Bony Saw>

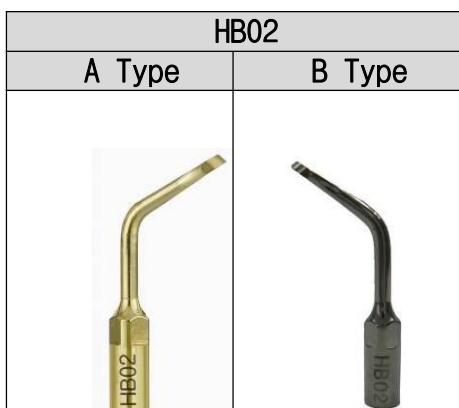
Useful for osteotomy high efficiency / left bended.



<Osteoplasty>

Useful for bone remodeling and for biopsy.

Mess for osteoplastic operation or collecting bone chip.



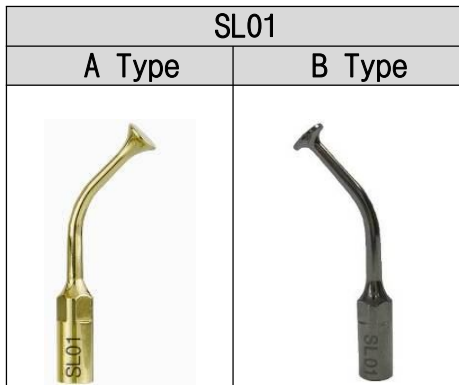
<Osteoplasty>

Useful to un-stick the sinus membrane.

Osteoplasty for high precision.

Collecting bone chips.

Osteoplasty of Sinus lift.

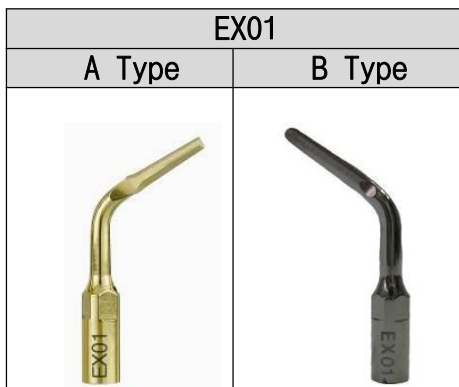


<Sinus Membrane separator>

Useful for sinus membrane separation

Useful for sinus membrane elevator and lift.

Use on low power

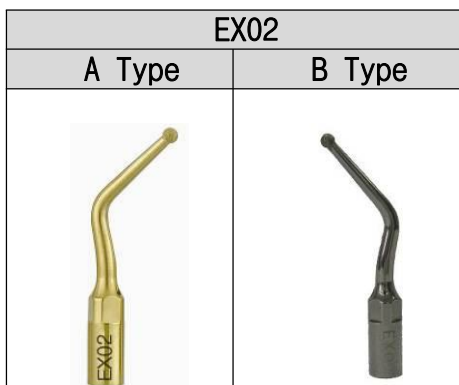


<Flatten mess for root exodontias>

Useful for simple and complex extraction enclosed tips.

Mess for Periodontal ligament osteotomy or periradicular osteotomy.

Use on low power

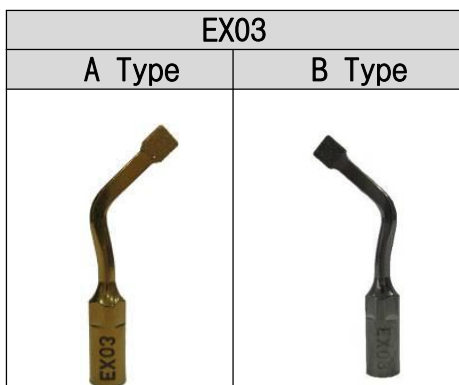


<Osteoplasty>

Use for Bone Orthosis and Osteoplasty.

Cutting bone in the adjacent areas of Soft tissue.



Bone grinding in tight areas



<Osteoplasty>

Face a Bone surface smoothly to make it flat.

Cutting bone-thin and sharp.

| CA00 | |
|---|---|
| A Type | B Type |
|  |  |

<Osteotome>

Useful for final preparation of the implant site

4. Cleaning & Maintenance

4.1 How to use and manage the store

1) Handpiece and the handpiece cable

- ① Cleaning: After you use the tip, please replace the saline with distilled water. Work the handpiece to remove debris left & saline in the internal tube then dry it



<Distilled water>

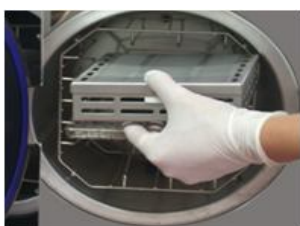


<Remove saline>



<Dry>

- ② Sterilization: Before every use, handpiece must be sterilized in autoclave at 135°C for 3 minutes, drying time 0~1minutes. Surgery Tip, Handpiece tubing, peristaltic pump tubing, torque wrench are fully sterilizable together. However, details about setting Sterilization depend on information provided by the Sterilizer manufacturer.



- ③ Wipe by soft cloth soaked with alcohol.



- ④ Dry the handpiece connector dry before connecting

- ⑤ Please do this process after every single use.

* Note: If you drop the hand piece, it can be damaged.

Do not wash in ultrasonic cleaner.

2) Tip (Tip)

- ① Immerse tips in distilled water for 10 minutes after every use.



② Put in ultrasonic cleaner or clean by alcohol..

③ Dry it completely.

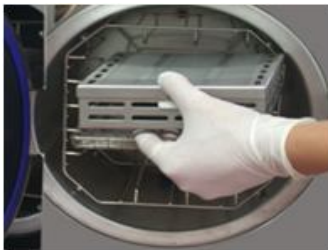


<Remove remain water by air>



<Dry>

④ Sterilization: Before every use, tips must be sterilized in autoclave at 135°C for 3 minutes, drying time 0~1minutes. Surgery Tip, Handpiece tubing, peristaltic pump tubing, torque wrench are fully sterilizable together. However, details about setting Sterilization depend on information provided by the Sterilizer manufacturer.



3) Body (Main Unit)

① After removing the dust (if you use detergents, do not use physics, chemical changes in the surface) then storage.

4) Touch Screen

① Wipe surface by using dried towel with a soft cloth.



5) Foot switch, adapter

Clean by using soft cloth soaked with alcohol gives ①

*Caution : Water not to go into Foot switch, adapter

*** Caution**

- In case of operating without water flow, handpiece and tip would be overheated.
- The handpiece does not have a heating effect. Water spray is sufficient to cool the point of friction between the tip and the tooth.

5. Technical specifications

IEC 60601-1

| | |
|--|--|
| Type of protection against electric shock: | Class 1, with AC/DC Adaptor |
| Degree of protection against electric shock: | Applied part type BF |
| Degree of protection against harmful ingress of water: | Unit IP40 Foot switch IPX8 |
| Method of sterilization or disinfection: | See chapter 4. Cleaning & maintenance <ul style="list-style-type: none">- Steam sterilizer in accordance with EN 13060 or EN285 validated in accordance with ISO17665- Maximum sterilization temperature 135°C.- Sterilization time at least 3min, drying time 0~1min.- The manufacturer assumes no responsibility for the use of other sterilization procedures.- Verification of the fundamental suitability of the products for effective steam sterilization was provided by an independent, accredited testing laboratory.(Validated according to ISO11737-1, ISO11737-2 :Test report AT12-00305,306,307,308)- The hot-air sterilization and radio-sterilization procedure may not be used. (destruction of products.) |
| Specification of sterilization | |
| Degree of safety of application in presence of a flammable anesthetic mixture: | Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. |
| Mode of operation: | Continuous operation |

CSA S. No.125

Risk class 2

93/42/EEC

IIb

Conditions for use

+10°C to +40°C

0% to 75% relative humidity

700hPa to 1060hPa

-10°C to +40°C

Storage and transport conditions

0% to 95% relative humidity

500hPa to 1060hPa

Specifications of unit

Model:

Surgy Star, AIC SURGERY

Supply voltage:

DC +24V, 2.7 A

Ultrasonic output characteristics:

Frequency: 24-32kHz

AC/DC Adaptor

Input: 100-240V~, 50-60Hz, 1.5 A

Output: DC +24V, 2.7 A

Dimensions / Weight

Unit Dimensions:

315mm(W) x 235mm(D) x

115mm(H)

Unit Weight:

2.14Kg

6. Guidance and manufacturer's declaration

6.1 Electromagnetic emissions

| The Model Surgy Star is intended for use in the electromagnetic environment specified below. The customer or the user of the Model Surgy Star should assure that it is used in such an environment. | | |
|---|------------|---|
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The model Surgy Star uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The model Surgy Star is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |


6.2 Electromagnetic immunity

| The model Surgy Star is intended for use in the electromagnetic environment specified below. The customer or the user of the model Surgy Star should assure that it is used in such an environment. | | | |
|---|--|--|---|
| Immunity test | IEC 60601 testlevel | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge(ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |

| | | | |
|--|---|---|--|
| Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11 | <p>< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle</p> <p>40 % U_T (60% dip in U_T) for 6 cycles</p> <p>70 % U_T (30% dip in U_T) for 30 cycles</p> <p>< 5 % U_T (>95% dip in U_T) for 5s</p> | <p>< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle</p> <p>40 % U_T (60% dip in U_T) for 6 cycles</p> <p>70 % U_T (30% dip in U_T) for 30 cycles</p> <p>< 5 % U_T (>95% dip in U_T) for 5s</p> | Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Surgy Star requires continued operation during power mains interruptions, it is recommended that the model Surgy Star be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60Hz) IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| Note : U is the A.C. mains voltage prior to application of the test level. | | | |

6.3 Electromagnetic immunity

| | | | |
|---|-------------------------------|-------------------------------|---|
| The model Surgy Star is intended for use in the electromagnetic environment specified below. The customer or the user of model Surgy Star should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80MHz | 3 Vrms 150 kHz to 80MHz | Portable and mobile RF communications equipment should be used no closer to any part of the model Surgy Star, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |

| | | | |
|-----------------------------|------------------------------|------------------------------|---|
| Radiated RF IEC61000-4-3 | 3 V/m 80 MHz to 2.5GHz | 3 V/m 80 MHz to 2.5GHz | <p>Recommended separation distance</p> $d=[3.5/V1]\sqrt{P}$ $d=[3.5/E1]\sqrt{P} \text{ 80MHz to 800MHz}$ $d=[7/E1]\sqrt{P} \text{ 800MHz to 2.5GHz}$ <p>where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metre(m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
|-----------------------------|------------------------------|------------------------------|---|

Note 1 At 80MHz and 800MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1]V/m.

7. Trouble-shooting

7.1 The unit is not switched on, when press the power ON/OFF switch

- 1) The power cord is not completely connected to power source wall socket, or else to the socket at the back of the unit.
⇒ Connect the power cord securely.
- 2) Apparatus is supplied with a different voltage power to the one prescribed.
⇒ Check that the value of the applied voltage power supply corresponds to that indicated on the identification plate at the bottom of unit.

7.2 The unit is switched on, but does not work

- 1) The plug of foot switch cord is not connected or not completely connected to its socket at the back of the unit.
⇒ Connect the footswitch cord securely.
- 2) Tip is not properly tightened onto handpiece.
⇒ Unscrew the tip and screw again completely.
- 3) The structure of the tip is distorted.
⇒ Replace with a new one
- 4) Tip is worn out.
⇒ Replace with a new one.
- 5) Handpiece is not connected to its cord.
⇒ Connect the handpiece to the cord.
- 6) Break in handpiece wire and current leakage through patient.
⇒ Turn off the unit at the Power switch and disconnect transformer from the AC power source wall outlet. Contact dealer or our company.
- 7) Breakage of handpiece.
⇒ Replace with a new one.

7.3 Insufficient power / vibration

- 1) Tip is not properly fastened onto handpiece.
⇒ Unscrew the tip and screw again completely.
- 2) Tip is distorted.
⇒ Replace new one.
- 3) Tip is worn out.
⇒ Replace new one.

7.4 No water comes out from tip

- 1) Water control setting is not enough.
⇒ Touch the water control button ▲ on LCD screen to regulate water flow.
- 2) The water tube is not connected or not completely connected to the coupling at the water bottle and handpiece.
⇒ Connect the water tube securely.
- 3) Tip has not been fastened correctly onto handpiece.
⇒ Unscrew the tip and screw again completely with torque-wrench.
- 4) Tip is distorted.
⇒ Replace with a new one.
- 5) Tip is worn out.
⇒ Replace with a new one
- 6) Handpiece is not connected to Main Unit.
⇒ Connect the handpiece to the Main Unit.
- 7) Break in handpiece wire and current leakage through patient.
⇒ Turn OFF the Unit Power switch and disconnect transformer from the power source of wall outlet. Contact dealer or our manufacturer.
- 8) Breakage of handpiece.
⇒ Replace with a new handpiece..

7.5 The handpiece play a whistle

- 1) Tip is not properly tightened onto handpiece..
⇒ Unscrew the tip and screw again properly with torque-wrench.

7.6 The connection problem in handpiece with cable to main unit (body)

- 1) Correctly connect ↑ point of handpiece with cable into white ▽ point of main unit.
(just push handpiece into main unit until click sound)
- 2) When pull out, do not twist or turn off the handpiece, just pull out handpiece as opposite direction as connection.
- 3) if the connector of handpiece and the connector of main unit is not fit, kindly adjust handpiece connector by disassembling handpiece connector. (.1.release handpiece connection part - back in handpiece, 2.fit the inside black with handpiece ,3.insert the two holes with same direction main unit,4.tighten the connection part.)

*** Electromagnetic interference.**

This product needs special precautions

- Certain types of mobile telecommunication equipment could potentially interfere with this product.

- The separation distances recommended in the note "Electromagnetic compatibility" must be taken into account.
- This product should not be used adjacent to or stacked with another unit.

*** PRODUCT DISPOSAL**

- The product, its accessories and its packaging do not contain any substances that are dangerous for the environment.
- Disposal of this product must be handled according to local laws and regulations.

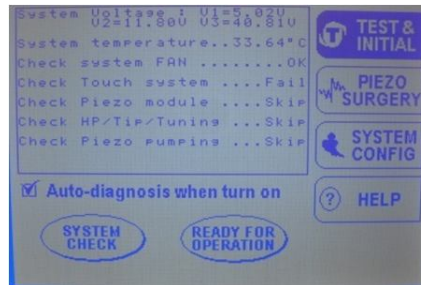
7.7 Error Messages

*** Touch panel error**



- Screen is suppressed by something.
- LCD guide silicon gets out of line

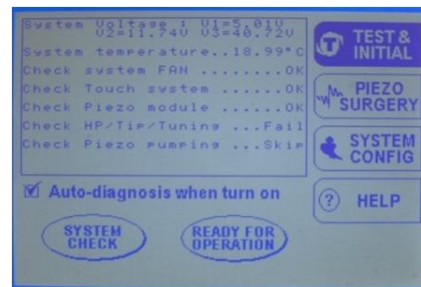
*** Check touch system ... f a i l**



*** Check HP / Tip /Tuning ... f a i l * Piezo Tuning failure ... f a i l**



- Re- tighten tip with torque wrench
- Check the connection of Handpiece code.
- Handpiece wire could be broken.
- Screw of tip could be worn out.
- Foreign substances on the screw.





DMETEC CO., LTD since 1983

DENTAL APPLIANCE MANUFACTURER & SUPPLIER

Guarantee Card

◆ Dmetec guarantees its service as below ◆

1. This product, SurgyStar, is passed strict Quality Management, and Test Process by Dmetec QA Department.
2. In case of trouble under the correct using by customer, Dmetec repairs device for free of charge during warranty term at Dmetec's Maintenance center.
3. In case of trouble under the incorrect using by customer, it will come under the case of Charge Service. Customer will charge for repair.
4. Pls. submit the Guarantee card when you need to repair.

| | | | |
|--------------------|-------------------|---------------|------------|
| Product Name | | Model Name | Surgy Star |
| Date of Purchasing | | Serial Number | |
| Warranty | 2years -Main Body | | |

This Guarantee Card will not be re-issued. Please keep it tightly