

USER MANUAL KULLANMA KLAVUZU

ELECTROSURGICAL UNIT



MODEL : NS04.00



MODEL : NS02.50

TABLE OF CONTENTS

1.	GENERAL INFORMATION	4
2.	INTRODUCTION	5
3.	FOR YOUR SAFETY	6-12
3.1.	General Information	6
3.1.1.	Monopolar Cut	6-7
3.2.1.	Monopolar Coagulation	7-9
3.1.3.	Bipolar Cut and Coagulation	9
3.2.	Symbols and Explanation	10
3.2.1.	Identification Label	10
3.2.1.1.	Labeling on the Rear Panel	10
3.2.1.1.1.	Meaning of the Graphical Symbols	10-11
3.2.1.2.	Front Panel	12
4.	PACKAGING AND STORAGE	13
4.1	AUDIBLE AND VISUAL INDICATORS	14
5.	PRESENTATION	15-16
5.1.	Intended Use and Areas of Use	15
5.2.	Technical Specifications	16
6.	INSTALLATION AND USE OF THE DEVICE	17-40
6.1.	Installation	17
6.2.	Use	18
6.3.	Operation Mode	19
6.3.1.	Operation	19
6.3.2.	Patient Plate Circuit (Patient Plate Electronic Control)	19
6.3.3.3	Program	20
6.4.	Monopolar	21-22
6.4.1.	Cut and Coagulated Cut	22
6.4.2.	Enhanced Cut Current	23
6.4.3.	Blend Current	23
6.4.4.	Superficial Coagulation Current (Speedy Coag)	23
6.4.5.	Deep Coagulation Current (Deep Coag)	23
6.4.6.	Spray Coagulation Current	23
6.4.7.	Spray Argon Coagulation Current	23-24
6.4.8.	Cautery Pen and Foot Pedal (Monopolar 1, Monopolar2)	24
6.5.	Bipolar	25
6.5.1.	Bipolar Cut Current	26
6.5.2.	Blend Current (Bipolar Cut)	26
6.5.3.	Bipolar Coagulation Current (Bipolar Coag)	26
6.5.4.	Vessel Sealing	26

6.5.5.	Autostart / Autostop	27
6.6.	Forceps and Foot Pedal (Bipolar)	28
6.7.	Patient Plate Circuit Excessive Impedance Signal (OC)	28
6.8.	Pre-Setting by the User.....	28
6.9.	Internal Parameters Automatic Control	28
6.10.	Connections	29-30
6.11.	Rear Panel	30
6.12.	Connections	31
6.13.	Mechanical ON/OFF Button	31
6.14.	Standard and Optional Accessories Options	32-33
6.15.	Technical Specifications.....	33-36
6.16.	Safety	36
6.16.1.	General	37-40
7.	PATIENT PLATE.....	41
7.1	Patient Safety	41
7.2	Correctly Positioning the Patient	41
7.3	Correctly Positioning the Patient Plate	41-42
7.4.	Use of the HF Electrosurgical Unit in Laparoscopy	44
8.	CLEANING AND MAINTENANCE& REPAIR.....	44-46
8.1.	General	44
8.1.1.	Device Cleaning	44
8.1.2.	Accessory Parts Cleaning and Sterilization.....	44
8.2.	Maintenance& Repair.....	44
8.2.1.	Fuse Replacement	44
8.2.2.	Checking the unit at every use.....	45
8.2.3.	Function, Safety Check and Test	45
8.2.4.	Information about Device Disposal	45
8.2.5	Probable Failures and Troubleshooting	46
9.	Electromagnetic comp. EMC declaration.....	47-52
9.1.	EMC Test and Graphics.....	51
9.1.1.	EMC Emission Test Result.....	52
10.	RECYCLING.....	53
11.	AUTHORIZED SERVICES	53

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CE Declaration of Conformity

This electrosurgical unit conforms to the requirements specified in "General Requirements for Medical Electrical Equipment" EN 60601-1, EN 60601-1-2, EN 60601-2-2 and MDD/93/42/EEC Medical Devices Directive.

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Patent

Trade name and brand qualification are held by İNSPİTAL A.Ş.

Guarantee Period

İnsipital brand electrosurgical devices, including all parts, are under warranty for 2 (two) years against material defects, faulty workmanship and manufacturing defects provided that they are used as shown in user manuals. However, the following are not under warranty:

1. Damages and failures that result from misuse,
2. Damages and failures that occur during loading & unloading and transportation after the delivery of the product to the customer,
3. Damages and failures that result from under- or over-voltage, faulty electrical installation or using at a voltage different from the one specified in the product label,
4. Failures that result from using the product in contravention of the matters contained in user manuals.

Thank you for purchasing İNSPİTAL brand electrosurgical unit. Our product has been meticulously designed and produced for offering quality and performance to you in the best possible way. Please carefully read all information about the operation and safety of this unit.

This manual explains the steps of Installation, Use, Cleaning and Maintenance & Repair for İNSPİTAL brand electrosurgical units.

Points to Consider During Handling and Transportation

Please follow the instructions on equipment boxes during handling and transportation.

Matters Related to Maintenance and Repair

Please call the authorized service of the equipment in case of situations that require Maintenance and Repair.

Information about Connection and Assembly

Please refer to the following parts for connection and assembly information.

Life of Device:

The life of the product is expected to be 10 years.

3.1. GENERAL INFORMATION

NS04.00 high-frequency electrosurgical unit is designed to give monopolar cut and coagulated cut current in monopolar mode and cut and coagulation current in bipolar mode. The unit features automatic activation in bipolar coagulation mode.

10 modes in total and power level can be stored and these modes can be easily called afterwards for re-use. It is possible to use single-surface patient plate or conductive region double-surface patient plate during surgical intervention.

The unit is controlled by means of the buttons and indicators on the front panel; the main inlet of the unit is located on the rear panel.

The unit is equipped with an automatic control system that monitors internal parameters and signals the errors and failures it detects.

Operating parameters are continuously stored. So, if the unit is turned off or used in another mode, the parameter which has been stored can be easily called back.

Each user can set current sound level as he/she desires depending on his/her working conditions. The unit can be used with a cautery pen or with a bipolar forceps and a double foot pedal.

3.1.1. MONOPOLAR CUT

Monopolar cut sections biological tissues as high-frequency current condensed with active electrode tips passes highly strongly.

The heat that occurs at the point of arc is high and can be calibrated. Thus, it exceeds the melting point of water in the cell.

Just as high-frequency current is applied to the tissue from the tip of the active electrode, it causes an intensive molecular heating and explosion in cells.

Cutting operation is performed by moving the electrode on the tissue and destroying cells one by one. Electrodes' movement prevents the spread of horizontal heating inside the tissue and consequently the destruction of cells in a single line.

The best high-frequency current for cutting is pure sinus wave that cuts evenly without any setting and does not create high-temperature effect during cutting. Due to the fact that cutting current is fully controlled, it can be used without harming the bone. However, for a good coagulation, it is necessary to make some settings during cutting.

NS04.00 and NS02.50, cut in the form of pure sinus waves is capable of ensuring a cut as much as the blend comprising two-level different factors. Thus, more haemostatic effects are obtained from the cut in the form of pure sinus waves.

The following recommendations help the operator for a good cutting operation.

- Keep the tissue not wet but humid,
- Hold the electrode perpendicular to the tissue,
- Start the electrode output before it contacts with the tissue,
- Keep the electrode tip clean (It is recommended to use electrode cleaning sponge),
- Cool the tissue before a new cutting operation,

If a correct current level is received, the following effects are obtained:

- The electrode easily detaches from the tissue.
- No change in the color of the cut tissue.
- No tissue sticks to the electrode.
- Transuteral Resection (TUR)

For cutting tissue from bladder or prostate, special electrodes are available for use in liquid environments. In that case, high energy disperses towards the liquid and it is of high importance to use cut current for such energy dispersion.

Using coagulation and/or blend cut reduces blood loss.

3.1.2. MONOPOLAR COAGULATION

In case of an increase in the temperature for creating joule (thermal) effect in the tissue, thermal coagulation occurs and the liquid regionally solidifies. Fibrin takes place in the blood and solidifies itself and blood vessels are obstructed.

If the aim is to obtain coagulation with electrocautery needle, it is necessary to ensure intermittent current in the active electrode. By this way, the liquid disappears without harming the cell. Even though current is given intermittently, if the strength of current is high, it creates a cut effect.

Spherical, straight or spear active electrodes are adapted especially for coagulation.

Coagulation is applied in two different methods; namely, desiccation and fulguration.

Coagulation with Desiccation

It is the coagulation effect created by giving low voltage to the electrode without creating any spark. The electrode is placed so as to have a direct contact with the tissue and the amount of advanced heat creates a desiccation effect on the tissue.

In general, the coagulated cellular surface acts as an insulating layer and thus coagulates the tissue before current goes deeper.

For coagulation, modulated type current is used. Modulation's percentage function shows the accuracy of cutting, the goodness of homeostasis and the level of destroyed cells. A greater modulation of current generates a more irregular cut, a deeper tissue loss but a better coagulation.

The following points help the operator for a good cutting operation.

- Select a spherical electrode or a larger cable,
- After removing the effluent blood in the region, localize the bleeding vein,
- Before activating the electrode, touch the bleeding vein gently,
- For preventing the tissue from harm, stop the electrode when the tissue gets white.
- Service and clean the electrode (It is recommended to use electrode cleaning sponge).

Coagulation in Fulguration or Spray Mode

High voltage is given to the electrode. Thus, as the electrode leaves the tissue, one or more electric arcs turn off in different areas. This method is employed for the purpose of preventing blood loss in large areas and/or giving coagulation current in open surgeries such as heart surgery.

Coagulation with Anatomic Forceps

It consists of clamping the pressure between multiple-use coagulation forceps tips and stopping hematic flow.

Upon clamping the tissue or the vein, coagulation is performed and it is contacted with active electrode forceps' triple proximal metal parts. For preventing faradic effects, high frequency activation should be carried out following such contact.

3.1.3. BIPOLAR CUT AND COAGULATION

As the relevant tissue is clamped between two forceps, high frequency current passes from one tip to another tip of the forceps. Tissue part explosion acts as an electric bridge.

- Bipolar cut sections biological tissues as high-frequency high-density current passes through the tips of the forceps. This method has attracted a great deal of attention in recent times and offers a more reliable operation in the spread of endoscopic and miniminvasive surgical techniques.
- Bipolar coagulation is the hemostasis of small blood vessels in the body tissue between two forceps tips. If current strength is reduced, desiccation effect takes place on cellular surface.

Bipolar technique is safer because the direction of high-frequency current is definite at all times. No unknown factors and probable errors exist in this technique. Furthermore, the current used is lower than the current used in monopolar techniques. For these reasons, this technique is used in all clinical surgical operations. So, cleaning and maintenance of forceps tips are essential since the particles left by coagulated tissues accumulate on these tips and limit the passage of current.

Neutral electrode application is not necessary in bipolar mode.

3.2. SYMBOLS AND EXPLANATION




















3.2.1. IDENTIFICATION LABEL

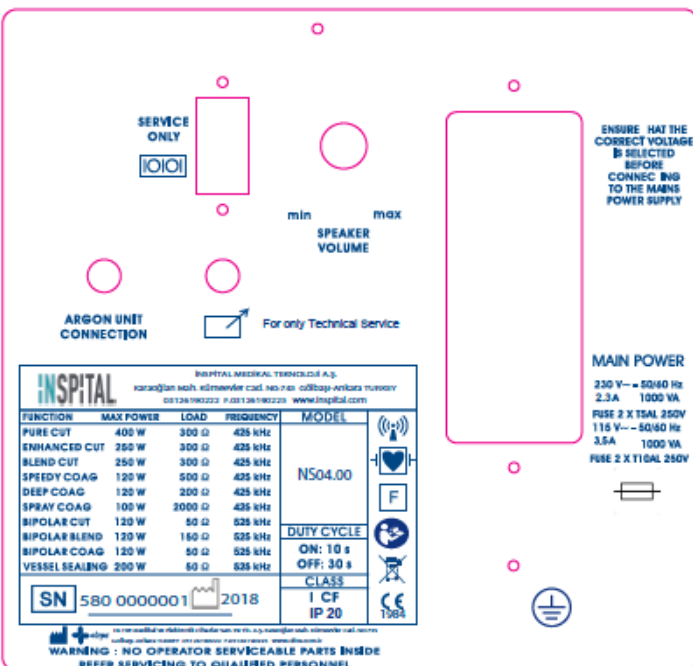
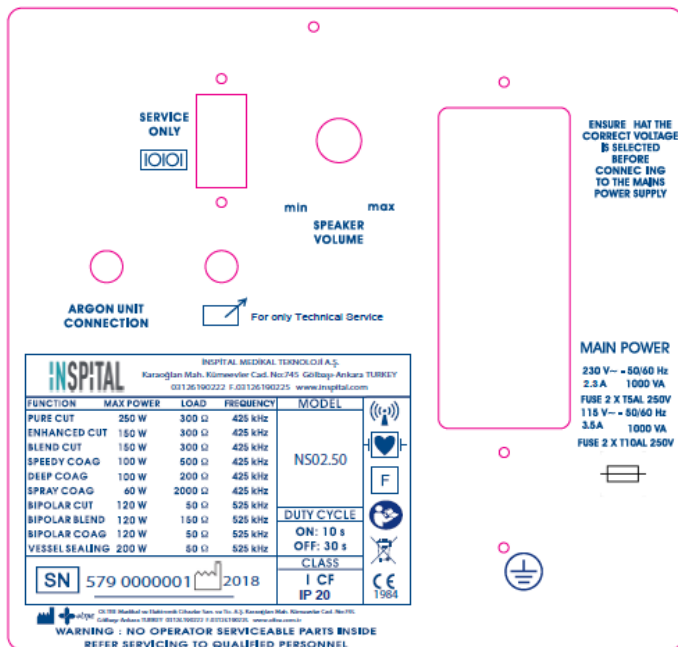
3.2.1.1. LABELLING ON THE REAR PANEL

For the safety of high-frequency electrosurgical device, the unit cabinet or the generator panel has labels and symbols that indicate the operating conditions required for correct operation on it.

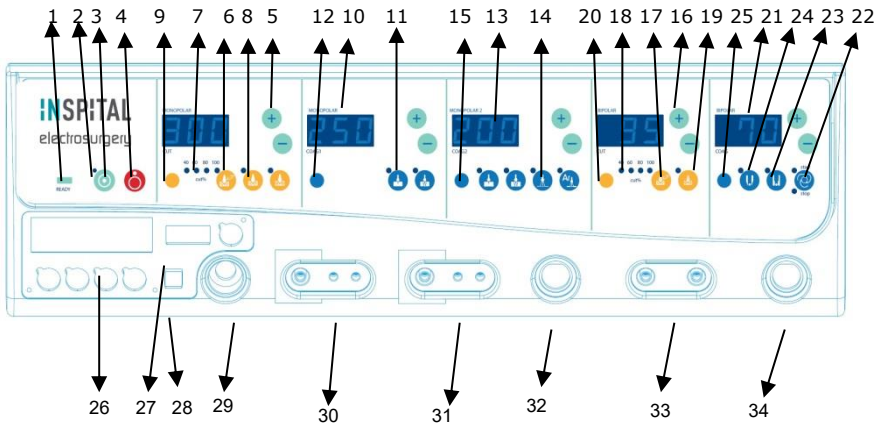
3.2.1.1.1 Meaning of the Graphical Symbols

The graphical symbols on NS04.00 and NS02.50 have the following meanings;

Symbols	Explanation	Symbols	Explanation
	Caution!		In conformity with Medical Device Directive MDD 93/42/EEC
	Keep dry		This way up
	Date of Manufacture		Attention! Fragile, handle with care
	Floating Patient's plate		Protected against Cardiac Defibrillator discharge
	Not Ionizing Radiation emitted.		Notified Body Number
	The product mustn't be thrown in the containers.		Manufacturer Data
	Serial Number		Consult instructions for use
	immovable with hook		Fuse Holder
	remote control for technical service		Earth Ground
	technical service connection port.		



3.2.1.2. FRONT PANEL



PART NO	PART NAME	PART NO	PART NAME
1	LED indicator showing there is power on the unit	19	Bipolar cut selection button
2	LED indicator showing the unit is turned on	20	Bipolar cut output warning light
3	On button	21	Coagulation level control and indicator section
4	Off button	22	Bipolar automatic coagulation selection button
5	Monopolar 1 cut level control and indicator section	23	STOP warning light
6	Monopolar cut1 selection button 40%, 60%, 80%, 100%	24	Selection for VESSEL SEALING
7	40%, 60%, 80%, 100% cut warning lights	25	Bipolar coagulation warning light
8	Selection button and monopolar 1 cut functions	26	Indicator and information buttons
9	Warning light for Monopolar 1 cut output	27	Impedance reading and approval section
10	Monopolar 1 coagulation level control and indicator section	28	Alarm indicator for exceeding neutral electrode circuit impedance
11	Selection button and monopolar 1 coagulation functions	29	Neutral electrode connection connector
12	Warning light for Monopolar 1 coagulation output	30	Active electrode holder connection for monopolar cut and coagulation
13	Monopolar 2 control section	31	Active electrode holder connection for monopolar cut and coagulation.
14	Monopolar 2 selection button and coagulation functions	32	Foot pedal connection for Monopolar2 current distribution
15	Monopolar 2 coagulation output warning light	33	Bipolar output connector
16	Bipolar cut level output and indicator section	34	Foot pedal connection for bipolar current distribution
17	Bipolar cut selection button 40%, 60%, 80%, 100%		
18	Bipolar cut 40%, 60%, 80%, 100% warning lights		

4. PACKAGING AND STORAGE

Ambient Temperature	: +10oC ~ +40oC (Operation) - -10oC ~ +50oC
(Storage) Humidity	: 30% ~ 75% (Operation) - 10% ~ 100% (Storage)
Atmospheric Pressure	: 0.69atm ~ 1,04atm

The electrosurgical unit is dispatched with accessories as packaged in its special box. Upon receiving the electrosurgical unit;

- Carefully open the closed box from its appropriate sections,
- Carefully examine the electrosurgical unit and its accessories for the purpose of determining whether or not they were damaged during transportation. For the electrosurgical unit and its accessories that were damaged during transportation, consult the relevant point of sale.
- You can store the electrosurgical unit in its box by stowing.

CAUTION

Never use sharp objects such as knife while opening the nylon package of the electrosurgical unit. Or else, you may damage the unit and/or its accessories.

4.1. AUDIBLE AND VISUAL INDICATORS:

Blue color and blue light represent coagulation.

Yellow color and yellow light represent cutting.

The warnings provided with the device are as follows;

- When the device is switched on from the first stage, the ready lamp lights up, the on button must be pressed.
- When the on button is pressed, the system pulls itself and gives an audible warning during this time. This warning lasts 6 seconds. When it is ready, the green led on the on button lights up and the device is ready on the LCD Screen.

When the patient plate is not attached, the red warning lamp lights up.

When the yellow button is pressed on the handpiece and the yellow pedal is pressed on the handpiece, whichever unit is active (monopolar 1, monopolar 2 or bipolar), the yellow light lights up on that unit, it gives an audible warning while the handpiece is active, the audible warnings of the cut and coagulation modes are different. . Cut thin Coag gives a thick audible warning.

- When the blue button is pressed on the handpiece and the yellow pedal is pressed on the handpiece, the blue light on that unit is active, gives an audible warning while the handpiece is active, and the audible warnings of the cut and coagulation modes are different. Cut thin Coag gives a thick audible warning.
- Vessel Sealing mode is activated in the bipolar unit, it gives a bright blue warning in the bipolar unit during vessel closure, and the audible warning is intermittent.
- Working power level is shown as led under the mode used. The color of the leds is green.

The visually worked power level is displayed on the screen.

5.1. INTENDED USE AND AREAS OF USE

İNSPİTAL brand electrosurgical unit is designed for short-term uses in surgical operations at emergency departments. It has monopolar cut, coagulated cut or coagulation or bipolar coagulation functions.

INDICATIONS

Electrosurgical Units have been used for a long time to stop bleeding during surgery, cut and remove unwanted tissues quickly, safely and effectively. Electrosurgical Units are operated with coagulation (coagulation), K.B.B, gynecology, general surgery, neurosurgery branches, used to burn and cut and remove tissue by burning.

PATIENT POPULATIONS (adults / children / infants, other aspects)

The patient population of the device is adults and children. Its use in infants depends on the approval of the attending physician.

CONTRAINDICATIONS

- High postoperative pain Oral pain and dehydration, especially in children, as a result of pain caused by thermal damage in the surrounding tissues.
- Postoperative prolonged analgesic use and higher postoperative hemorrhage compared to cold dissection.

The unit is designed for use in the following areas.

Explanation	NS04.00	NS02.50
Dermatology	○	○
Endoscopy	○	○
Gastroenterology	●	●
General Surgery	●	●
Gynecology	○	○
Neurosurgery	●	●
Orthopedic	●	●
Otorhinolaryngology	○	○
Pediatric surgery	●	●
Plastic surgery	●	●
Pinemology	○	○
Thoracic Surgery	●	●
TUR Operations (Trans Uteral) Resection)	●	●
Urology	●	●
Vascular Surgery	○	○
Veterinary medicine	○	○

● = Recommended
○ = Usable

5.2.1. TECHNICAL SPECIFICATIONS

MONOPOLAR APPLICATIONS	NS04.00	NS02.50
FREQUENCY	425 kHz	425 kHz
OUTPUT POWER CUT	400W – 300 Ω	250W – 300 Ω
OUTPUT POWER ENHANCE CUT	250W-300Ω	150W-300Ω
OUTPUT POWER BLEND CUT/ COAG	250W-300Ω	150W-300Ω
OUTPUT POWER SPEEDY COAGU- LATION	120W-500Ω	100W-500Ω
OUTPUT POWER DEEP COAG	120W-200Ω	100W-200Ω
OUTPUT POWER SPRAY COAG	100W-2000Ω	60W-2000Ω
BIPOLAR APPLICATIONS		
FREQUENCY	525 kHz	525 kHz
OUTPUT POWER CUT	120W - 50 Ω	120W - 50Ω
OUTPUT POWER BIPOLAR BLEND	120W - 150Ω	120W - 150Ω
OUTPUT POWER BIPOLAR COAG	120W - 50Ω	120W - 50Ω
VESSEL SEALING	200W - 50Ω	200W - 50Ω
FOR APPLICATIONS		
MAIN POWER	115-230V-50/60Hz	115-230V-50/60Hz
INPUT POWER	1000VA	1000VA
FUSE	(115 V~) 2xT10AL, 250V; (230 V~) 2xT5AL, 250V	(115 V~) 2xT10AL, 250V; (230 V~) 2xT5AL, 250V
DUTY CYCLE	10 sec. intermittent current /30	10 sec. intermittent current /30

6.1. INSTALLATION

- For installing the electrosurgical unit, perform the following operations respectively.
- The electrosurgical unit is safe provided that electrical installation and grounding are correctly performed in accordance with applicable safety rules. Basic safety measures have to be taken and, in case of any failure, it should be controlled by the technical staff. The manufacturer is not responsible for any loss arising from ground connections.
- Before installing the equipment, check if the necessary main supply voltage is compatible.
- In case of incompatibility between the feeder cable and the wall socket, they can be replaced with legally approved connectors and accessories. It is not recommended to use adapter, multiple connection and extension cable. Simple or multiple adapters that conform to applicable safety rules should be used.
- Do not expose the apparatus to atmospheric solutions. The unit is required to be protected against liquid leakages.
- Do not block ventilation or heat ventilation holes.
- Do not leave the unit as plugged in if it is not in use.
- It is not appropriate to use the unit in rooms having the risk of explosion.
- The intended use of NS04.00 electrosurgical unit is explained. It is not only inappropriate but also dangerous to use the unit for other purposes. The manufacturer is not responsible for any loss arising from misuse.
- It is dangerous to make or attempt to make changes in unit specifications.
- Disconnect all apparatus while cleaning and servicing the unit.
- If there is a problem in the operation of the unit, turn the unit off. Apply to authorized service centers for original spare parts and failures. Failure to pay attention to the safety warnings may pose a risk of danger for the user and the patient.
- Do not turn down the volume of generator's warning beeps, which protect the patient or the user against harms in case of a failure.
- Do not check the operation of the active electrode by short-circuiting it with metal parts.



CAUTION

Open the box of the unit and carefully read accompanying documents. The main voltage mentioned in INTRODUCTION should be compatible with the regional voltage. The unit is affected if used at 230 V main voltage 115/230 Vac. In case of 115 V, the fuse should be replaced according to the value specified on the label.

6.2. USE

Insert the main cable into a main outlet with good grounding. It is prohibited to operate the unit with an ungrounded connection.

- Install the unit on a flat surface. A space of minimum 25 cm is required around the unit.
- Insert the main cable of the unit into the socket on the rear panel.
- Insert the double cable into the connector on the front panel (MONOPOLAR 1 for monopolar cut and coagulation, BIPOLAR for bipolar cut and coagulation)
- Connect the forceps to the correct connector. In case a buttonless electrocautery pen is used, connect it to the active outlet (buckle).
- If a bipolar forceps is to be used, a special adapter should be used (Image 4.4.6) (Ref 00498.04)
- Operate the unit only in dry environments. Before starting the unit, make sure that all existing liquids have evaporated. Do not exceed ambient temperature and permissible humidity.
- If the unit is turned on by means of ON/OFF button on the front panel, it checks internal parameters and then operates with the recent parameters (During initial operation, power level is 00).
- Before using the unit, connect the patient plate cable. While using single- or double-surface patient plate, approve by pressing OK button. Thus, if the impedance value is accepted, OC indicator alarm and signal stop.
- Mount Monopolar 1 CUT and COAG 1 holder to the relevant outlet of CUT/COAG 1.
- For Monopolar CUT and COAG (CUT/COAG2), with Monopolar 2 currents, mount the holder to CUT/ COAG 2 connector and to the relevant outlet of the foot pedal.
- For bipolar cut and coagulation, mount the bipolar holder and the double foot pedal to their respective outlets in BIPOLAR.
- The unit may be connected to the external ARGON device by means of the connector on the black panel.

6.3. OPERATION MODE

6.3.1. OPERATION

When the electrosurgical unit is started, the program mode that is used is displayed on the LCD screen and it is automatically tested whether or not the unit and its accessories operate accurately.



In case of any abnormality, error definition and one of the error codes indicated in the maintenance section of the manual are displayed on the LCD screen. This test lasts approximately 10 seconds. At the end of the check, the unit ensures the recent usage conditions and activates OC alarm.

6.3.2. PATIENT PLATE CIRCUIT (PATIENT PLATE ELECTRONIC CONTROL)

The neutral electrode circuit is continuously monitored by a special circuit that prevents burns and dangers in the event the contact between the patient skin and the patient plate is lost (patient plate electronic control).

The impedance value in the neutral electrode circuit sends a signal so as to inform the user whether or not it is available for the operation he/she shall perform. The user approves the value by pressing OK button. If the impedance value is too high, it is not accepted by unit's micro control (UP is displayed on the screen). For this reason, OC signal does not turn off and power distribution is not allowed.

If the impedance value is accepted, the impedance indicator is recalled and displayed and OC indicator turns off.

If the impedance displayed is accepted, impedance increases to the accepted value. The unit does not conduct distribution and, without giving any audible signal, displays OC conditions and a new impedance value. The operator knows the impedance value on the patient by pressing OK button. The value that is controlled on the patient is displayed for 2 seconds on the indicator and then turns off.

6.3.3. PROGRAM

During current distribution, the user is informed about the parameters used on the LCD screen.

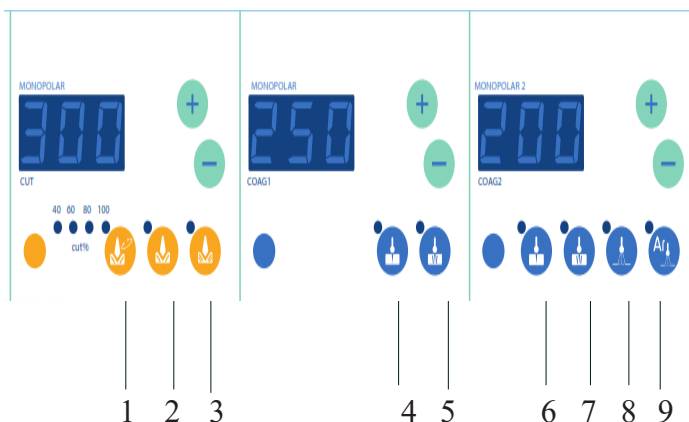
At distribution state, the operator can enter MENU functions. PROGRAM section's LCD indicator is displayed. By pressing the approval button (enter) and selecting '←I', the following installations are reviewed by means of '↑' and '↓' buttons.



1. Store: Use '←I' button for entering the program section that comprises maximum 11 letters. Select letters by using up and down buttons and then store. Each time, approve with '←I' button. Upon completing storage, press ←I button for the last time and then you can exit. If you want to exit the program before entering a name, select '←' button.
2. Program: For entering, select '←I' button and read different memory programs by pressing up '↑' and down '↓' buttons. In order to select a desired program, press '←I' button. You can exit this section without making any selection by pressing '←' button.
3. Errors: For entering, select '←I' button and read the list of errors by pressing up '↑' and down '↓' buttons (more than 100 stored errors can be read). In order to exit this section, press '←' button.
4. Postponing clamp: For entering and making installation, press ←I button. With the help of up and down buttons, current distribution to the bipolar holder tissue contact is postponed. Select ←I button for postponing installation. This function can be configured if you have selected automatic bipolar coagulation.

6.4. MONOPOLAR

The monopolar cut current that is obtained can be changed by means of the buttons in coagulated cut and coagulation MONOPOLAR and MONOPOLAR 2 sections. For each function, it is possible to change power level with + and – buttons of CUT, COAG1 and COAG2. Installation power level is stored.



CUT

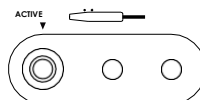
1. Cut and coagulated cut
2. Enhanced Cut
3. Blend

MONOPOLAR 1 COAGULATION

4. Speedy coagulation
5. Deep Coagulation

HANDLE CONNECTOR

CUT/COAG1



CUT

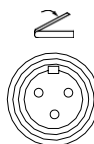
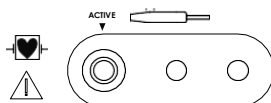
1. Cut and coagulated cut
2. Enhanced Cut
3. Blend

MONOPOLAR 1

COAGULATION

6. Speedy coagulation
7. Deep Coagulation
8. Spray Coagulation
9. Spray Coagulation with Argon

HANDLE AND FOOT PEDAL CONNECTOR CUT/COAG2

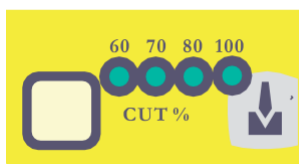


For using the functions of cut and coagulation2, the holder or the foot pedal is required to be connected to the relevant outlet of CUT/COAG2 in monopolar 2 section.

6.4.1. CUT AND COAGULATED CUT

The best current for cut is non-modulated sinusoidal weak current. It is performed with 100% duty cycle. Being suitable for non-coagulated cut, this current can be modulated for conducting cut at different levels in the coagulation mode.

The level of modulation varies between the values of 100%, 80%, 60% and 40%. Duty cycle is selected with +/- buttons. The warning light under the value selected turns on. If the duty cycle decreases, the level of coagulation naturally increases.



- %40 Blend1
- %60 Blend2
- %80 Blend3
- %100 Pure Cut

6.4.2. ENHANCED CUT CURRENT

Enhanced cut current is the sinusoidal current that is modulated with a wide modulation and suitable for cutting the tissue.

6.4.3. BLEND CURRENT (BLEND-DEEP)

Blend current is suitable for coagulated cut if cutting is to be performed with deep coagulation. This current is obtained by combining weak cut current and low-voltage coagulation (deep coagulation).

6.4.4. SUPERFICIAL COAGULATION CURRENT (SPEEDY COAG)

In case of superficial coagulation current, a superficial carbonization effect occurs in the tissue as current is given. The advantage of this coagulation type is that the effect occurs speedily.

6.4.5. DEEP COAGULATION CURRENT

Low-voltage and low-modulation current is applied in the event the tissue layer is deep. Operating time in this type of coagulation is longer than that in speedy coagulation.



CAUTION

CUT, BLEND, SPEEDY, DEEP COAG can be distributed from CUT/ COAG1 (with the cautery pen) and from CUT/ COAG2 (with the cautery pen and the foot pedal).

6.4.6. SPRAY COAGULATION CURRENT

High-voltage spray coagulation goes to the active electrode which is not in contact with the tissue piece for giving coagulation current. This method is ideal for preventing blood loss in larger surfaces and realizing coagulation in open surgeries such as heart surgery.

6.4.7. SPRAY ARGON COAGULATION CURRENT

It is possible to connect the equipment to the argon device by means of the connector on the black panel on the device with an external connector and to provide argon gas using the cautery pen or the foot pedal. Argon is an inert gas used for getting a coagulation effect on patient's tissue. If the output voltage function is activated, the gas inside the bottle is given towards the tissue under low pressure (without any contact between the active electrode and the tissue). The result is considerably effective and useful in general open surgical operations.

**CAUTION**

The mode of spray argon should be used with the buttonless cautery pen because high frequency may damage the buttons of the cautery pen.

6.4.8. CAUTERY PEN AND FOOTPEDAL (MONOPOLAR 1, MONOPOLAR2)

Two-Button Cautery Pen without Foot Pedal: In order to give cut current (CUT, CUT/COAG80%, CUT/ COAG60%, CUT/COAG40%, ENHANCED CUT, BLEND currents are obtained by pressing the relevant button on the unit), press the yellow button on the cautery pen. Or, for giving coagulation current (SPEEDY COAG, DEEP COAG, SPRAY GOAG currents are obtained by pressing the relevant button on the unit), press the blue button on the cautery pen.

Two-Button Cautery Pen and Double Foot Pedal: In order to select and provide cut current, press the yellow button on the cautery pen or step on the yellow section on the foot pedal (CUT, CUT/COAG80%, CUT/ COAG60%, CUT/ COAG40%, ENHANCED CUT, BLEND currents are obtained by pressing the relevant button on the unit). Or, for selecting and providing coagulation current, press the blue button on the cautery pen or step on the blue section on the foot pedal (SPEEDY COAG, DEEP COAG, SPRAY GOAG currents are obtained by pressing the relevant button on the unit).

Buttonless Cautery Pen (Bipolar Forceps) and Foot Pedal: Connect the cautery pen to the active connector. In order to select and provide cut current, step on the yellow section on the foot pedal (CUT, CUT/COAG80%, CUT/ COAG60%, CUT/COAG40%, ENHANCED CUT, BLEND modes are activated by pressing the relevant button on the unit). As you can remember, the double foot pedal and the buttonless cautery pen are used also in the mode of spray argon coagulation.

FOOTPEDAL:



Foot pedal is not produced by Inspital Medical Technology Inc. Footswitch is optional. Pedals with international standards, suitable for use in electrosurgical units, with a blue and yellow cut / coagulation pedal, can be used.

6.5. BIPOLAR

In bipolar mode, current distribution is selected with the help of the relevant buttons in the BIPOLAR section on the unit. For each function, it is possible to set power level with + and – buttons of CUT and COAG. The current level that is selected is stored.



CUT

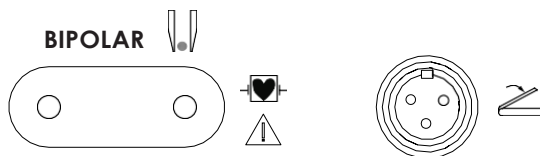
1. Cut
2. Blend

BIPOLAR

COAGULATION

3. Bipolar Coagulation
4. Vessel Sealing

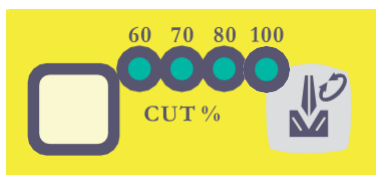
FORCEPS AND FOOT PEDAL CONNECTOR



In bipolar mode, the forceps and the foot pedal are needed for cut and coagulation.

6.5.1. BIPOLAR CUT FUTILE (BIPOLAR CUT)

This is the high-voltage non-coagulated cut current obtained from the bipolar forceps. The level of bipolar module can vary between the values of 100%, 80%, 60% and 40%. Duty cycle is selected with +/- buttons. The warning light under the value selected turns on. If the duty cycle decreases, the level of coagulation naturally increases.



%40 Blend1
%60 Blend2
%80 Blend3

6.5.2. BLEND CURRENT (BIPOLAR CUT)

Blend bipolar current is obtained by means of the forceps and given if, together with deep coagulation, cut, cut and coagulated cut are desired. In this modulation, sinusoidal current is given for low-voltage coagulation and cut.

6.5.3. BIPOLAR CUAGULATION CUT (BIPOLAR COAG)

This is the type of coagulation that can be performed with the bipolar forceps. It is possible to obtain current with the foot pedal.

It has a RF output power of 100 ohm impedance value. This value is normal for the tissue between the forceps. This mode can be started with the selection button.

6.5.4 VESSEL SEALING

Type of function for practicable vessel sealing.

The procedure is as follows: Select Level between 1, 2 and 3. In theory the level 1 is for use with SMALL, 2 for MEDIUM and 3 for

LARGE Artesy Sealer Forceps; Clamp the vessel and press it down slightly but not overly; Press footswitch and keep it pressed during

the whole procedure; During coagulation, exert slight progressive pressure with the Artesy Sealer Forcep; When the coagulation process

is completed, the power shuts down, and can release footswitch.

6.5.5 AUTOSTART / AUTOSTOP

In bipolar mode, 4 different functions can be selected with the selection button in the bipolar coagulation section.



- 1) There is no automatism for current distribution (during the initial operation of the unit). Current distribution is started by stepping on the foot pedal and stopped by releasing the foot pedal.
- 2) **START:** This function is realized upon pressing **SELECT** button for the first time and the relevant warning light turns on. If there is a contact between the active electrode and the tissue, current distribution is started by stepping on the foot pedal and stopped by releasing the foot pedal.
- 3) **STOP:** This function is realized upon pressing **SELECT** button for the second time and the relevant warning light turns on. Current distribution is started by stepping on the foot pedal (if there is no contact between the active electrode and the tissue). It stops itself when the impedance value exceeds 200 ohm. Thus, if the impedance value has already exceeded 200 ohm when the foot pedal is pressed, no current distribution is carried out.
- 4) **AUTOSTART/AUTOSTOP:** This function steps in upon pressing **SELECT** button for the third time and **START/ STOP** warning lights turn on. Bipolar coagulation is automatically activated and deactivated.

If there is a contact between the active electrode and the tissue, current distribution is started by stepping on the foot pedal. If the impedance value is higher than 200 ohm, current distribution stops automatically.

No automatism function steps in again upon pressing **SELECT** button for another time. (1) Current distribution stops every time the foot pedal is released.



6.6. FORCEPS AND FOOT PEDAL (BIPOLAR)

Bipolar Forceps and Double Foot Pedal: Connect the bipolar forceps to the bipolar connector. The unit becomes ready to give current only in bipolar function (BIPOLAR CUT, BIPOLAR CUT/COAG80%, BIPOLAR CUT/COAG 60%, BIPOLAR CUT/COAG 40%, BIPOLAR BLEND and BIPOLARCO- AG). Step on the yellow section of the foot pedal for BIPOLAR CUT or BIPOLAR BLEND current and the blue section of the foot pedal for BIPOLAR COAG current. Do not short-circuit in order not to damage the forceps.

6.7. PATIENT PLATE CIRCUIT EXTREME IMPEDANCE SIGNAL (OC)

For the explanation of this warning signal, please pay attention to the explanations in the section of patient plate circuit.

If the circuit is turned on, OC warning light is on. As the plate turns off, the light is off and the parameters that are selected are followed and the current distribution is carried out with audible signals

6.8. PRE-SETTING BY THE USER

The unit enables the operator to change the settings specified: audible alarm distribution signal and power setting.

For changing current distribution audible signal, set “speaker volume” button on the rear panel between minimum and maximum levels.

In order to set sound level, use volume knob on the rear panel. Power level is integral from 0 W to 50 W. Levels above 50 W increase by 10.

6.9. INTERNAL PARAMETERS AUTOMATIC CONTROL

The unit features an automatic control system for some internal parameters. Upon starting the unit, it controls bipolar and monopolar functions and displays 7 segments on the indicator as Control A and Control B. In case of positive control results, “Check Monopolar OK” and “Check Bipolar OK” signals are displayed on the LCD screen in PROGRAM section. However, in case of negative results, “Err xxx” code and the explanation of the relevant error are displayed on the LCD screen. For detailed information, please see “Troubleshooting”.

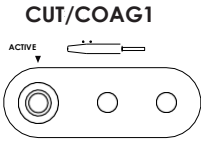
6.10. CONNECTIONS

Patient Plate Connector

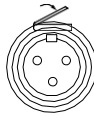
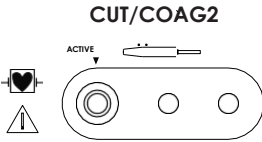


This is the point of connection of the patient plate to be administered to the patient. Single-use and multiple-use patient plates are available.

Cautery Pen for Monopolar 1 Cut and Coagulation

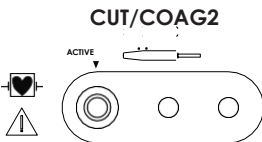


This is the point of connection of the two-button cautery pen used for operating Cut and Coagulation 1 functions. The buttonless cautery pen is required to be connected to the active connector.



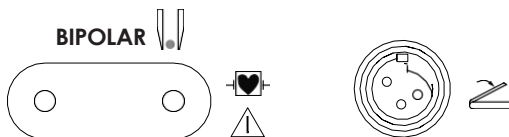
This is the point of connection of the two-button cautery pen used for operating Cut and Coagulation 2 functions. The yellow button is used for cut while the blue button is used for coagulation.

Monopolar 2 Cut ve Koagülasyon İçin Ayak Pedali



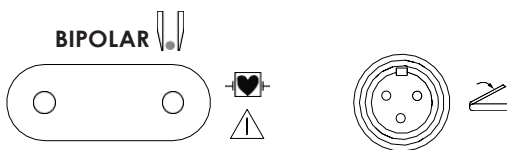
This is the point of connection of the foot pedal used for monopolar 2 cut and coagulation. Of the foot pedal, the yellow section is used for cut while the blue section is used for coagulation.

Bipolar Forceps Connector



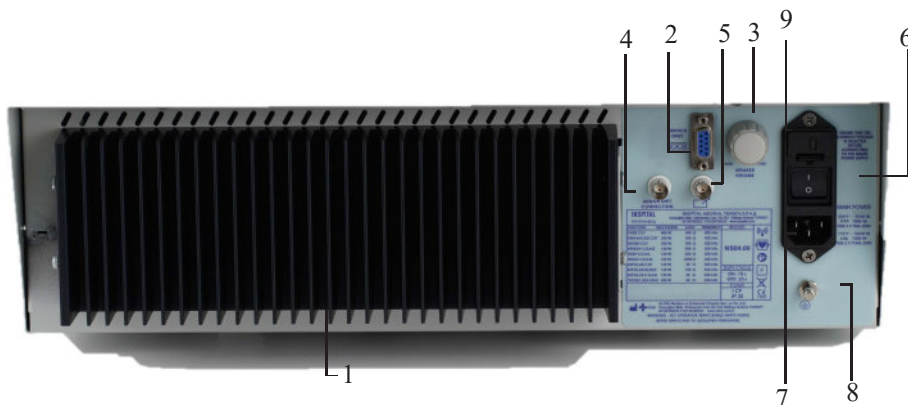
This is the point of connection of the bipolar forceps that performs bipolar cut and coagulation.

Double Foot Pedal for Bipolar Cut and Coagulation



This is the point of connection of the foot pedal. Cut is performed by stepping on the yellow section while coagulation is performed by stepping on the blue section.

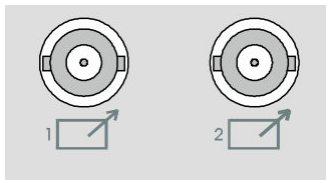
6.11. REAR PANEL



PART NO	PART NAME	PART NO	PART NAME
1	Ventilation	6	Master switch
2	Socket RS-232 (for service)	7	Main socket
3	Sound level button	8	Equipotential connector
4	External Argon Unit Connection	9	Fuse holder / voltage selector
5	Connection for external devices		

6.12. CONNECTIONS

1. External Argon Device Connector



This is the point of connection of the external argon device. After the argon coagulation spray selection button is pressed and current distribution starts, connector 1 receives a signal indicating that this gas is active.

2. External Device Connector (Except for the Argon Device)

This is the point of connection of the external device except for the argon device.

Device power supply module and voltage selector

Power supply module is the point of connection of the main voltage supply. This module is ensured with the line fuse and the voltage selector.



CAUTION

Before starting the device, the operator should make sure that the necessary voltage is received from the electric network.

6.13. MECHANICAL ON/OFF BUTTON

The power on/off button is used for controlling the power supplied to the equipment. For supplying power to the unit, press the button in 1 direction. As soon as there is power on the unit, the light inside the mechanical on/ off button and the red light “READY” on the left of the front panel turn on. For ending the power connection to the unit, press the button in 0 direction. This operation is also used to stop operation in case of a failure or emergency. When there is power on the unit, use the electronic on button on the front panel for starting the unit.

6.14. STANDARD AND OPTIONAL ACCESSORIES

Code	Explanation	NS04.00
-	NS04.00 Electrosurgical Unit	
00100.01	5 MT 3x1,5mm Main Cable	●/1
00301.04	HP Double Foot Pedal	●/2
00404.07	Patient Plate Cable F7915/F7930	■
00404.08	Single-Use Patient Plate Cable /5365	●/1
0350	Single-Use Patient Plate	□
110-750NS	Bipolar Artery Sealer 27cm TIP 3	0
110-755NS	Bipolar Artery Sealer 25.5 cm TIP 3	0
110-760NS	Bipolar Artery Sealer 17cm TIP 2	0
152-110	Knife Electrode (7 cm)	●/3
152-115	Knife Electrode (16 cm)	●/3
152-120	Needle Electrode (5.5 cm)	●/3
152-122	Bent Needle Electrode (7 cm)	□
152-125	Needle Electrode (13 cm)	□
152-130	Spherical Electrode (2mm – 6 cm)	□
152-132	Bent Spherical Electrode (2 mm – 6 cm)	□
152-140	Spherical Electrode (3 mm- 6 cm)	□
152-142	Bent Spherical Electrode (3 mm – 5 cm)	□
152-145	Spherical Electrode (3mm – 14 cm)	□
152-150	Spherical Electrode (4mm-6 cm)	●/3
152-152	Bent Spherical Electrode (4 mm – 6 cm)	○
152-160	Spherical Electrode (5mm – 6 cm)	□
152-162	Bent Spherical Electrode (5mm – 6 cm)	□
152-165	Spherical Electrode (4mm – 14 cm)	□
152-175-10	Loop Electrode 10x10 (15 cm)	□
152-190-13	Loop Electrode 20x13 (15 cm)	□
152-190-20	Loop Electrode 20x20 (15 cm)	□
152-195	Conical Electrode (13 cm)	□
190-260	Monopolar Cable M4-MP4	□
310-110-05	Bipolar Forceps (11,5 cm TIP 0,5mm)	□
310-140-10	Bipolar Forceps (20 cm TIP 1mm)	□
310-140-20	Bipolar Forceps (20 cm TIP 2 mm)	□
310-142-10	Bent Bipolar Forceps (20 cm TIP 1mm)	□
310-142-20	Bent Bipolar Forceps (20 cm TIP 2 mm)	□
310-180-10	Angular Bipolar Forceps (20 cm TIP 1 mm)	□
310-180-20	Angular Bipolar Forceps (20 cm TIP 2mm)	□
310-182-10	Angular Bipolar Forceps (20 cm TIP 1 mm)	□
310-185-10	Bent Bipolar Forceps (20 cm TIP 1mm)	□
310-510	Bipolar Forceps (20cm)	□
310-550	Bipolar Electrode (20 cm)	□
310-590	Bipolar Electrode (20 cm)	□
320-134-20	Monopolar Forceps	□
330-160	Surgical Scissors	□
755VL	Single-Use Buttoned Cautery Pen	●/5
CB462	Silicon Bipolar Cable 3 m	●/1

Code	Explanation	NS04.00
F4243	Multiple-Use Buttoned Cautery Pen	●/1
F4814	Multiple-Use Buttonless Cautery Pen	□
F7520	Electrode Cleaner 47x50mm	●/1
F7915	Conductive Rubber Neutral Patient Plate	□
F7920	Single-Use Discrete (Double) Patient Plate	●/5
F7930	Conductive Rubber Discrete (Double) Patient Plate	□
MA307	User Manual	●/1

6.15. TECHNICAL SPECIFICATIONS

Tolerance	Explanation	NS04.00
-	Electrosurgical Unit Code	
-	Operating Conditions Memory	
-	Digital Power Monitoring	
-	Continuous Control	
-	Patient plate connection automatic control	
-	Impedance automatic control	
-	Current dispersion time automatic control	
-	Automatic power level control	
-	Automatic activation in bipolar coagulation	
-	Argon device connection	
-	Minimum pre-selection power	
-	1-step power between 0W-50W	
-	10-interim step power for levels above 50W	
-	Digital power level indicator	
-	Power selection with buttoned cautery pen	
%20+/-	Max. Output Power CUT (W)	400W – 300 Ω
%20+/-	Max. Output Power CUT %80 (W)	300W – 300 Ω
%20+/-	Max. Output Power CUT %60(W)	250W – 300 Ω
%20+/-	Max. Output Power CUT %40(W)	200W – 300 Ω
%20+/-	Max. Output Power ENHANCED CUT (W)	250W – 300 Ω
%20+/-	Max. Output Power CUT BLEND (W)	250W – 300 Ω
%20+/-	Max. Output Power SPEEDY COAG (W)	120W – 500 Ω
%20+/-	Max. Output Power DEEP COAG (W)	120W – 200 Ω
%20+/-	Max. Output Power SPRAY COAG(W)	100W – 2000 Ω
%20+/-	Max. Output Power SPRAY COAG ARGON (W)	100W – 2000 Ω

Tolerance	Explanation	NS04.00
%20+/-	Max. Output Power BIPOLAR CUT (W)	120W – 50 Ω
%20+/-	Max. Output Power BIPOLAR CUT/COAG %80 (W)	100W – 50 Ω
%20+/-	Max. Output Power BIPOLAR CUT/COAG %60 (W)	100W – 50 Ω
%20+/-	Max. Output Power BIPOLAR CUT/COAG %40 (W)	60W – 50 Ω
%20+/-	Max. Output Power BIPOLAR BLEND (W)	120W – 150 Ω
%20+/-	Max. Output Power BIPOLAR COAG (W)	120W – 50 Ω
%20+/-	Maximum output bipolar power VESSEL SEALING (W)	200W → 50 Ω
%5+/-	Modulation Factor CUT/COAG%80 (kHz)	10
%5+/-	Modulation Factor CUT/COAG%60 (kHz)	10
%5+/-	Modulation Factor CUT/COAG%40 (kHz)	10
%5+/-	Modulation Factor ENHANCED CUT (kHz)	1.25
%5+/-	Modulation Factor SPEEDY COAG (kHz)	8-12
%5+/-	Modulation Factor SPRAY COAG (kHz)	1
%5+/-	Modulation Factor SPRAY COAG ARGON (kHz)	1
%5+/-	Modulation Factor BIPOLAR CUT %80 (kHz)	10
%5+/-	Modulation Factor BIPOLAR CUT %60 (kHz)	10
%5+/-	Modulation Factor BIPOLAR CUT %40 (kHz)	10
0.2 +/-	Peak Factor CUT	1.6
0.3 +/-	Peak Factor CUT/COAG%80	1.8
0.3 +/-	Peak Factor CUT/COAG%60	2.1
0.3 +/-	Peak Factor CUT/COAG%40	2.6
0.3 +/-	Peak Factor ENHANCED CUT	1.6
0.3 +/-	Peak Factor BLEND	1.6
0.3 +/-	Peak Factor SPEEDY COAG	3.4
0.3 +/-	Peak Factor DEEP COAG	1.6
+/-0.3	Peak Factor SPRAY COAG	3.4
+/- 0.3	Peak Factor SPRAY COAG ARGON	3.4
+/-0.2	Peak Factor BIPOLAR CUT	1.5
+/-0.3	Peak Factor BIPOLAR CUT/COAG %80	1.7
+/-0.3	Peak Factor BIPOLAR CUT/COAG %60	2.0
+/-0.3	Peak Factor BIPOLAR CUT/COAG %40	2.4
+/-0.3	Peak Factor BIPOLAR BLEND	1.7
+/-%10	Operating Frequency MONOPOLAR	425 kHz

Tolerance	Explanation	NS04.00
+/-%15	Operating Frequency BIPOLAR	525 kHz
+/-%15	Max. Output Voltage CUT (Vpp)	1500
+/-%15	Max. Output Voltage CUT/COAG %80 (Vpp)	1500
+/-%15	Max. Output Voltage CUT/COAG %60 (Vpp)	1500
+/-%15	Max. Output Voltage CUT/COAG %40 (Vpp)	1500
+/-%15	Max. Output Voltage ENHANCED CUT (Vpp)	1500
+/-%15	Max. Output Voltage BLEND (Vpp)	2500
+/-%15	Max. Output Voltage SPEEDY COAG (Vpp)	2500
+/-%15	Max. Output Voltage DEEP COAG (Vpp)	800
+/-%15	Max. Output Voltage SPRAY COAG (Vpp)	4500
+/-%15	Max. Output Voltage SPRAY COAG ARGON (Vpp)	4500
+/-%15	Max. Output Voltage BIPOLAR CUT (Vpp)	480
+/-%15	Max. Output Voltage BIPOLAR CUT/COAG %80 (Vpp)	480
+/-%15	Max. Output Voltage BIPOLAR CUT/COAG %60 (Vpp)	600
+/-%15	Max. Output Voltage BIPOLAR CUT/COAG %40 (Vpp)	640
+/-%15	Max. Output Voltage BIPOLAR BLEND(Vpp)	650
+/-%15	Max. Output Voltage BIPOLAR COAG (Vpp)	650
+/-%15	Maximum output voltage VESSEL SEALING (Vpp)	550
+/-5	Dimensions	47x15x38 cm
+/-10	Weight	18 Kg
+/-%5	Selectable supply power (Vac)	115-230
+/-%1	Supply Frequency (Hz)	50-60
+/-0	Fuses 230 Vac (5x20) Timed	2xT 5A
+/-0	Fuses 115 Vac (5x20) Timed	2xT 10A
+/-%10	Electrical Input Power (VA)	1000
+/-%10	Electrical Input Current (230Vac) (A)	4.5
+/-%10	Electrical Input Current (115Vac) (A)	9
+/-5	5-step sound setting level	
	Self-control	
	Sound accuracy output warning	
	Patient plate electronic control	
	Discrete or integral patient plate compatibility	
	Operating conditions storage	10 (2)
-	Software Name	SW-346-1
-	Software Version	3.0.3

Tolerance	Explanation	NS04.00
	Electrical Class (EN60601-1)	1 CF
	MDD 93/42 EEC Class	I Ib
	EN55011 (CISPR 11) Class (Class /Group)	2/B
	Patient Current	F
	Work Cycle	10/30
	Cautery Pen and Foot Pedal Control	
	Defibrillation Prof	
	10-second current warning (OVT)	
	Equipotential Binding	
	Metal Cabinet	
	Polycarbonate coated panel	
	EN60601-1 (1998) conformity	
	EN60601-1-2 (2003) conformity	
	EN60601-2-2 (2000) conformity	
-	Operating conditions storage	10 (2)
-	Software Name	SW-346-1
-	Software Version	3.0.3

6.16 SAFETY



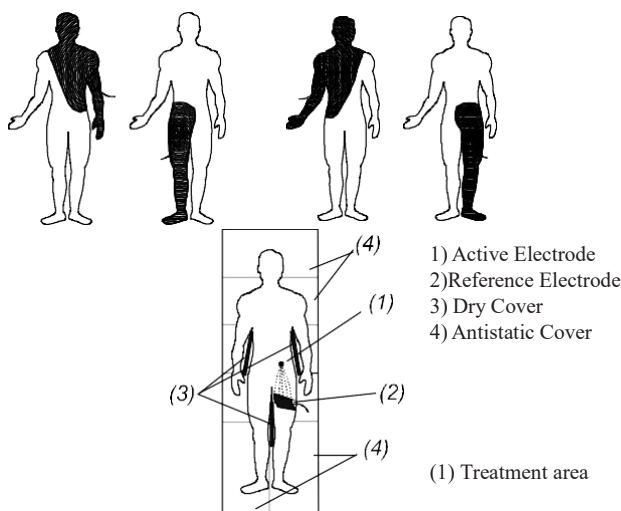
CAUTION

The electrosurgical practice may be dangerous. Misuse of any part in the electrosurgical system may lead to severe burns in the patient. Please carefully read all warnings, precautions and instructions before activating the electrode. Neither İNSPİTAL A.Ş. nor any dealer organization can be held responsible for losses or damages that result in personal or material damage and result from misuse. The characteristic features of the accessories provided in company with the unit are compatible with the electrosurgical unit but may be incompatible with other electrosurgical units. The user, before using other accessories, should check compatibility.

6.16.1. GENERAL

The following precautions reduce the risk of accidental burns:

- Place the patient plate close to the surgical area and onto a vascular muscle of the patient. Avoid the contact of the patient plate with bone protrusions, prosthesis, critical tissues and body parts having liquid flow. The part to which the plate is to be attached is required to be hairless, dry and clean. Do not use alcohol for cleaning the skin. It is not recommended to use gelatinous substances.
- Pay attention to expiration date before using the patient plate.
- In case of multiple-use electrodes, make sure that they are tightly attached to the system.
- Especially in case of double surface patient plate, do not use the patient plate transversely. Instead, vertical or diagonal positioning is preferred. By this method, current disperses equally on the surface and the risk of burn is minimized.
- If it is impossible to correctly use the patient plate, instead of monopolar techniques, apply bipolar techniques.
- Avoid the contact of the patient with a metal part having ground connection or high electrical conductivity.
- Avoid the contact of skin with skin (for instance: contact of the arm with the body). For this, dry surgical materials can be used. Besides, dry excessively perspiring body parts.



- In case the high-frequency electrosurgical unit and the physiological imaging device are used together on the same patient, imaging device electrodes should be as far from electrosurgical unit electrodes as possible.
- Place electrode connections so as not to contact with the patient and other cables. Place the cables so that the staff does not thread on them and they are not crushed under other devices. Do not mount cables to the operating room with tools.
- In case of surgical practices in which current passes through body cross sections, in order to avoid undesired coagulation, bipolar techniques may be used.
- Power should be at a level suitable for the work.
- If the electrosurgical unit fails to create the desired effect, always check the patient plate. The reason of low power outlet or incorrect effects may be patient plate misconnection or misplacement.
- Avoid inflammable anesthetics such as oxygen and nitrous oxide in operations at head and chest level. Before starting the electrosurgical unit, make sure that combustibles used in cleaning have evaporated. Combustibles may be left under the patient or in patient's body cavities such as belly button. Remove the liquids in such body parts before starting the unit. If saturated with oxygen, materials such as cotton, wool and tulle may inflame due to sparks generated by the unit during usage.
- There is a risk in patients connected to heartbeat regulating devices. There may be interference with stimulator signals or the stimulator may be damaged. In such case, please apply to the cardiology unit.
- The electrosurgical unit emits high-frequency indefinite radiation. For this reason, it may affect other medical devices, irrelevant electrical appliances and communication and navigation systems.
- Regularly check accessories. Check especially electrode cables and endoscopy accessories and make sure that they are not damaged.
- Do not assemble the accessories which are incompatible with the unit. Request the list of replacement parts and their characteristic features from the manufacturer.
- Attention: Electrosurgical unit failure may lead to an uncontrolled increase in the output power.
- Flames caused by low electric current between the patient and the electrode may cause undesired stimulation in patient's muscles or nerves.
- In case of neuromuscular stimulation, stop the surgery and check all of the connections to the generator. If the problem is not solved in this manner, have the generator controlled by the technical staff.



WARNING & RISKS

- The electrosurgical unit emits smoke and odors during operation. This smoke and odor is harmful to users and healthcare professionals. The device should be used in an air circulating environment or it should be smoke absorbent in the environment. Get information from authorized personnel during installation. Otherwise, it poses a risk to users and healthcare professionals.
- The Electrosurgical Unit should be used by Specialist Personnel. The user must be a medical doctor and be an expert in the branch to be applied. It cannot be used by other healthcare professionals. Otherwise, they pose a risk for patient health and safety.
- As accessories, use the accessories described in the user manual for the purposes specified. Accessories may not be available from the manufacturer. Accessories of different brands designed for monopolar and bipolar electrosurgery units can be preferred. When choosing accessories, make sure that the accessories meet the required standards and CE certificate is available.
- Otherwise, your device's performance may be affected. Pay attention to the sterilization conditions offered by the accessory manufacturer. Do not reuse disposable accessories. Otherwise, they pose a risk both for device performance and patient health and safety.
- To use the device at the desired performance, fulfill the maintenance conditions in the MAINTENANCE and REPAIR section. The warranty period specified for the device is 2 years. Spare parts are supplied by the manufacturer for 10 years.

- Please request training from the Authorized Service in the installation of the device. Use of the device by untrained persons poses a risk to patient health and safety.
If the device is damaged, definitely contact an Authorized Service. Never use the device that has not been checked by specialist technical personnel after damage. This can pose a risk to both the user and the patient.
- Do not use the electrosurgical unit in an environment with flammable gases. It may cause an explosion or fire.
- In case of overheating of the device or the environment, the device closes itself and protects it. When this happens, you consider the ambient temperature to the operating level. When the device is cool enough, it will start working again. During this time, wait without interfering with the device. Otherwise, the device may be damaged.
- Position the electrosurgical unit on a dry, non-slip surface table or trolley without the risk of tipping, falling. Ensure that the feet of the appliance are in full contact with the surface and are balanced. Otherwise there is a risk of the device falling and being damaged.
- For the reusable accessories, follow the sterilization rules recommended by the manufacturers. Otherwise, there is a risk of contamination for the patient.

7. PATIENT PLATE

7.1 PATIENT SAFETY

During the usage of the electrosurgical unit, the patient is a conductor for electric potential against grounding potential. So, in the event the patient and a material having electrical conductivity contact, electrical current occurs at the point of contact and may lead to thermal necrosis. For this reason, all accessories should be carefully examined before using the unit and all safety rules should be followed.

7.2 CORRECTLY POSITIONING THE PATIENT

For preventing any accidental contact between the patient and grounded metal parts, pay attention to the following;

The patient should not be in contact with metal parts.

Suction unit's flexible hoses should not be in contact with the patient. Operating tables having ground connections always allow electrostatic energy discharge.

- The patient should be lying so as to have adequate number of connections, thick tissue and isolation.
- The patient should not be in contact with connections and wet mats.
- Organic secretions, cleaning agents or other liquids should not wet connections.
- There should be no liquid under the patient.
- Dispose urinary waste with the help of catheters.
- Dry extremely perspiring body parts and prevent the contact of skin with skin.
- Correctly isolate all conductive and grounded supports and leg supports.
- Check the amount of anesthetic gas.

7.3 CORRECTLY POSITIONING THE PATIENT PLATE

It allows current to return to the scalpel (bistoury). There are two types of patient plates.

- Single Surface Patient Plate: The contact between the patient plate and the patient is not controlled.
- Double Surface Patient Plate: The contact between the patient plate and the patient is controlled.

Make sure that the patient plate is positioned so as to eliminate the risk of burn or other risks to the patient and that this position is maintained. By paying attention to the following, you can ensure it:

In the next image, the double surface patient plate is correctly positioned. Place the patient plate perpendicular to the area of operation. Avoid placing the patient plate transversely. Instead, place it vertically or crosswise. Thus, current disperses equally on both surfaces and the risk of burn is minimized.

The patient plate is usually placed parallel to the body. However, this is a wrong method because current does not disperse equally on both surfaces of the plate. If it is placed in this manner, a warning beep starts and the unit hinders current. Before applying the patient plate, remove dust, dirt, etc. on the plate.

Do not attach the patient plate onto wounds or bone protrusions or close to prosthesis or monitor electrodes. Place the plate onto a muscle close to the area of practice. In case of single-use patient plate, pay attention to expiration date.

In case of multiple-use patient plate, check whether or not junctions are tightly placed.

For preventing burns, make sure that the entire surface of the patient plate is attached correctly. If a part of the plate is not attached, current precision increases. Due to the fact that the precision of the current that passes under the neutral electrode is not equal, a uniform heating can not be obtained on the borders of the patient plate.

If the plate is placed to an area subject to pressure during operation, the skin may be harmed due to pressure. Temperature reduces and thus the risk of burns increases.

7.4. USE OF THE HF ELECTROSURGICAL UNIT IN LAPAROSCOPY

In laparoscopic operations, generally monopolar HF electrosurgical methods are employed. These methods can be easily used in different modes (pure cut, coagulation, blend cut where cut and coagulation are used together). However, this mode includes the risk of burns.

Factors such as the use of laparoscopic tools in a confined space, surgeon's lack of knowledge about such tools, the capacity of the current given to the patient, etc. may result in burns and visceral apertures. The structure of the place of surgery – proximity of the active electrodes to other conductive tools and to the tissue – may cause invisible and undesirable tissue burns because of the following:

- Direct Contact
- Insulation Failure
- Contact Capacity

If the active electrode contacts another metal part, direct contact occurs, electrical current transfer emerges and may cause organ burns.

Faulty or deficient insulation may result from over voltage, misuse, wear or crack, accidental electric shaft during laparoscopic operations or malpractices during disinfection. Minor cracks are more dangerous than major breaks because current focuses more and thus may cause burns.

- For preventing and minimizing the risk of accidents to the patient, take the following precautions;
- Make sure that the medical personnel is fully and adequately trained in the use of the unit,
- Visually inspect the surgical tools before using them,
- Use single-use electrodes,
- Prohibit the use of plastic-metal canulla.

8. CLEANING AND MAINTENANCE& REPAIR

8.1. GENERAL

No user-adjustable parts inside the unit for calibrating or servicing purposes. Never open the frame of the unit. Otherwise, its warranty shall become void. In case of any repair or adjustment need, send the entire unit to the authorized service together with the explanation of the failure. The maintenance to be done by the user includes cleaning the frame, cleaning and sterilizing the accessories and checking the unit before each use. The functional and safety inspection of parameters accuracy has to be conducted by the expert technical staff.

8.1.1. DEVICE CLEANING

Before starting to clean, turn the main switch of the unit off and disconnect the main power supply cable. Wipe the outer surface of the unit with a wet cloth. Do not use chemicals. It is possible to use nonabrasive soft cleaners. Devices sent to the manufacturer for technical service must be sent free of contamination. Any uncleaned device must be specified.

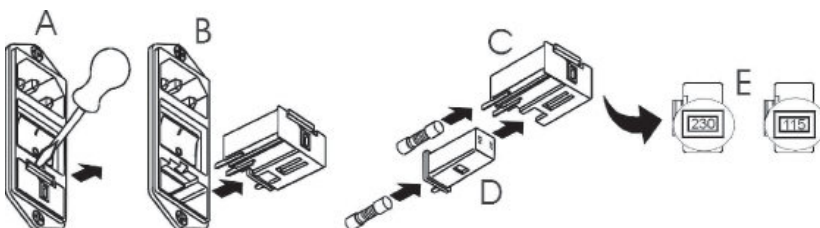
8.1.2. ACCESSORY PARTS CLEANING AND STERILIZATION

The best thing to do for this is to use single-use accessories. Before using multiple-use accessory parts for the second time, carefully clean and sterilize them. Follow the instructions of the relevant supplier in cleaning multiple-use accessory parts for each part.

8.2. MAINTENANCE AND REPAIR

8.2.1. FUSE REPLACEMENT

Fuses to be replaced for NS04.00 are 2xT5A (230 vac main voltage) or 2xT10A (115 vac main voltage). Before replacing fuses, disconnect the unit.



8.2.2. CHECKING THE UNIT AT EVERY USE

Before using the electrosurgical unit, the following should be taken into consideration;

- Check if cables and connections are damaged.
- Make sure that all electrical connections of the unit are grounded.
- Make sure that all accessories used are sterilized.
- Make sure that the package of sterile accessories have not been opened.
- Check reference electrode cable connection, OC light function and alarm tone.
- Check CUT and COAG power switches activation, emission lights and warning beeps.

8.2.3. FUNCTION, SAFETY CHECK AND TEST

- The following checks and tests should be performed at least once a year by a biomedical engineer or an expert technical staff member;
- Checking connectors and the main power supply cable,
- Visual inspection for mechanical protection,
- Checking if the unit meets the data on the label,
- Checking the presence of a user manual,
- Checking the high-frequency output functions,
- Grounding conductivity resistance test,
- Grounding leakage current test.

8.2.4. INFORMATION ABOUT DEVICE DISPOSAL

If the unit completes its physical life, do not dispose it in urban waste landfill sites.

If the product is disposed improperly, some parts of it may be hazardous on the environment and on human health.

The next symbol indicates that the unit, at the end of its physical life, should not be disposed in urban waste landfill sites.

8.2.5 PROBABLE FAILURES AND TROUBLESHOOTING

In case of any failure, first of all check if the unit has been correctly installed and the accessories have been correctly mounted. If there is a failure, error code is indicated on the 7-segment indicator and error definition is displayed on the LCD screen.

Failure	Causes	Troubleshooting
The unit does not start.	There is a cut in the main power supply.	Make sure that the main power supply is connected.
Check if the fuse is inserted. If necessary, replace the fuse.		
OC alarm is always active.	There may be a disconnection in the patient place circuit.	Check the patient plate cable.
Replace the connection cable of the patient plate.		
The device does not respond to activation command.	The cautery pen or the foot pedal may be faulty.	
The cautery pen or the foot pedal may be misconnected.		
OVT alarm is active.	Replace the cautery pen or the foot pedal.	
Check the connections of the cautery pen or the foot pedal.		
Wait until the OVT warning signal turns off.		
Error Code 001	While the unit is started, the current distribution control current is activated.	Disconnect and then reconnect the cautery pen or the foot pedal.
Error Code 002	Motherboard failure	Call the authorized service.
Error Code 003	Motherboard failure	Call the authorized service.
Error Code 004	Failure in the data exchange circuit	Call the authorized service.
Error Code 005	Failure in the reference voltage circuit	Check the main voltage
Call the authorized service		
Error Code 009	Failure in the power output activation circuit	Call the authorized service.
Error Code 011	The foot pedal is pressed.	Check the status of foot pedal.
Error Code 013	Bipolar DAC is not ensured.	Call the authorized service.
Error Code 014	Bipolar power is not ensured	Call the authorized service.
Error Code 016	The Fuse Module is blown BIPO	Call the authorized service.
Error Code 017	The fuse is blown 12 V or 8V BIPO	Call the authorized service.
Error Code 018	The fuse is blown 20 BIPO	Call the authorized service.
Error Code 019	The fuse is blown +HV BIPO	Call the authorized service.
Error Code 020	MONOPOLAR circuit failure	Call the authorized service.
Error Code 021	BIPOLAR circuit failure	Call the authorized service.
Error Code 022	MONOPOLAR information not available	Call the authorized service.
Error Code 023	BIPOLAR information not available	Call the authorized service.

Emission of electromagnetic interference (IEC 60601-1-2, Table 201)

The NS04.00 is intended for operation in an electromagnetic environment as described below. The customer or user of the NS04.00 should ensure that it is operated in such an environment.

Interference emission measurement	Conformity	Electromagnetic environment guideline
HF emissions according to CISPR 11	Group 2	The NS04.00 must emit electromagnetic energy in order to perform its intended function. Nearby electronic devices may be affected.
HF emissions according to CISPR 11	Class B	The NS04.00 is suitable for use in facilities other than those suitable for a residential environment or those connected directly to the public power grid, which also supplies power to buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Classes A and D	
Emission of voltage fluctuations and flickere according to IEC 61000-3-3	Conforms	

Immunity to electromagnetic interference (IEC 60601-1-2, Table 202)


The NS04.00 is intended for operation in an electromagnetic environment as described below. The customer or user of the NS04.00 should ensure that it is operated in such an environment.

Interferenc immunity test	IEC 60601 test level	Conformit level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV discharge	±6 kV discharge	Floors should be wooden or concrete or finished with ceramic tiles. If the floor is finished with a synthetic material, the relative humidity must be at least 30%.
	±8 kV air discharge	±8 kV air discharge	
Fast transient electrical noise or bursts according to IEC 61000-4-4	±2 kV on AC supply lines	±2 kV on AC supply lines	The quality of the AC power should correspond to that of a typical business or hospital environment.
	±1 kV on input and output lines	±1 kV on input and output lines	
Surges according to IEC 61000-4-5	±1 kV between external conductors	±1 kV between external conductors	The quality of the AC power should correspond to that of a typical business or hospital environment.
	±2 kV between external conductor and ground	±2 kV between external conductor and ground	
Voltage dropouts, brief interruptions and supply voltage fluctuations according to IEC 61000-4-11	< 5% U_T for one half-cycle (> 95% dropout) 40% U_T for 5 cycles (60% dropout) 70% U_T for 25 cycles (30% dropout) < 5% U_T for 5 s (> 95% dropout)	< 5% U_T for one half-cycle (> 95% dropout) 40% U_T for 5 cycles (60% dropout) 70% U_T for 25 cycles (30% dropout) < 5% U_T for 5 s (> 95% dropout)	The quality of the AC power should correspond to that of a typical business or hospital environment. If the NS04.00 user requires it to continue operating in the event of a power dropout, it is recommended to power the NS04.00 from an uninterruptible power supply or a battery.

Note: U_T is the AC supply voltage before the test level is applied.

Immunity to electromagnetic interference (IEC 60601-1-2, Table 204)

The NS04.00 is intended for operation in an electromagnetic environment as described below. The customer or user of the NS04.00 should ensure that it is operated in such an environment.

Interference immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment guidelines
Conducted HF interference according to IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	<p>Portable and mobile wireless devices should not be used inside the recommended protective distance from the NS04.00 and its cables, as calculated using the equation for the relevant transmission frequency.</p> <p>Recommended protective distance:</p> <p>$d = 0.35 \times \sqrt{P}$</p> <p>$d = 0.35 \times \sqrt{P}$ for 80 MHz to 800 GHz</p> <p>$d = 0.75 \times \sqrt{P}$ for 80 MHz to 2.5 GHz</p> <p>where P is the rated transmitter output power in watts (W) as specified by the transmitter manufacturer and d is the recommended protective distance in meters (m).</p> <p>The field strength of stationary transmitters as determined by on-site measurements^a should be lower than the compliance level^b at all frequencies.</p> <p>Interference is possible in the vicinity of devices that bear the following symbol:</p> 
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	
Note 1	The higher frequency range applies in case of 80 MHz and 800 MHz.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection by buildings, objects and people.		
a	Field strengths from stationary transmitters, such as base stations for radio telephones, land mobile radios, amateur radio, AM and FM radio broadcasting and TV broadcasting, cannot be predicted accurately based on theoretical considerations. A survey of the electromagnetic conditions at the site should be performed to determine the electromagnetic environment resulting from stationary transmitters. If the measured field strength at the location where the NS04.00 is used exceeds the stated compliance level, the NS04.00 should be monitored to verify that it operates correctly. Additional measures, such as altering the orientation or location of the NS01.60, may be necessary if abnormal operation is observed.		
b	The field strength should be lower than 10 V/m over the frequency range of 150 kHz to 80 MHz.		

Recommended protective distances between portable and mobile HF telecommunication

devices and the NS04.00 (IEC 60601-1-2, Table 206)

The NS04.00 is designed for operation in an electromagnetic environment in which HF interference is monitored. The customer or user of the NS04.00 can help to prevent electromagnetic interference by complying with the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the NS01.60. This distance depends on the output power of the communication device, as specified below.

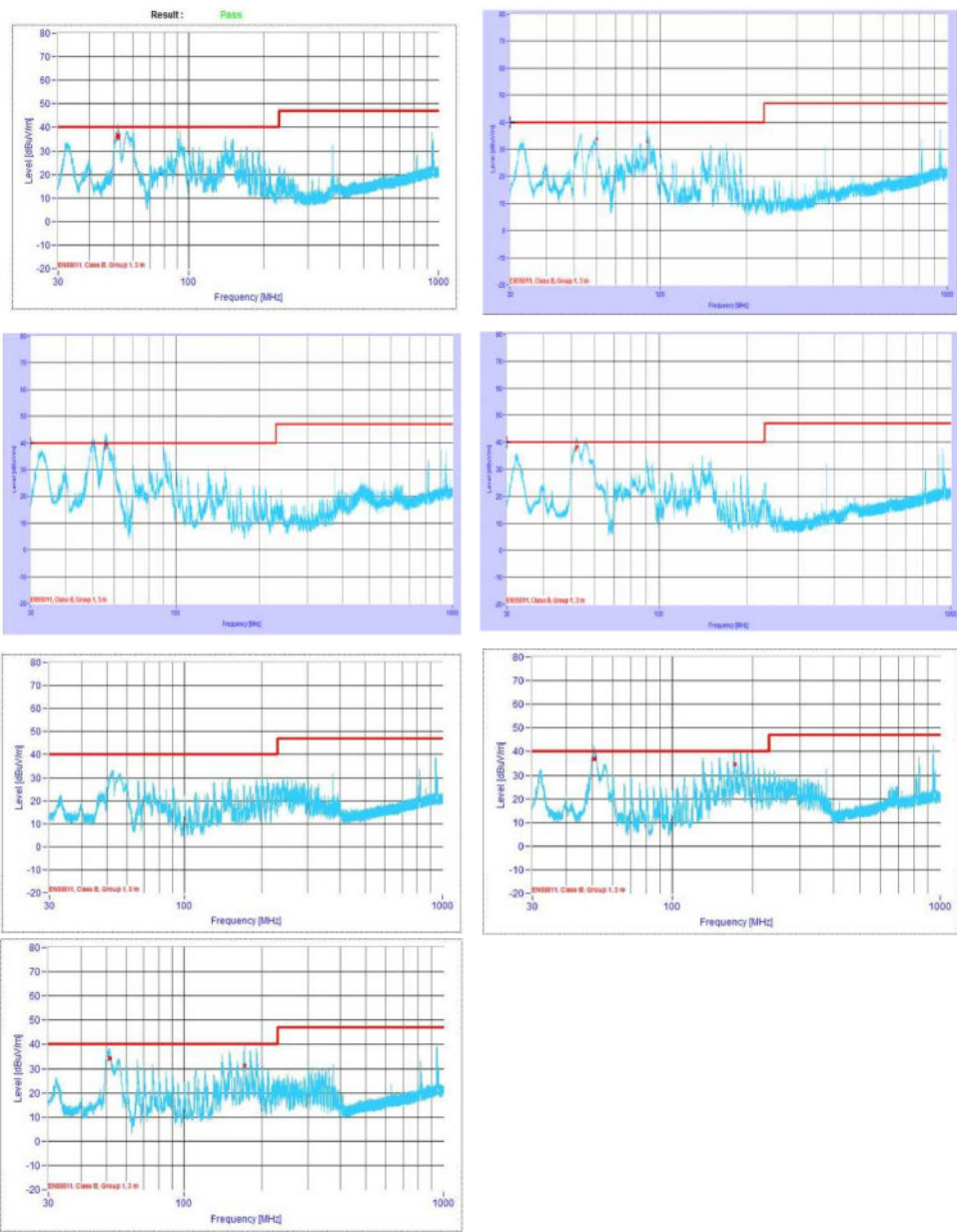
Rated transmitter power (W)	Protective distance (m) at various transmission frequencies		
	150 kHz to 80 MHz $d = 0.35 \times \sqrt{P}$	80 MHz to 800 GHz $d = 0.35 \times \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \times \sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters whose maximum rated power is not specified in the table above, the recommended protective distance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum rated output power of the transmitter in watts (W) as specified by the transmitter manufacturer.

Note 1	The higher frequency range applies in case of 80 MHz and 800 MHz.
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection by buildings, objects and people.

9.1. EMC TEST END GRAPHICS

The test results are shown in the graphs below.



9.1.1. EMC Emmision Test Results

Deney Tarihi : 11.05.2018
Test Date

Frequency (MHz)	Class A (dBuV)		Class B (dBuV)	
	Quasi-peak	Average	Quasi-peak	Average
0.15 - 0.50	79	66	66-56	56-46
0.50 - 5.00	73	60	56	46
5.00 - 30.00	73	60	60	50

9.7.2 Deney Cihazları

Test Instruments

Cihazın Tanımı <i>Device Description</i>	İmalatçı <i>Manufacturer</i>	Kodu <i>Code</i>	Sertifika Numarası <i>Certificate No</i>	Kalibrasyon Bitiş Tarihi <i>Calibration Due Date</i>
Receiver	Frankonia	LC92	E1803658	02/2019
LISN LS16C10	AFJ	LC290	0417-17	06/2019

9.7.3 Deney Prosedürü

Test Procedure

Numune ekranlı odanın 0.4 metre uzağında olacak şekilde konumlandırılır ve beslemesi LISN üzerinden gerçekleştirilir. Diğer destek üniteleri (varsa) güç beslemesine başka bir LISN ile bağlanır. Ölçü cihazı için bu LISN'lar 50 ohm / 50 uH 'lık bir empedans sağlamaktadır. Beslemenin her hattı en yüksek iletkenlik girişimine karşı kontrol edilir. Frekans aralığı 150 kHz – 30 MHz arasında taranır. Limitlerin 10 dB altındaki seviyeler raporlanmaz.

The EUT was placed 0.4 meters from the conducting wall of the shielded room with EUT being connected to the power mains through a line impedance stabilization network (LISN). Other support units were connected to the power mains through another LISN. The two LISNs provide 50 Ohm/ 50uH of coupling impedance for the measuring instrument. Both lines of the power mains connected to the EUT were checked for maximum conducted interference. The frequency range from 150 kHz to 30 MHz was searched. Emission levels over 10dB under the prescribed limits could not be reported.



9. RECYCLING

If you shall dispose of the device or replace any part of it, check the recyclability of each part.

For more information about recycling, please get in contact with relevant institutions and foundations or visit the websites that give information about recycling.

10. AUTHORIZED SERVICES

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