Instruction Manual

Ap439 2.0 Nxt

Precautionary Instructions

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:

CAUTION - Text with a “CAUTION” indicator will explain possible safety infractions that may cause minor to moderate injury or damage to equipment.

WARNING - Text with a “WARNING” indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.

DANGER - Text with a “DANGER” indicator will explain possible safety infractions that will cause instant hazardous situations resulting in death or serious injury.

NO SITTING – Text with a” NO SITTING” indicator will explain possible safety instructions that will potentially cause serious injury and equipment damage.

NO STEPPING ON SURFACE - Text with a **“NO STEPPING ON SURFACE”** indicator will explain possible safety infractions that will cause equipment damage.

NOTE: Throughout this manual “NOTE” may be found. These NOTES are helpful information to aid in the particular area or function being described.

NOMENCLATURE: The following are the symbols used in manual and sticker:

Hardware symbols:

 Type B	 IEC 60601 Medical Electrical Equipment Class TYPE BF
 Electrical TYPE Class II Symbol	 Output Indication
 DC Input Symbol	 Output 2 Lead Wires
 Output 1 Lead Wires	

Contents

1. INSTRUCTION FOR THE USER

Please read this instruction manual carefully before using Ap439 2.0 Nxt. Using the device without reading the instruction manual is unsafe and may have moderate to serious repercussions. The instructions on the following pages will illustrate how to use and care for your Ap439 2.0 Nxt device in general. You should be particularly familiar with the prescription and information precautions before proceeding.

Purpose of This Manual

This manual contains important information regarding the safe and effective use and operating of your Ap439 2.0 Nxt. Ap439 2.0 Nxt is an electrical device having effective long-lasting usage over the years, if properly cared and maintained, as described in this manual.

1.1 CAUTION

- USA Federal law restricts these devices to sale by, or on order of a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner
- DO NOT use sharp objects such as pencil point or ballpoint pen to operate the buttons on the touch screen
- This unit should be operated in temperature between +10°C to +40°C, transported and stored in temperature between -30°C to +60°C, with relative humidity ranges from 10% to 95%
- The Ap439 2.0 Nxt system is not designated to prevent the ingress of water liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient

1.2 Warnings

- The long-term effects of chronic electrical stimulation are unknown
- Stimulation should not be applied over the carotid sinus nerves, particular in patient with known sensitivity to the carotid sinus reflex
- The electrode should not be applied over the neck or mouth, or anywhere else on the head If stimulation is applied over the neck or mouth especially, severe spasm of the laryngeal and pharyngeal muscle may occur and the contraction may be strong enough to close the airway or cause difficulty in breathing
- Stimulation should not be applied trans-thoracially in that the introduction of electrical current into the heart may cause cardiac arrhythmias
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruption, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesion

1.3 Precautions

- Safety of the Ap439 2.0 Nxt for use during pregnancy has not been established
- Caution should be used for patient with suspected or diagnosed heart problems
- Caution should be used for patients with suspected or diagnosed epilepsy

Caution should be used in presence of following:

- When there is a tendency of haemorrhage following acute trauma or fracture following recent surgical procedures when muscle contraction may disrupt the healing process
- Over the menstruating or pregnant uterus
- Over area of the skin which lack normal sensation. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement
- Stimulation settings should be based on the guidance of the prescribing practitioner Electrode placement should be based on the guidance of the prescribing physician
- Ap439 2.0 Nxt should be kept out of the reach of children. The Ap439 2.0 Nxt should be used only with the electrode cables and electrodes recommended for use by the manufacturer
- The Ap439 2.0 Nxt should not be used while driving, operating machinery or during any activity in which Involuntary muscle contraction may put the user at undue risk of injury
- Ensure the intensity is adjusted slowly and smoothly and not increased beyond the patient's tolerance
- While treatment do not lift electrodes off the skin without the intensity being turned down to zero first
- Also be aware of the skin's resistance as this may suddenly drop causing the intensity to increase

1.4 Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with use of this device.

1.5 Conditions that affect use

The device should not be used in following conditions:

- The unit should not be used in wet environment
- Patient should not move while the treatment is ON, this may cause electrodes to leave the skin or electrode cables may break

1.6 Contraindicated conditions

It is contraindicated to apply Electrotherapy to patients with any of the following conditions:

1. Pregnancy
2. Cardiac pacemaker
3. Skin diseases

1.7 Contraindicated Areas

It is contraindicated to apply to any of the following areas:

1. To the eye
2. To the ear
3. Over a carotid sinus
4. To the heart

2. INTRODUCTION

Ap439 2.0 Nxt is an electrotherapy device with multi-waveform tailored to offer pain-relief and fulfil rehabilitation needs of the patients with most comfortable electrical stimulation. Ap439 2.0 Nxt device has capacitive panel for user- interface with two outputs (4 channels) of electrical stimulation (ESTIM). The clinician can provide two different treatments simultaneously through the two outputs. Ap439 2.0 Nxt is a user-friendly device and is a must have for every advanced physiotherapy clinic.

The device offers series of standard protocols:

- IFC (Interferential Traditional),
- IFC Pre modulated,
- Russian,
- Galvanic (DC and Interrupted),
- Faradic (Rectangular, Triangular)
- TENS (Conventional, Burst, and Modulation) and
- High-voltage pulsed current (HVPC) (Pulse, Continuous)

Whose parameters can be adjusted before the treatment and during the treatment.

The device has predefined (Pre-set) Protocols. The 8 Predefined Protocols which can be instantly utilized for specific conditions are:

- Oedema,
- Deconditioning,
- Chronic Pain,
- Acute Pain,
- Wound Healing,
- Endurance,
- Nerve block and
- Muscle Re-education.

2.1 Intended Use

A) Interferential current stimulation, Pre modulated Bipolar Mode, and Faradic stimulation mode is indicated for:

1. Symptomatic relief and management of chronic (long term) intractable pain
2. Adjunctive treatment in the management of post-traumatic and postsurgical acute pain condition

B) EMS (Russian and galvanic interrupted) is indicated for:

1. Relaxation of Muscle spasm
2. Prevention or Retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

c) Galvanic-DC Continuous mode is indicated for:

1. Relaxation of Muscle spasm

3. ACCESSORIES

The device comes with the necessary components as shown below:

S. No.	Particular	Quantity
1	User Manual-CD	1
2	Quick Reference Guide (QRF)	1
3	Adapter 24VDC 2.5A with AC Cord	1
4	Electrode Carbon size: 3" color: Gray	8
5	Electrode Sponge Pouch, Size:8.5X8.5 CM	8
6	Lead Wire 5pin 4 core	2
7	Patient Safety Cable	1
8	Elastic Belt 36cm	2
9	Elastic Belt 18cm	4
10	Pen Electrode	1

4. SPECIFICATIONS

4.1 General Specification

Length	:	300mm
Width	:	170mm
Height	:	75mm
Net Weight	:	Approx. 1.90 Kg
Power Input	:	220/110AC, 50/60Hz
Electrical Class	:	CLASS II A
Operating Temperatures	:	Between +10°C to +40°C
Storage Temperatures	:	Between -30°C to +60°C
Relative humidity of Operating	:	10% to 95%, non-condensing
Relative humidity of Non-Operating / Storage	:	10% to 95%, noncondensing
Frequency of use	:	2-3 times per day.

4.2 Technical Specification

Ap439 2.0 Nxt Predefined IFC Treatments

- **IFC (Interferential) Traditional (4 Pole) P1 –Specifications.**
  a. Beat Frequency:80 -150 Hz (fmin=80Hz, fmax=150Hz);
    - Sweep Low Beat Frequency: 80 Hz (fmin=80Hz);
    - Sweep High Beat Frequency: 150 Hz (fmax=80Hz);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC.

- **IFC (Interferential) Traditional (4 Pole) P2 –Specification**
  a. Beat Frequency:1 -50 Hz (fmin=1Hz, fmax=50Hz);
    - Sweep Low Beat Frequency: 1 Hz (fmin=1Hz);
    - Sweep High Beat Frequency:50 Hz (fmax=50Hz);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC

- **IFC (Interferential) Traditional (4 Pole) P3 –Specification**
  a. Beat Frequency:0 -10 Hz (fmin=0Hz, fmax=10Hz);
    - Sweep Low Beat Frequency: 0 Hz (fmin=0Hz);
    - Sweep High Beat Frequency: 10 Hz (fmax=10Hz);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC.

- **IFC (Interferential) Traditional (4 Pole) P4 –Specification**
  a. Beat Frequency:1 -150 Hz (fmin=1Hz, fmax=150Hz);
    - Sweep Low Beat Frequency: 1 Hz (fmin=1Hz);
    - Sweep High Beat Frequency: 150 Hz (fmax=150Hz);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC.

- **IFC (Interferential) Traditional (4 Pole) P5 –Specification**
  a. Beat Frequency:1 -250 Hz (fmin=1Hz, fmax=250Hz);
    - Sweep Low Beat Frequency: 1 Hz (fmin=1Hz);
    - Sweep High Beat Frequency: 250 Hz (fmax=250Hz);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC

- **IFC (Interferential) Traditional (4 Pole) CUSTOM –Specification**
  a. Beat Frequency:0 -250 Hz (fmin=0 -250 Hz, fmax=0 -250 Hz);
    - Sweep Low Beat Frequency: 0 -250 Hz (fmin=0 -250 Hz);
    - Sweep High Beat Frequency: 0 -250 Hz (fmax=0 -250 Hz);
    - System should contain protection that Low Beat Freq (fmin) must be lower than High Beat Freq (fmax);

  b. All other parameters as well as the waveforms are the same as they are defined for general IFC

- **IFC Premodulated Specification**
  a) Waveform: Step Sine Wave;
  b) Topology: ESTIM CV (Constant Voltage);
  c) Configuration:2P (it is working in 4P, please consider comment);
  d) Available on Channel(s):1&2 or 3&4;
  e) Carrier Frequency:4000 Hz;
  f) Beat Frequency: 1 -250 Hz (Fixed)
    - Sweep Rate:1Hz/200msec;
  g) Cycle ON Time:1 –30 Sec;
  h) Cycle Off Time:0 –30 Sec (0 for continuous);
  i) Ramp up/down time: 2/2 Sec (cannot be changed);
  j) Intensity: 0 – 100%;
  k) Output voltage: 0 –70Vpp @ 500Ω Resistive load;

- **IFC Russian Specification**
  a) Waveform: Step Sine Wave;
  b) Topology: ESTIM CV (Constant Voltage);
  c) Configuration:2P (it is working in 4P, please consider comment);
  d) Available on Channel(s):1&2 or 3&4;
  e) Carrier Frequency:2500 Hz sine wave frequency modulated by a 2550 Hz fixed frequency sine wave of equal amplitudes;
  f) Cycle ON Time:1 –30 Sec;
  g) Cycle Off Time:0 –30 Sec (0 for continuous);
  h) Ramp up/down time: 2/2 Sec (cannot be changed);
  i) Intensity: 0 – 100%;
  j) Output voltage: 0 –70Vpp @ 500 Resistive load;

4.3 TENS

- **TENS Conventional**

  TENS Conventional protocol is performed through one ESTIM channel (two electrodes). This protocol can be started on single channel (channel #1 or channel #2) or on both channels simultaneously.

Specification:

a) Waveform: Symmetrical Biphasic Square wave;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Frequency:1–150 Hz;
f) Pulse Width:50–400 µsec;
   - Step 50 µsec;
g) Cycle ON Time:1 –30 Sec;
h) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
i) Ramp up/down time: 2/2 Sec (cannot be changed);
j) Intensity: 0 – 100%;
k) Output voltage: 0 –80Vpp @ 500Ω Resistive load;

- **TENS Burst**

a) Waveform: Symmetrical Biphasic Square wave;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Frequency:1–150 Hz;
f) Pulse Width:50–400 µsec;
   - Step 50 µsec;
g) Burst rate:7 Pulses per Burst in 14 slots (7 ON / 7 OFF);
h) Cycle ON Time:1 –30 Sec;
i) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
j) Ramp up/down time: 2/2 Sec (cannot be changed);
k) Intensity: 0 – 100%
l) Output voltage: 0 –80Vpp @ 500Ω Resistive load;

- **TENS Modulation**

a) Waveform: Symmetrical Biphasic Square wave;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Frequency:1–150 Hz;
f) Pulse Width:50 –400µsec;
   - Step 50 µsec;
g) Modulation: Pulse width (PW) modulation;
h) Modulation Period: total 4sec; 2 Seconds for changing Pulse Width from 100% of PW to PW-40% of PW (60% of PW) and 2 seconds for return back to 100% of PW;
i) Cycle ON Time:1 –30 Sec;
j) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
k) Ramp up/down time: 2/2 Sec (cannot be changed);
l) Intensity: 0 – 100%
m) Output voltage: 0 –80Vpp @ 500Ω Resistive load;

4.4 Galvanic

- **Galvanic–Continuous DC**

a) Waveform: Constant value;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Polarity Reversal: On or Off;
   - With Polarity Change On, polarity will change every 5 minutes;
f) Cycle ON Time:1 –30 Sec;
g) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
h) Ramp up/down time: 2/2 Sec (cannot be changed);
i) Intensity: 0 – 100%;
j) Output voltage: 0 –16Vpp @ 500Ω Resistive ohm load;

- **Galvanic –Interrupted DC**

a) Waveform: Monophasic Rectangular Pulses;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Pulse ON Period: from 1msec to 2msec in accordance with rule:
   - 2msec for Intensity 0 – 50% (Output Voltage: 0 – 17.5Vpp); linear dependency from 2msec to 1msec for Intensity 50% -100%
   - (Output Voltage 17.5 – 35.0Vpp);
f) Frequency:1Hz (fixed);
g) Polarity Reversal: On or Off;
h) Cycle ON Time:1 –30 Sec;
i) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
j) Ramp up/down time: 2/2 Sec (cannot be changed);
k) Intensity: 0 – 100%;
l) Output voltage: 0-35Vpp @ 500Ω Resistive ohm load;

4.5 Faradic Current (Rectangular)

a) Waveform: Monophasic Rectangular Pulses;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Pulse width:0.1 –1 msec (selectable);
   - Step:0.1 msec;
f) Frequency:30 –70 Hz (selectable);
   - Step:1Hz;
g) Polarity Reversal: On or Off;
h) Cycle ON Time:1 –30 Sec;
i) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
j) Ramp up/down time: 1 –9 Sec (selectable);
k) Intensity: 0 – 100%;
l) Output voltage:
   - 0 – 70Vpp @ 500 Resistive ohm load when the Pulse Width is in the range 0.1 –0.5msec;
   - 0 – Vmax @ 500 Resistive ohm load when the Pulse Width is in the range 0.5 –1msec. In this case, the Vmax depends of selected value of Pulse Width and it is linear function defined by these two points: [Pulse Width, Vmax] = [0.5msec, 70Vpp] and [Pulse Width, Vmax] = [1msec, 35Vpp];

4.6 Faradic Current (Triangular)

a) Waveform: Monophasic Triangular Pulses;
b) Topology: ESTIM CV (Constant Voltage);
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Pulse width:0.1 – 5 msec (selectable);
   - Step:0.1 msec;
f) Frequency:5 – 60 Hz (selectable);
   - Step:1Hz;
g) Polarity Reversal: On or Off;
h) Cycle ON Time:1 – 30 Sec;
i) Cycle OFF Time:0 – 30 Sec (0 for continuous mode);
j) Ramp up/down time: 1 – 9 Sec (selectable);
k) Intensity: 0 – 100%;
l) Output Voltage:
   - 0 – 70Vpp @ 500 Resistive ohm load when the Pulse Width is in the range 0.1 –1msec;
   - 0 – Vmax @ 500 Resistive ohm load when the Pulse Width is in the range 1 – 5msec. In this case, the Vmax depends of selected value of Pulse Width and it is linear function defined by these two points: [Pulse Width, Vmax] = [1msec, 70Vpp] and [Pulse Width, Vmax] = [5msec, 14Vpp];

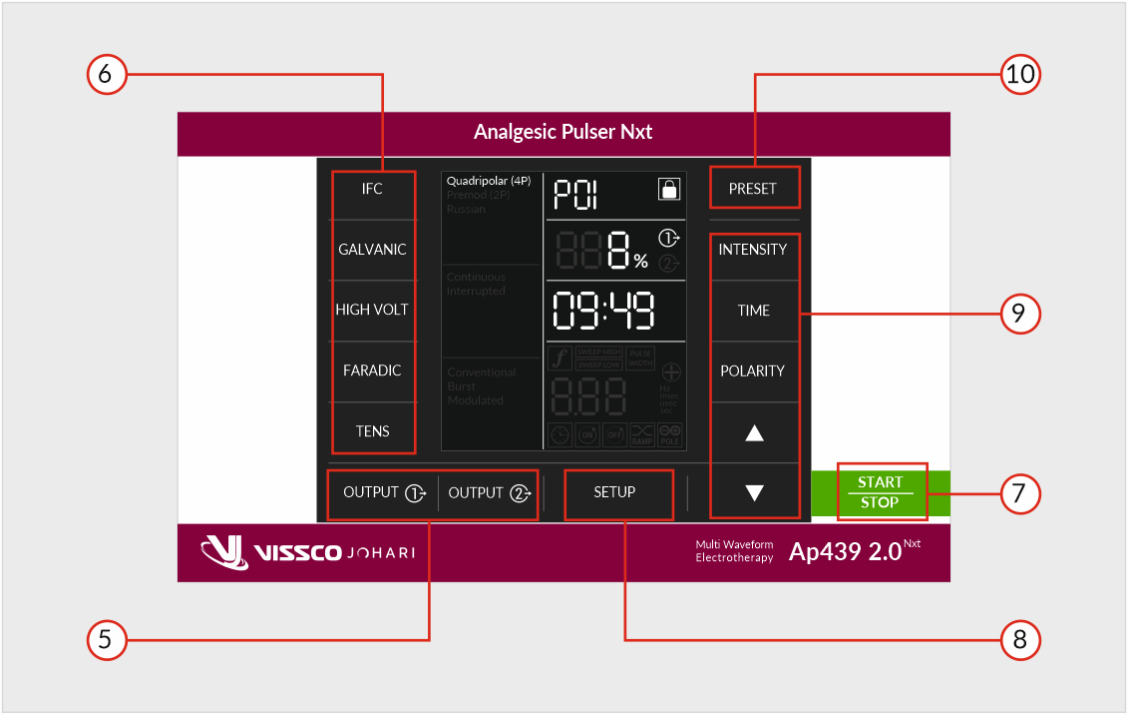
4.7 High Voltage Continuous

a) Waveform: Two monophasic pulses on the distance of ~70usec;
b) Topology: HVPC;
c) Configuration: 2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Polarity: Positive or Negative
f) Frequency: 10 – 120Hz / step 10Hz;
g) Cycle ON Time: 1 – 30 Sec;
h) Cycle OFF Time: 0 – 30 Sec (0 for continuous mode);
i) Ramp up/down time: 0.5 Sec, 1 Sec, 2 Sec, 5 Sec;
j) Intensity: 0 – 100%;
k) Output Voltage: 500Vpeak@ 500Ω Resistive ohm load;

4.8 High Voltage Pulsed Current (HVPC)

a) Waveform: Two monophasic pulses on the distance of ~70usec;
b) Topology: HVPC;
c) Configuration:2P (it is working in 4P, please consider comment);
d) Available on Channels: 1&2, 3&4;
e) Polarity: Positive or Negative
f) Sweep: Pulsed, 80/120 pps; 1/120 pps; 1/10 pps;
g) Cycle ON Time:1 –30 Sec;
h) Cycle OFF Time:0 –30 Sec (0 for continuous mode);
i) Ramp up/down time: 0.5 Sec, 1 Sec, 2 Sec, 5 Sec;
j) Output voltage: 500Vpeak@ 500Ω Resistive ohm load;
k) Intensity: 0 – 100%;

4.9 CONTROLS & FUNCTIONS



The front panel of Ap439 2.0 Nxt has following functions explained below.

1. **Output Socket:** Used to give the output for the treatment with the help of lead wire
2. **Patient Switch:** The patient emergency stop switch is connected to the device via cable to turn off the device immediately by patient in case of emergency. When the Patient presses the Emergency Stop Button, the device will pause all stimulations (all started treatments) without any delay. The treatments can be resumed only through main user interface. This means that paused treatments cannot be resumed by Patient Switch, you have to start the treatment by tapping on the start/stop option
3. **Adaptor Socket:** It is used to connect the line cord into the grounded wall outlet
4. **Rocker Switch:** To start (ON) the device press the rocker switch
5. **Output 1 and 2 Icon:** This Icon is used to select the output channel 1&2 or channel3&4. The backlight indication will provide info about selected channels (output)
6. **Mode Selection Icon:** This option is used to select the treatment modes as per requirement: IFT (IFC), TENS, GALVANIC, HIGH VOLTAGE, FARADIC

7. **Start/Stop Icon:** Start/Stop icon on the panel is provided to start or stop a particular treatment
8. **Setup Icon:** This icon is used to select or enter the following parameters of treatment: Cyclic ON, Cyclic OFF, Ramp Up/Down, Frequency, Low Beat Frequency; High Beat Frequency, Pulse Width
9. **Time/Intensity/Polarity/ Increment / Decrement (Up/Down) Selection Icon:** This icon is used to setup the treatment time/Intensity/Polarity. You can increase or decrease the following parameters: Time, Cyclic ON, Cyclic Off, Ramp Up/Down, Frequency, Low Beat Frequency, High Beat Frequency, Pulse Width, pre-set Protocols, Time, Intensity
10. **Pre-set:** This icon is used for selecting pre-set treatments

Note:

1. No Load Detection: At no load user will not be able to increase the intensity above 5% but this is not applicable to High voltage Pulse Current Treatment Mode
2. Output Switching: In order to switch between two outputs, Select Output on Panel
3. Screen Lock: After 60 sec of inactivity, screen gets locked. To unlock, long tap on any Icon for 3 seconds

4.10 DEVICE TREATMENT MODE

1. The device supported the treatment modes:

- IFC has three sub wave forms:
  a. (Interferential Traditional),
  b. IFC Pre-modulated
  c. Russian
- Galvanic has two sub wave forms:
  a. DC
  b. Interrupted
- Faradic has two sub wave forms:
  a. Rectangular
  b. Triangular
- TENS has three sub wave forms:
  a. Conventional,
  b. Burst,
  c. Modulation and
- High-voltage pulsed current (HVPC) has two sub wave forms:
  a. Continuous
  b. Pulse

Note: The above parameters can be adjusted before or in between the treatment.

2. This device supports 8 predefined protocols as mentioned below:

Preset	Protocol Name	Current/Waveform
P1	Oedema	High voltage Pulsed Current
P2	Deconditioning	Biphasic Square Wave
P3	Chronic Pain	Pre-modulated sine wave
P4	Acute Pain	Interferential (IFT)
P5	Wound Healing	High voltage Pulsed Current
P6	Endurance	Biphasic Square wave
P7	Nerve Block	Faradic Current
P8	Muscle Re-education	IFT (Russian)

Note: The above parameters are predefined and can be selected through Preset mode.

5. DEVICE OPERATION MODE

5.1 PREPARING ELECTRODES:

- Use only the electrode cables and electrodes provided with the device by manufacturer.
- Make sure that the entire surface of the electrode is in firm contact with the skin.
- Prepare the skin prior to electrode application. Cleaning of skin shall eliminate any impairment to current conduction on the patient's skin such as an oily or dry surface, or excessive hair coverage. Shaving may be necessary depending upon the density of hair coverage.
- Failure to provide for maximum current conduction efficiency could result in skin irritation relating to increase in current density at electrode site.
- We strongly recommend careful maintenance of the electrodes. This includes the maintenance of electrode cable and the electrodes. Worn cables and/or poor electrodes (or wrong sized electrodes) can have a significant impact upon treatment results.

5.2 PREREQUISITES:

- Electrodes should never be placed in such a manner as to produce current flow through the cardiac area. The patient should be suitably positioned ensuring maximum comfort and suitable exposure of the body part to be treated.
- Carefully mark the points where electrodes are to be placed and place the electrodes accordingly.
- The electrodes should be applied to the marked points.
- The patient should be explained about the subjective sensory motor feeling that he/she will experience. The patient should experience a sensation of deep, sufficiently strong but pleasant vibrations at rhythmical frequencies and a pleasant tingling sensation.
- Patient should immediately inform the therapist, of any unpleasant sensation or any other discomfort.
- Review prerequisites, contraindications and adverse reactions listed above before starting the device.

5.3 PREPARING THE SKIN

Before applying electrodes, ensure that the areas selected for electrode placement are cleaned properly and the skin is clear and free of surface debris.

6. How to Operate Device

6.1 PLUG IN THE DEVICE

Connect the line cord to the back side of the device. Plug the line cord into the grounded wall outlet that has 110 or 220VAC/50,60Hz. Your supply must match the voltage requirements. Do not connect the Ap439 2.0 Nxt to a power supply rated differently than described above.

6.2 Device ON

You can switch ON the device with the help of rocker switch, located on the back side of the device.

6.3 Audio Indication

There is audio indication provided through buzzer, which beeps on below respective condition.

- Key pressed sound - The single “beep” effect
- Error sound –Repeated 2 times beep;
- Treatment time timeout indication – Long beep

6.4 Visual Indication

There is visual indication provided through LED, which blink or stable which is described below

- Blinking: Active state, it can be changed by user.
- Stable: Inactive state or selected state, the displayed information shows the user selected choice.
- All LEDs Blinking: It states that Error has generated.

6.5 DEVICE OPERATION RUN TIME

Default treatment time is 10 minutes for all standard treatments. But user can change the time duration from 5 minutes to 60 minutes with the help of increment option as required. The increment (step) in process of setup the treatment time is 5 minutes.

6.6 DEVICE INTENSITY

The strength of stimulation will be controlled by Intensity. The Intensity can be adjusted during a treatment or when the treatment is paused. You can adjust the intensity from 1 to 100 with the help of increment option.

Note:

1. Polarity can be changed (Either positive/negative) before the treatment starts. User cannot alter the polarity once the treatment begins.

2. HOW TO START THE MODE SELECTION TREATMENT IN THE DEVICE?

- Select any output (Output 1 or Output 2) and then tap on any of the treatments (Galvanic, TENS, IFC, High volt and Faradic) by tapping on the setup icon. After the selection of the treatment, press the start icon present on the panel.
- In any of the treatments (Galvanic, TENS, IFC, High volt and Faradic), user can change the intensity and time by tapping on the Up/down arrow icon on the panel and then pressing the start icon.

6.7 How to go back to the treatment:

To go back to the any treatment mode long tap on the start/stop button.

7. Turning off the device

- Press the rocker switch to Switch OFF the device.
- Remove adaptor's pin from DC input socket on the back side of the device.
- Disconnect the adaptor's AC cord into a grounded wall outlet that has 110-220 V AC, 50/60 Hz.

8. TROUBLESHOOTING

OBSERVATION	POSSIBLE CAUSE	REMEDY
Weak stimulation or No stimulation even at maximum intensity setting	Poor electrode contact	Check the electrodes
	Electrode conduction is low or lead wire is worn out	Change electrodes. Change electrode wires.
Uncomfortable stimulation or too strong stimulation	Lack of conductive gel	Pause the stimulation, put more conductive gel and reposition the electrodes on the treatment area. Then restart treatment.
Skin irritation at electrode placement site	Improper contact/gel fried up	Wet or change the electrode
Sudden high intensity while increasing intensity level	Increasing too fast	Increase slowly giving time to patient to his comfort

9. MAINTENANCE

9.1 Cleaning the device

- The device must be switched off by the main switch when cleaning. The main power switch has to be in OFF ("0") position
- The device must be cleaned thoroughly prior to usage to remove visible soil. To clean the device, use a soft cloth slightly moistened with water. Never use agents containing alcohol, chlorine, ammonia, acetone, benzene or thinners
- Clean the touch screen gently by using a dry soft cloth. The cloth may be slightly moistened with a commercially available screen cleaner. Never apply the cleaner directly on the screen! Never use abrasive materials, otherwise the surface of the device or accessories could get damaged
- Always turn the device off before disinfecting the lead wires. Disinfectants must not reach the air vents
- Clean the lead wires after each use with disinfectants approved for use in medical environments. Do not use agents containing chlorine or those with a high alcohol content (more than 20%)
- Use a soft cloth slightly moistened with disinfectant. After disinfection, the accessories must be rinsed with a soft cloth slightly moistened with clean water so as to prevent an undesired allergic reaction!
- The device's accessories are designed for non-invasive use; therefore, they do not require sterilization

9.2 Cleaning the accessories

Electrode Cables:

- For routine cleaning of the electrode cables use soap and water and thoroughly dry them after cleaning
- Electrode wires should be kept loosely winded or breakage may occur

9.3 Care for Electrodes:

- Use the electrodes recommended by the manufacturer
- Adhere to the instructions attached to the electrodes
- Do not use a single pack of electrodes on multiple user's / patients. Each patient should have its own electrode pack.
- Do not immerse electrodes in any liquids
- Store the electrodes in a re-sealable pouch or plastic bag
- If electrodes get soiled or lose their adhesion; it is advised that you replace them
- After using any of these electrodes, grasp the corner of the electrode and gently remove it from your skin
- Do not pull on the electrode snap or wire connection. Reapply the release liner to the adhesive side of the electrode. Store the electrode in a re-sealable pouch or plastic bag'

10. Routine Maintenance

10.1 Overview

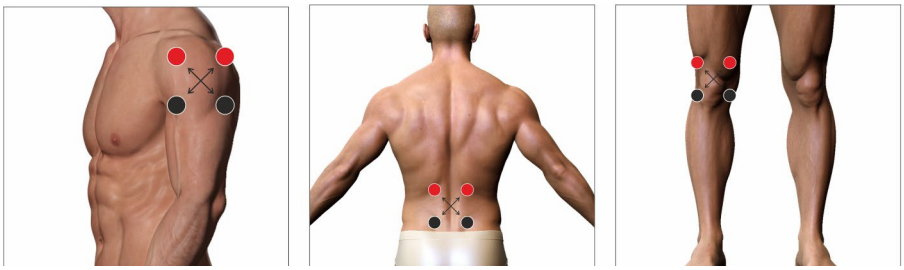
- Before any maintenance, switch the device off and unplug it from the mains! Observe all safety principles. Never dismantle the device and its accessories during cleaning!
- Do not repair the device. All servicing must be carried out by an authorized Johari Digital service centers. Only original parts can be used for repair; otherwise, Johari Digital bears no responsibility for further operation of the device.
- Before contacting your authorized Johari Digital service center, make sure you have the device model number, serial number and a detailed description of the issue you have encountered

11. SUGGESTED ELECTRODE PLACEMENT CHART

⚠ **Caution:** The device should only be operated under supervision of a registered medical practitioner.

Electrode placements shown in this library are only for reference purposes. Actual electrode placement may vary according to pain area or patient's condition

For Interferential



For TENS

12. WARRANTY

This product warranty extends to the original consumer/ purchaser of the product.

12.1 WARRANTY COVERAGE

This product is warranted to be free from defects in materials and workmanship for a period of one (1) year. This warranty ceases if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, repair by unauthorized personnel or cause not arising out of defect in materials or workmanship. This warranty does not extend to any units which are used in violation of the guidelines set forth in this manual, or to units which have been altered or modified, or to damage to products or parts which have had the serial number removed, altered or defaced or rendered illegible

12.2 WARRANTY DISCLAIMERS

This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer any other liable in connection with the sale of our products. There shall be no claims for defects or failure of performance or product failure/ any theory of tort, contract or commercial law including, but not limited in negligence, gross negligence, and strict liability, breach of warranty and breach of contract. Some states do not allow the exclusion or limitation of implied warranties or consequential damages, so the above limitations may not apply to you. Manufacturer is not responsible or liable for indirect special or consequential damages arising out of or in connection with the use/performance of the product or other damage with respect to loss of property or loss revenues or profit

12.3 LEGAL REMEDIES

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

12.4 WARRANTY PERFORMANCE

During the above one-year warranty period, a product with a defect will be repaired or replaced with a reconditioned comparable unit at distributor's discretion, when the product is returned to the distributor. The repaired or replacement product will be in warranty for the balance of the one-year warranty period and an additional one-month period. No charge will be made for such repair or replacement.

12.5 CUSTOMER SERVICE

For in warranty service for a product covered under the warranty period, no charge is made for service and return postage. Please return the product insured, packed with sufficient protection, postage insurance, prepaid to the address. Customer's duty/brokerage fee, if any, must be paid by the consumer.

12.6 Warranty Period

12-months standard warranty, 1-3 year's optional warranty

12.7 OUT OF WARRANTY SERVICE

There will be charges rendered for repairs made to the product after the expiration of the one (1) year warranty period, after purchaser is advised appropriately. The distributor cannot assume responsibility for loss or damage during shipment. For your protection, carefully pack the product for shipment and insure it with the carrier. Ensure that you return the unit and accessories related to your problem and also that you indicate full return address. Also send a copy of sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

Please send above warranty information and in the case if replacement of any accessory is needed to following address:

12.8 End of Life Disposal - Environmental Information

The Ap439 2.0 Nxt must be disposed of according to local laws and hospital practices. This product is considered electronic equipment and must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

JOHARI DIGITAL HEALTHCARE LTD.
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TOLL FREE: 1800-102-8684 | Email : info@joharidigital.com
www.joharidigital.com

List of Accessories: (In case of replacement or ordering)

S.No.	Description	JDHL Part
1	Elastic Size 3" x 18" w/2 Side Hooks, with logo BOM	20MF24005
2	Elastic Size 3" x 36" w/2 Side Hooks, with logo BOM	20MF24007
3	Lead Wire 5pin 4 core length 2.5mtr colour gray (Printed RedA+;BlackA-;RedB+;BlackB-);	50CFG00011
4	Electrode Carbon size: 3" color: Gray	50AFG00003
5	Electrode Sponge Pouch, Size:8.5X8.5 CM	40SFG00002
6	Cable Assembly 3.5mm Jack Patient Switch BOM	20MF32052
7	Adaptor 24VDC 2.5A Color: Black	50AEE00046
8	AC Cord Round 3Pin 5A	40SEE00033
9	Pen Electrode	20MF04001

A statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of the EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL

Marketed By

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