

Quick Reference Guide

NuEra tight

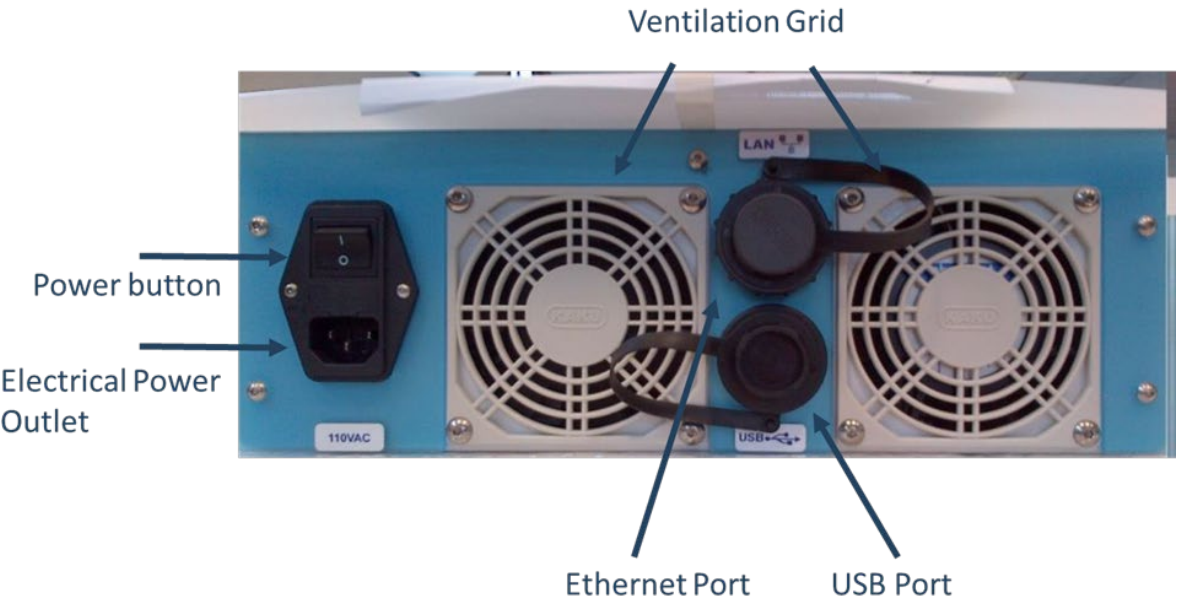


Device overview

Console Front View



Console Rear Panel



Handpieces, Electrodes, , Massage head and Return Pad



(Large handpiece): recommended size of the electrode: 40~100 mm



Face and small treatment areas (Small handpiece): recommended size of the electrode*: 20~40 mm



Bipolar handpiece- face



Patient return pad (silicone pad)

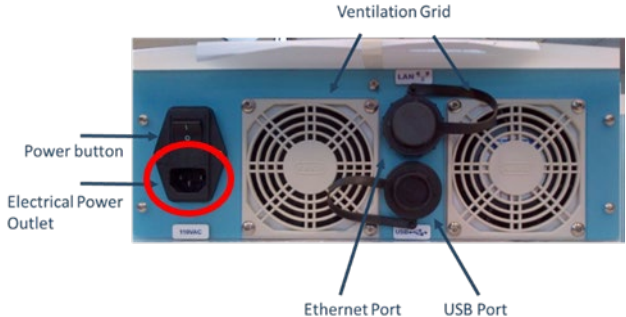
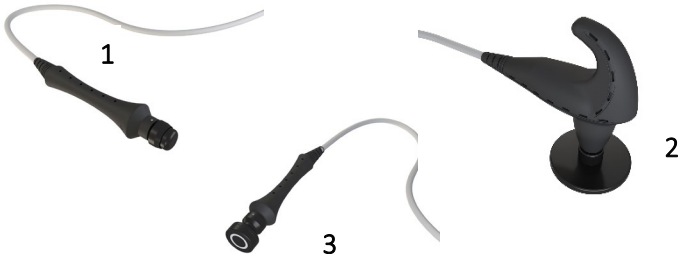


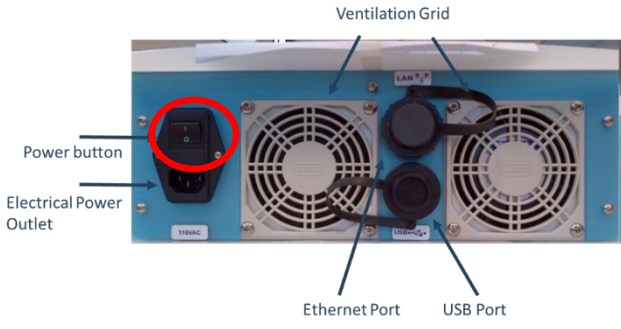
Electrodes

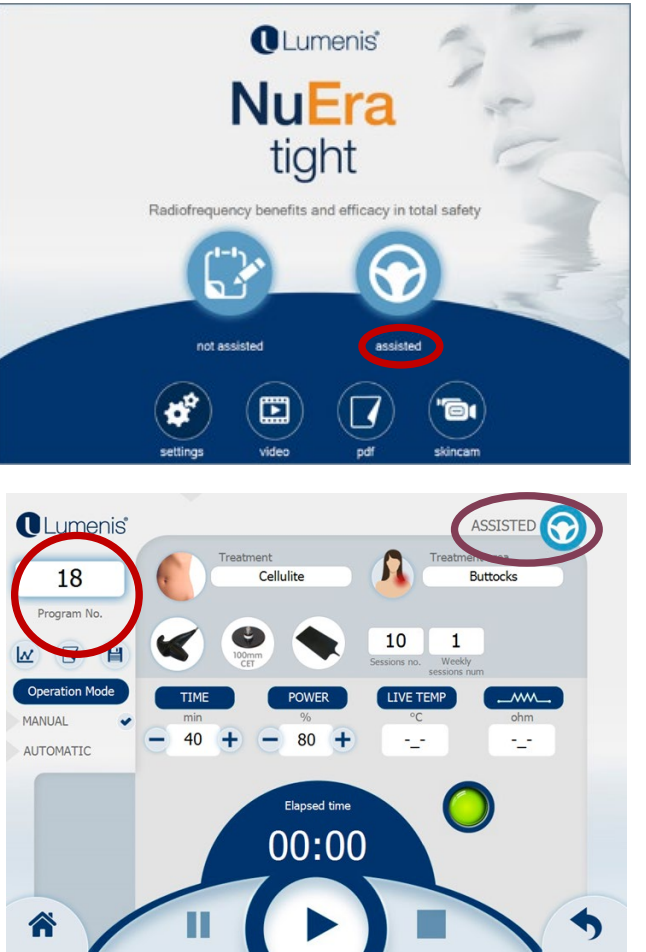


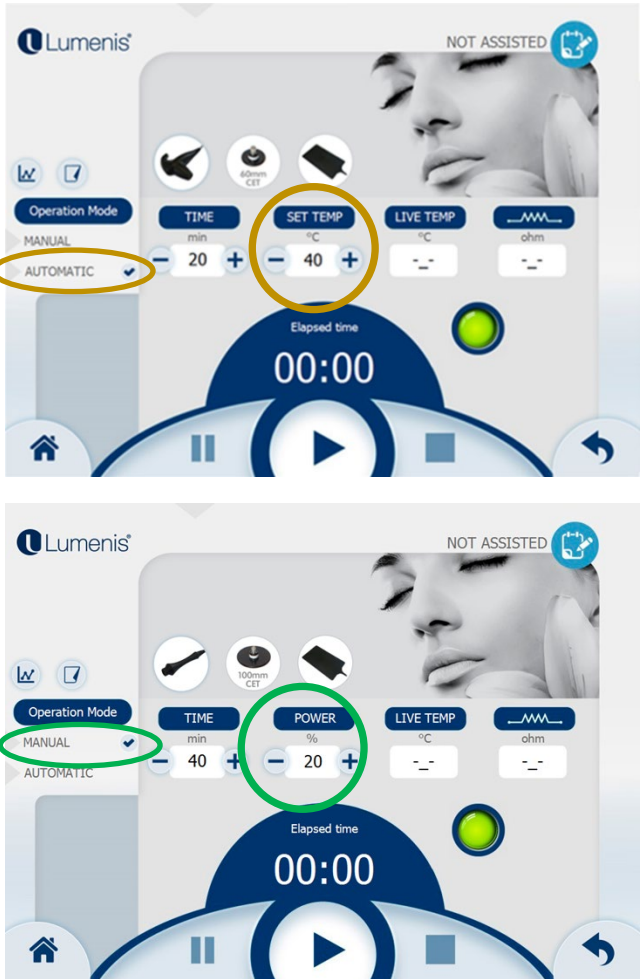
Lymphatic massage head

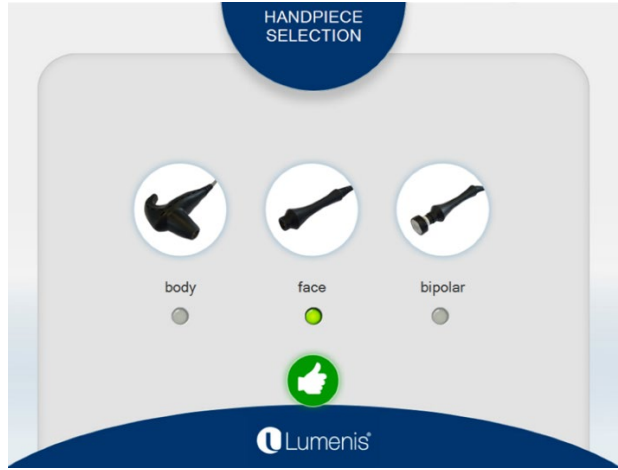
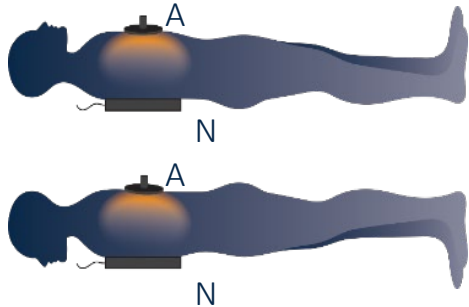
Preparation and system initialization

1.	Verify that the NuEra system including the Handpiece and all accessories (coupling lotion, electrodes, return pad) are made available, perfectly clean and undamaged	
2.	Plug the system main power plug into a dedicated wall socket	
3.	Connect the appropriate handpiece <u>Small</u> (face handpiece): recommended size of the electrode*: 20~40 mm <u>large</u> (body handpiece): recommended size of the electrode*: 40~100 mm <u>Bipolar</u> handpiece – fixed electrode. The return pad is not required	
4.	Connect the appropriate electrode For <u>large treatment areas</u> (i.e thighs, abdomen), preferably choose an electrode with a larger diameter For <u>small localized treatment areas</u> (face, neck, eyes...) preferably choose a smaller diameter electrodes (The smaller the electrode size, the faster the set temperature is achieved)	

5. Connect the Return pad cable to the connection on the front right side of the machine, lining up the two red dots.	
6. Turn the main On/Off switch on the rear panel to the "I" (I/O) position.	
7. Access the system 'settings' using the touch screen display to set the preferred language and the max temperature you wish to use during the treatment procedure	

		
Modes of Operation		
8.	Assisted Mode Press the 'assisted mode' button in order to choose one of the <u>pre-defined</u> programs with a suggested combination of settings To select the desired program go to the <u>top left window</u> and select the appropriate indication and anatomic area. The system will set all the single suggested parameters. You can adjust all secondary configurations at any time: ○ Automatic or manual operation ○ Electrode size ○ Handpiece type ○ Procedure time ○ Power/temperature ○ Number of sessions and treatment intervals	

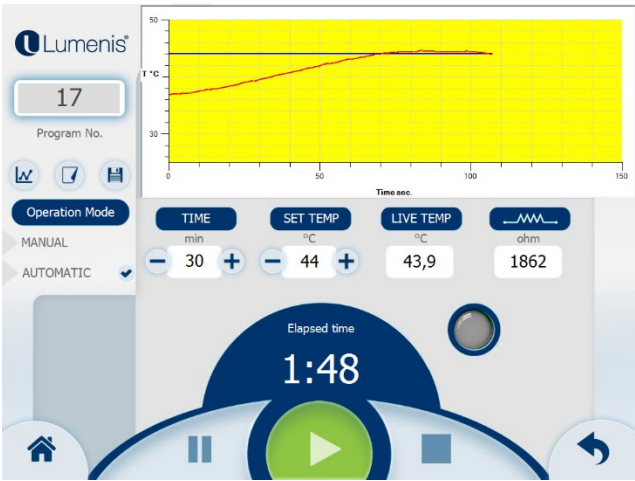
9. <u>Non-Assisted menu</u> Set all of the parameters and perform the treatment <u>without</u> any predefined settings - Treatment time (5 minutes interval) - Electrode size (20-100 mm) - Handpiece type (Large, small or Bipolar)	
10. <u>Automatic or Manual mode</u> If you choose <u>'Automatic Mode'</u> - In this mode, <u>the temperature is set</u> to reach the set temperature and then modulates to keep the temperature steady (The goal is to reach the maximum temperature tolerated by the patient, and to maintain this temperature for the desired time suggested). If you choose <u>Manual Mode</u> - In this mode, <u>the user selects the power percentage</u> and is able to regulate it during treatment in accordance to the reached temperature . The temperature is measured and the graph is displayed, same as in Automatic mode. Power can be set (5-100%)	

11. <u>Handpiece Selection</u>	
12. <u>Electrode selection</u>	
13. <u>Apply return pad:</u> Place the return pad on an appropriate location for application zone - Select the back or the abdomen as first choice for all the treatment. Return pad should maintain full contact with dry skin at all times Avoid return pad placement on bony prominences and thicker areas of hair If patient is repositioned during application, pause RF output and reposition return pad prior to resuming application	

14. Press the start button



15. Treatment is completed when the treatment time ends and a slight redness (erythema) in the treated area appears



User Safety precautions

DO	DON'T
Ensure that the treated area and target location of the return plate is hair free (It is recommended to shave a day prior to the treatment)	DO NOT allow untrained personnel to operate the system
Wear gloves	DO NOT remove any system covers. Only Lumenis-authorized service engineers are licensed to do so
Ask patient to remove any jewelry and all metal objects	DO NOT stay on one area for more than 10-20 seconds, this can create excess heat, potentially causing erythema or burn, especially when you have reached the target temperature
Remove from yourself all metal objects	DO NOT touch the screen if you have residuals of cream on the gloves
Ensure patient position allows electrode and return plate to remain in <u>FULL CONTACT</u> with skin surface for entire treatment duration	Avoid treating with big electrode the body area that cannot be fully covered (ie with the 80 mm on the knee). The full electrode surface must be in contact with the skin (mid pressure)
Pay attention to the patient's ongoing feedback during the treatment and the temperature as presented on the touch screen	
Always turn the system OFF when the system is not in use. Ensure that the system is in OFF position before storing the handpiece	
Place the electrode on the treatment area before pressing the start button and starting the treatment	

Contraindications*

- Pregnancy
- Pacemaker, defibrillators or other implanted devices which activity can be affected by RF exposure
- Active local or systemic infections
- Any disease in which a temperature increase is contraindicated
- Any other clinical contraindication according to doctor's examination

Warnings

- DO NOT use the NuEra over PIERCINGS and tattoos
- DO NOT treat directly over areas containing injectable fillers and toxins for one month.
- DO NOT use the NuEra in patients with any active condition in the treatment area, cut, wounded or infected skin
- DO NOT use the NuEra in patients with insensitivity to heat in the treatment area
- DO NOT use anesthesia (local, oral, or systemic) should be used prior to or during the NuEra treatment
- DO NOT use the NuEra in patients with metal implant(s) in the treatment area

*For the complete list of contraindications, refer to the NuEra user manual

Application Protocol

- Patient signed consent forms
- Patient signed Photos release form, if applicable
- It is recommended to take before and after treatment photographs (Consistency is essential in positioning of the patient, camera and lighting)

Marking the treatment area:

- The application zone should be 4x to 6x the size of the electrode



Pre-treatment preparations

- Dry the treatment area well prior to the NuEra tight treatment
- Place the return pad on an appropriate location for application zone. The patient should **NOT MOVE** during treatment. If patient is repositioned during application, **PAUSE THE TREATMENT** and reposition return pad prior to resuming application
- Apply conductive cream on the treatment area (moderate amount – 1mm height) and on the electrode, and keep it moisturized during the entire treatment session

Treatment Application

- **MAKE SURE THAT THE ENTIRE ELECTRODE SURFACE IS IN FULL CONTACT ON THE SKIN**
- It is recommended to set the initial target temperature to 40°C and increase it gradually to the desired target temperature (usually within 2 minutes)
- Press play after the electrode is in touch with the skin
- Treatment should be done with slow movements in a circular motion (Erythema should be present during and at the end of application and may be present for hours after application)
- Treatment movement's speed can be slow at first (to enhance the temperature elevation), then gradually increased and stabilized for the entire session. Movement speed should be adjusted in accordance to the patient feedback and the temperature as appear on the touch screen.

Post-Application Care

- Wipe away any remaining cream from the electrode and from the skin
- The console, handpieces and electrodes can be wiped using a non alcoholic, non abrasive cleaner/disinfectant wipes (e.g. Protex)
- There are no physical restrictions post-treatment. The patient may resume activity or exercise routinely

Suggested Treatment Parameters

NuEra tight offers a two (2) Steps approach:

STEP 1 - GETSMOOTH: An initial treatment regime designed to meet the patient's expectations. Mostly includes series of **four (4) to six (6)** treatments **once every week or any other week**, depends on the treated indication and the patient's clinical condition.

STEP 2 – STAYSMOOTH: Maintain the achieved results with a routine FU treatments. Mostly includes **one (1) additional treatment** after two (2) or three (3) months.

The following treatment parameters are based on the physician experience, in accordance with the size of the treatment area and patient's tolerance to varying degrees of temperature

Intensive increase in local microcirculation

Program	Area	Mode	Electrode Type	Electrode Diameter	Temperature C°	Power	Time (Min)	Number of treatments	Treatment intervals (weeks)
1	Chin	AUTO	BIPOLAR	-	40°C	-	20	5	1
10	Abdomen	AUTO	CAPACITIVE	40 massage	41°C	-	20	6	1
11	Hips	AUTO	CAPACITIVE	40 massage	41°C	-	10	6	1
12	Buttocks	AUTO	CAPACITIVE	40 massage	41°C	-	10	6	1

Increase in local microcirculation

Program	Area	Mode	Electrode Type	Electrode Diameter	Temperature C0	Power	Time (Min)	Number of treatments	Treatment intervals (weeks)
2	Face	AUTO	BIPOLAR	-	40°C	-	20	6	2
3	Eye contour	AUTO	CAPACITIVE	20	39° C	-	10	4	2
4	Chin	AUTO	CAPACITIVE	30	40°C	-	15	5	1
5	Decolletè	AUTO	CAPACITIVE	40	40°C	-	20	6	2
6	Arms	AUTO	CAPACITIVE	40	42°C	-	15	6	1
7	Breast	AUTO	CAPACITIVE	60	40°C	-	20	4	2
8	Abdomen	AUTO	CAPACITIVE	100	40°C	-	30	6	1
9	Hips	AUTO	CAPACITIVE	70	40°C	-	15	6	1

Muscle spasm

Program	Area	Mode	Electrode Type	Electrode Diameter	Temperature C0	Power	Time (Min)	Number of treatments	Treatment intervals (weeks)
25	Abdomen	MANUAL	CAPACITIVE	100	40°C	70	30	6	1
26	Hips	MANUAL	CAPACITIVE	70	40°C	70	15	5	1
27	Buttocks	MANUAL	CAPACITIVE	100	45°C	80	20	6	1
28	Thighs	MANUAL	CAPACITIVE	80	40°C	80	20	5	1
29	Face	AUTO	BIPOLAR	-	40°C	-	10	5	1

Relief of Pain

Program	Area	Mode	Electrode Type	Electrode Diameter	Temperature C°	Power	Time (Min)	Number of treatments	Treatment intervals (weeks)
30	Chin	AUTO	CAPACITIVE	40	40°C	-	15	5	1
31	Arms	AUTO	CAPACITIVE	70	40°C	-	10	6	1
32	Abdomen	AUTO	CAPACITIVE	60	40°C	-	20	6	1
33	Hips	AUTO	CAPACITIVE	80	45°C	-	20	6	1
34	Thighs	AUTO	CAPACITIVE	60	40°C	-	15	6	1

Cellulite

Program	Area	Mode	Electrode Type	Electrode Diameter	Temperature C°	Power	Time (Min)	Number of treatments	Treatment intervals (weeks)
13	Breast	AUTO	Monopolar	60	40	--	20	4	1
14	Breast	AUTO	Monopolar	40 mass	40	--	20	4	1
15	Abdomen	AUTO	Monopolar	100	42	--	30	6	1
16	Abdomen	AUTO	Monopolar	40 mass	42	--	30	6	1
17	Hips	AUTO	Monopolar	70	41	--	15	6	1
18	Hips	AUTO	Monopolar	40 mass	41	--	15	6	1
19	Buttocks	MANUAL	Monopolar	100	43	80	20	6	1
20	Buttocks	AUTO	Monopolar	40 mass	43	--	20	6	1
21	Thighs	AUTO	Monopolar	80	40	--	20	6	1
22	Thighs	AUTO	Monopolar	40 mass	40	--	20	6	1
23	Legs	AUTO	Monopolar	40	40	--	15	6	1
24	Legs	AUTO	Monopolar	40 mass	40	--	15	6	1