

TEKRA CT



MANUAL

Instructions for use

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INDEX

Cap.1 – PRESENTATION	5
1.1 – What is TEKRA CT?	5
1.2 Why use TEKRA CT?	5
1.3 – Who is TEKRA CT for?	5
1.4 – Indications	5
1.5 – Contraindications	6
Cap.2 –OPERATION	7
2.1 – Connection and application of electrodes	7
2.2 – Turning device on	8
2.3 – Selection of program type	8
2.3.1 - - Manual mode	8
2.3.2 - Reset program mode	8
2.3.3 - Personal program mode	8
2.4 – Start of stimulation	8
2.5 – Setting time and intensity of emission	9
2.6 – Interrupt / end therapy	9
2.7 – Turning device off	9
2.8 – Configuration	9
Cap.3 – PRESET PROGRAMS	9
Cap.4 – FREE PROGRAMS	11
4.1 – Setting a new program	11
4.2 – – Use and modification of a personal program	11
Cap.5 – APPLICATIONS	11
5.1 – Therapy sessions	11
5.2 – Adjusting emission power output	11
5.3– Posture to be kept during the sessions	12
Cap.6 – – POWER SUPPLY	12
Cap.7 – SYMBOLS	12
DO NOT DISPOSE OF IN COMMON WASTE	13
Cap.8 – MAINTENANCE	13
8.1 – Knob	13
8.2 – Device	13
8.3 – Immediate maintenance:	13

Cap.9 – WARNINGS	14
Cap.10 – TECHNICAL FEATURES	14
10.1 – Power supply.....	14
10.2 – Output features.....	15
10.3 – Other features	15
Cap.11 – BASIC SUPPLY AND ACCESSORIES	15
11.1 – Basic supply	15
11.1 – Accessories and consumption material	16
Cap.12 – BIBLIOGRAPHY	16

ATTENTION:

- **READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE USE.**
- **IT IS RECOMMENDED TO SEEK THE ADVICE OF MEDICAL PERSONNEL FOR THE THERAPEUTIC INDICATIONS REQUIRED.**

Cap.1 – PRESENTATION

TEKRA CT is included in a new line of electromedical devices for professional physiotherapy. The main features of this innovative line of products are their small size, facility for us and versatility.

1.1 – What is TEKRA CT?

The ongoing research in the field of medical devices has led to the creation of the new system for deep diathermy, composed of the TEKRA XCRT generator with its professional features. The innovative software generates electromagnetic fields for therapeutic purposes to treat common pathologies (wounds, injuries, illnesses) by using **pre-set** ready-to-use programs. Furthermore, there is free space in the memory to set-up and record new protocols with custom-made parameters for the patient which can be modified or cancelled later on. The possibility of setting-up new programs, the technological innovation and the convenience of use make it **an extremely progressive product** in the sector of electromedical devices.

1.2 Why use TEKRA CT?

With TEKRA CT you can apply electromagnetic fields with beneficial effects for the reconstruction of bone tissue and, in general, for the regeneration of damaged tissues, besides obtaining an analgetic, anti-inflammatory and regenerating effect. By controlling the effects and progress of the therapy, new protocols can be implemented with parameters which are more effective for the patient.

1.3 – Who is TEKRA CT for?

The medical field (especially physiotherapy) is the sector most suited for TEKRA CT to fully express its potentialities.

– INDICATIONS AND CONTRAINDICATIONS

1.4 – Indications

The most common disorders treated with diathermy are those which attack the joints. Electromagnetic fields are specially indicated for treatment of:

- pseudarthrosis, arthrosis, arthritis;
- inflammatory and degenerative arthropathy;
- wound healing, bedsores;
- oedemas, arteriopathy;
- psoriasis.
- circulatory deficit
- muscular and tendinous injuries
- torn muscles and tendons
- bruised muscles
- tendonitis

We recommend consulting a doctor for the diagnosis and control of the therapy.

1.5 – Contraindications

Magnetic fields have some contraindications in common with other physical equipment which acts by means of endogenous heat production:

- presence of metallic fragments;
- neoplasms (tumours);
- tuberculosis;
- acute inflammatory processes;
- skin injuries;
- sensitivity alteration.
- pace-makers
- pregnancy.

Cap.2 –OPERATION



1 – Display TOUCH SCREEN

2 – KNOB + PUSH BUTTON

3 – Capacitive reference plate outlet

4 – Capacitive active electrode outlet

7 – STOP BUTTON

NOTE: check the contraindications and follow indications carefully before applying diathermy.

2.1 – Connection and application of electrodes

Connect the electrode and plate wires to the outlet sockets of the device. Each electrode or plate has its own specific connector. The connector is the bayonet type. Therefore once the contact has been inserted, fasten it by turning the connector clockwise.

2.2 – Turning device on

Press the rear switch to turn TEKRA CT on. An initial screen appears on the display presenting the device including: the name of the appliance version, the **START** key and the **CONFIGURE** key.

2.3 – Selection of program type

TEKRA CT can operate in 3 different modes:

- 1- Manual mode
- 2- Reset program mode
- 3- Personal program mode

2.3.1 - - Manual mode

Press **START** on the initial screen to access the manual mode area. In this area, by **TURNING THE KNOB** you can vary the value of the parameter selected, whereas by **PRESSING THE KNOB** you pass from one parameter to the next. The concerned parameters are: power output by the Capacitive stage, duration of the Capacitive therapy.

2.3.2 - Reset program mode

Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols where first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

2.3.3 - Personal program mode

The custom-made programs are at the bottom of the list of pre-set programs. Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols. At the bottom of the list first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

2.4 – Start of stimulation

Once a pre-set program has been selected or after having adjusted the parameters in the manual mode area, **START** appears on the display. **START** to begin the therapy.

2.5 – Setting time and intensity of emission

The duration of the therapy and the intensity can be set at any time by rotating the encoder. **PRESS THE KNOB** repeatedly to pass from the intensity parameter to the time parameter and vice versa. The minimum increase in intensity is 1% and the maximum intensity that can be set is 100%. Should the treated zone be in pain or too hot, reduce the intensity or interrupt the therapy by pressing **PAUSE** (on the touch screen) or **STOP** (on the keyboard).

2.6 – Interrupt / end therapy

Treatment emission is interrupted automatically when the Timer reaches 0 and an acoustic signal is heard. If you wish to interrupt treatment before the end, press **PAUSE** (on touch screen) or **STOP** (on the front panel). After the pause, to restart treatment press **START** (on touch screen).

2.7 – Turning device off

In order to turn the device off, press the switch on the back of the device.

2.8 – Configuration

The TEKRA devices can be set-up according to personal requirements. Press **CONFIGURE** (on touch screen) to access the setting area.

This section displays the following entries:

- 1) language: Italian, English, French, German, Spanish, Portuguese
- 2) brightness of display: from 0 to 10
- 3) volume of buzzer: from 0 to 10
- 4) timer of contact alarm: from 5 to 60 seconds
- 5) unblocking code: to enter before turning the device on the first time

Cap.3 – PRESET PROGRAMS

TEKRA CT has 35 preset programs and 20 free protocols. Preset programs are listed in the chart below:

PROGRAM	TIME	POWER %
acne rosacea	20' CAP	60%
postherpetic neuralgia	30' CAP	60%
pyoderma, acne conglobata	30' CAP	50%
ulcer	30'CAP	40%
saphenous drainage	20' CAP	80%
Cellulitis	20' CAP	80%
Varicose veins	20' CAP	60%
Eczema	15' CAP	80%
Psoriasis	25' CAP	80%
Scars and keloids	20' CAP	60%
Dermatosis	20' CAP	60%
Scaly dermatitis	20' CAP	60%
Itching	20' CAP	60%
Keratinization disorders	20' CAP	60%
Stretch marks	20' CAP	80%
vertebral contusions	20' CAP	80%
cervicobrachial neuralgia	15' CAP	60%
sciatica-lumbosciatica	20' CAP	80%
neuralgia of trigeminal nerve	15' CAP	60%
intracostal neuralgia	15' CAP	60%
spasmodic ischemia	15' CAP	40%
fibromatosis	20' CAP	60%
fibrositis	15' CAP	60%
cervical fibrositis	20' CAP	80%
Rhinoplasty	15' CAP	60%
headaches	15' CAP	70%
Rhinitis	15' CAP	60%
Sinusitis	15' CAP	60%
tarsal sinus	20' CAP	80%
tendonitis	20' CAP	80%
rheumatic inflammation of hip	20' CAP	80%
Facial paralysis	15' CAP	60%
chronic prostatitis	20' CAP	60%
hamstring cramps	20' CAP	60%
Plantar Fascia	20' CAP	80%

Cap.4 – FREE PROGRAMS

4.1 – Setting a new program

From the program section, press **NEW** (on touch screen) to enter the Free Program menu. By rotating the encoder you can choose which of the 20 custom-made programs available you wish to set. Press **CHANGE** (on touch screen) to enter the section for setting the name. **TURN THE KNOB** to change the letter and **PRESS THE KNOB** to move the letter selection cursor. Once you have chosen the name, pass on to the parameter setting phase. Press **PARAMETERS** (on touch screen) to move the cursor in the work phase setting section. In this zone, **ROTATE THE KNOB** to set the parameter value and **PRESS THE KNOB** to pass from one parameter to another. Up to 3 consecutive work phases can be set with TEKRA CT. Different intensity and time values can be used in each of them. When the parameters have been set, the name of the program can be modified once again. Press **NAME** (on touch screen), save the program by pressing **SAVE** (on touch screen) or else exit without saving by pressing **EXIT** (on touch screen).

4.2 – – Use and modification of a personal program

To modify a personal program, just carry out the instructions carried in paragraph 4.1

Cap.5 – APPLICATIONS

5.1 – Therapy sessions

Apply the diathermy according to medical prescriptions. Applications are done every day. Use the most suitable program for the patient until the ailment disappears or considerably decreases.

5.2 – Adjusting emission power output

Intensity adjustment is a main component for the diathermy program to be successful. It differs based on the type of program being used, the duration of the application and the characteristics of the patient. The intensity can be changed during the program to increase its affects. It can also be decreased in case of overheating or if pain is felt. The treatment starts from a low power output which gradually increases in intensity.

NOTE: if the intensity set or its regulation cause excessive heating or pain in the treated zone, the intensity of the stimulation must be reduced immediately or the application must be stopped.

The device is capable of automatically limiting the risk of unpleasant burns caused by the therapy. If the current supplied by the device exceeds 4.5A of absorption, the intensity bar automatically blocks or is limited. This limiting action is highlighted by a red bar.

5.3– Posture to be kept during the sessions

The ideal posture is to be relaxed, lying on ones back or facedown depending on the zone of application. This position must be maintained during the entire session to facilitate the effects produced by the electromagnetic field, especially the increased the blood flow due to dilation of the blood vessels, During the treatment, the active electrode must rest completely on the treated surface. It is therefore recommended to maintain a position perpendicular to the tissue. The point effect consists in having only a small part of the electrode touch the skin. In these conditions, there is a high risk of burns. At most one joint at a time must be placed between the reference plate and the electrode, or else the treatment session will not have success and the satisfactory thermal effect will not be attained. Apply a good dosage of GEL TEKRA between the electrode and the skin and between the plate and the skin. This strongly limits the risk of burns due to the point effect.

Cap.6 – – POWER SUPPLY

TEKRA CT must be powered by the electrical mains – Precautions for use

- (1) Do not short-circuit the terminals.
- (2) Do not set off sparks or flames.

Cap.7 – SYMBOLS



BF DEVICE



ATTENTION, CONSULT THE ATTACHED DOCUMENTATION



476

THIS DEVICE IS MARKED CE IN COMPLIANCE WITH
DIRECTIVE EEC 93/42.



DO NOT DISPOSE OF IN COMMON WASTE



TRANSMITTING DEVICE

Cap.8 – MAINTENANCE

8.1 – Knob

The connection cable must be checked regularly to make sure it has no cracks which can cause dispersion of the magnetic field. Clean the solenoids, pillow and rug regularly with a moist cloth.


8.2 – Device


Use a cloth moistened in water and alcohol to clean the device. **Do not use liquids at all since there is not protection against their entrance (IP20).**

8.3 – Immediate maintenance:

Immediate maintenance at New Age Italia or by authorised personnel if:

- the device has been subject to external mechanical stress (e.g.. serious drops);
- the device has been overheated excessively (e.g. if left near intense heat sources);
- you doubt that liquids may have penetrated inside;
- the power supply, the cover or other parts are damaged, broken or missing;
- it appears that the features of the device have been changed.

 for safety purposes, do not operate with accessories (e.g. knobs and power supply) other than those included in the basic supply.

 The frequency of maintenance, functional checkups and inspection for compliance with safety standards EN60601-1 for medical devices carried out with secur-tester is yearly. The useful life span of the instrument is guaranteed by the company only if maintenance is carried out regularly.

N. B.: have inspections carried out only by New Age Italia. The device can be sent directly to company assistance workshops or delivered to the dealer where the device was purchased.














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Cap.9 – WARNINGS

-  Pay special attention to use of the knobs in order not to jeopardise the effectiveness of the treatment.
-  Use the device only with electrical systems compliant with Safety Standards in force.
-  The device has IP20 protection rating (see chap. “Technical features”). It must not be used in the immediate vicinity of liquids because it is not protected from their entrance.
-  Do not use the device in the immediate vicinity of mobile phones (keep them at least a few meters away).
-  Operating near (for example 1 metre away) a short wave or microwave therapy device can cause instability in the output of the stimulator.
-  Do not connect the patient with TEKRA XCRT and an HF surgical device at the same time, to avoid danger for the patient and for the device itself.
-  The device works according to its specifications if the atmosphere is kept at a temperature between 5° and 40° C and less than 80% humidity. The same conditions must be maintained during transportation and storage.
-  In case of malfunctioning and failures, do not use the device but send it to be repaired.
-  Do not operate near flammable substances.
-  Do not use gel and accessories other than those supplied.
-  It is of the utmost importance to inform the patient about the type of sensations which must be perceived during the therapy. Should he perceive that the sensation is no longer the correct one, you must intervene immediately, stopping the session by the controls and disconnecting the solenoids.
-  If the intensity of the output set or its regulation cause excessive heating or pain in the treated zone, the intensity must be reduced immediately or the application must be stopped.
-  Keep the device out of the reach of children.

Cap.10 – TECHNICAL FEATURES

10.1 – Power supply

Internal power supply: MPU60-108

PRI: 100 - 240V ~ 47 - 63Hz SEC: 24V- 2,62A

10.2 – Output features

CAPACITIVE

Max power intensity (B): 300W

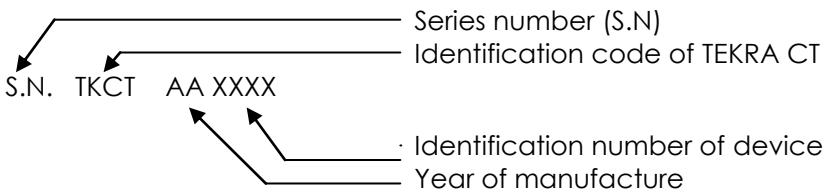
Frequency (f): 250 KHz

10.3 – Other features

- Size: 26x16x10h [cm]
- Weight: 1.7 [Kg] Class: IIB Type: BF
- Classification for entrance of liquids: IP20
- Safety in presence of flammable anaesthetic gas: it is not category AP or APG
- Device for functioning: continuous

Manufactured according to Standards:

- EN 60601-1 (2007) – Medical electrical equipment: General safety standards
- EN 60601-1-1 (2003) – Collateral safety standard
- EN 60601-1-2 (2003) – Collateral standard: Electromagnetic compatibility – Provisions and tests
- EN 60601-1-4 (1997): Collateral standard: Programmable electrical medical systems
- EN60601-1-4/A1 (2000) General requirements for safety of programmable devices.
- EN 980-2003 and EN 1041 – Graphical symbols for labelling of electrical medical devices



Cap.11 – BASIC SUPPLY AND ACCESSORIES

11.1 – Basic supply

TEKRA XCRT is complete with:

Device

1 capacitive therapy knob

1 capacitive therapy reference plate

- 1 set of capacitive electrodes
- 1 power cable
- 1 pack of TEKRA cream
- 1 User manual

11.1 – Accessories and consumption material

The following is the list of accessories which can be purchased apart to increase the supply of the device or to replace worn elements:

- knob for capacitive therapy
- capacitive reference plate
- electrodes for capacitive therapy
- GEL TEKRA ARTI 1000ml

Cap.12 – BIBLIOGRAPHY

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