# TheraTouch® DX2
## OPERATION MANUAL

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Declaration of Conformity:

Richmar, a Compass Health Brands Company, declares that the TheraTouch® DX2 complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2-3, ISO14971, ISO10993-1, ISO10993-5, ISO10993-10.

Complies with MDD 93/42/EEC and Amended by directive 2007/47/EC requirements.

ETL CLASSIFIED
Intertek
5009062

Conforms to AAMI STD ES 60601-1, IEC STD 60601-1-6, 60601-2-3; Certified to CSA STD C22.2 NO. 60601-1, IEC STD 60601-1-6, 60601-2-3.

## DANGER

This equipment generates radio frequency energy that may interfere with other devices if not installed and used in accordance with instructions.

## INTERFERENCE NOTE

This equipment and its components have been verified to comply with the specifications of IEC60601-1-2, which defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices. However, there is no guarantee against interference. This equipment and its external components are safe when used properly and in compliance with the explanations and instructions provided in this documentation. Nevertheless, the device and its external components can pose dangers. Therefore, it is imperative that anyone operating the shortwave diathermy device become aware of the potential dangers of the device and its external components before performing treatment, such as, no one with metal implants or metal in the body should operate within the RF field. Please read and abide by all safety instructions in this operation manual.

## INTERFERENCE CORRECTION

If this equipment emits harmful interference to other devices, it can be determined by turning the equipment on and off and then attempt to correct the interference by doing one or more of the following:

- Reorient or relocate the device receiving interference.
- Increase the separation between the equipment by consulting the EMC Table. If distance cannot be determined, the minimum distance should be no less than 40 feet (12.2 meters).
- Ensure that this equipment and the device receiving interference are connected to different circuits.

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# WARRANTY

The warranty period for this device is three years from the date of purchase. In case of a warranty claim, the date of purchase must be confirmed by the dealer from whom the device was purchased and may require proof by means of receipt or invoice.

Richmar's sole obligation in the case of any breach of its warranties set forth in this manual shall be, at Richmar's option, to replace the Product with a new or factory certified reconditioned Product without charge to the Purchaser or to refund the purchase price of the Product.

For returns, please contact your distributor or Richmar directly at 800-376-7263 to obtain a prepaid shipping label with the authorized RA number (if Product is within warranty). Any Product sent back without an authorized RA number will be returned to the sender. Richmar will not be responsible for damage due to improper packaging or shipment. If Richmar determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Richmar will refund the purchase price to the original Purchaser for the price of the defective Product, or replace the Product with a new or factory certified refurbished Product at Richmar's expense. If Richmar determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Richmar will inform the Purchaser and return the Product, freight billed to the Purchaser.

**NOTE:**

1. Repairs under warranty do not extend the warranty period either for the device or the replacement parts.
2. Shelf life is most influenced by several factors: exposure to light and heat, transmission of gases (including humidity), and mechanical stresses, this device is not sterile equipment, materials nor volatilization and degradation, this device has no restricted shelf-life.
3. This device has been evaluated according to IEC 60068-2-14 Tests. Test N: Change of temperature, can affect its safety and effectiveness prior to its first use under the claimed storage conditions described in its labeling.

**The following is excluded under the warranty:**

1. All damage which has arisen due to improper treatment, e.g. nonobservance of the manual instructions, warnings, cautions, and installation instructions.
2. All damage which is due to repairs or tampering by any unauthorized personnel or third parties.
3. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
4. Accessories which are subject to normal wear and tear (Accessories have a one year warranty).
5. Liability for direct or indirect consequential losses caused by the device is excluded even if the damage to the device is accepted as a warranty claim.

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# FOREWARD

Thank you for purchasing the TheraTouch® DX2, Shortwave Diathermy. This manual has been written for the owners and operators of the TheraTouch® DX2. It contains general precautionary practices in addition to operating, maintenance, and care instructions. To maximize use, efficiency, and the life of your device, please read this manual thoroughly and become familiar with the controls and accessories, before operating the device.

Before administering any treatment to a patient, the user of this equipment should read, understand, and follow the information contained in this manual for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of shortwave diathermy.

# DIATHERMY OVERVIEW

Shortwave diathermy equipment normally uses the band centered on 27.12 MHz administering electromagnetic energy to the body at shortwave frequencies that are converted to thermal energy by the induction of circulation currents and dielectric absorption, therefore, insulating tissue.

Shortwave diathermy is normally applied at a level which produces detectable heating and the benefits are those associated with a wide range of physiological effects (encouragement of healing, pain relief, reduction of muscle spasm, increase in mobility, etc.) and can be applied to larger areas of the skins surface.

The difference between shortwave diathermy and other methods of heating is that it provides “deep heat.” Other heating techniques such as infrared therapy, hot packs, etc., provide the heat externally whereas shortwave diathermy generates heat within the tissue

## PULSED & CONTINUOUS SHORTWAVE DIATHERMY

Pulsed shortwave diathermy (PSWD) equipment delivers the energy in pulses or bursts of shortwave energy. Other modalities such as ultrasound, have found that delivering the energy in pulses is often therapeutically more beneficial than providing the same amount of energy in continuous waveform. Pulsed shortwave diathermy appears to be effective for many conditions especially in the early stages of recovery.

Continuous (CSWD) shortwave diathermy creates eddy currents, small circular fields, within the tissues that causes heat generation continuously. Continuous shortwave diathermy seems to respond best to sub-acute or chronic conditions such as alleviating pain and increasing range of motion by eliciting a mild elevation of skin temperature.

Research has shown that pulsed output, although producing low average output power levels, can heat efficiently alone or while combining with stretching techniques to improve flexibility as well as extend tissue temperatures before returning to their baseline level.

The TheraTouch® DX2, in pulsed mode, provides a peak power of 200W and average powers ranging from a few watts to 64 watts and at its lowest average output can still produce effective treatment benefits.

# INDICATIONS

When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as:

- Pain Relief (Thermal and Subthermal)
- Muscle Spasm Reduction
- Increased range of motion of contracted joints using heat and stretch techniques
- Increased blood flow to tissues in the treatment area

# SAFETY INSTRUCTIONS

In this section you will find safety instructions related to Cautions, Warnings, and Dangers, which you should be aware of when using the TheraTouch® DX2. Due to the design of the monode drum, a strong magnetic field is produced with only a small incidental amount of electrical field. As the distance away from the inductive drum applicator increases, the amount of energy in the magnetic field drops rapidly and becomes equal to the energy in the electrical field.

## ⚠ CAUTIONS

- It is recommended that each user read, understand, and practice the precautionary instructions while operating this device. Observe the limitations and hazards associated with using any shortwave diathermy device, as well as the precautionary and operational decals on the device.
- Upon receipt of the device, check for any damage which may have occurred during transit. Should any signs of damage be apparent, please retain all packaging and inform the company with whom you purchased the device from.
- DO NOT operate the TheraTouch® DX2 in conjunction with any other devices or where other devices are being used and may radiate electromagnetic energy in an unshielded manner. Devices that can affect the medical electrical equipment can include but are not limited to portable and mobile RF communication equipment.
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel, as damage may occur.
- The device should be routinely checked before each use to determine that all controls function properly. It is important to determine that the intensity of the power output properly adjusts in a stable manner, as well as verify that the treatment time terminates power output when the timer reaches zero.
- This device should be transported and stored in temperatures between -4 °F and 131 °F (-20 °C and 55 °C) to prevent damage to the device or its components.
- Handle shortwave diathermy accessories with care as mishandling may adversely affect their ability to work efficiently and/or effectively.
- External conductive material (i.e. underwire bras, bracelets, necklaces, earrings, watches, etc.) should be removed from the immediate treatment area.
- Do not use accessories other than those supplied with the device or recommended by the manufacturer. The safety of other products has not been established, and their use could result in injury to the patient.
- Do not attempt to remove equipment covers unless done by a trained and qualified repair tech specifically for

shortwave diathermy and ensure the device is disconnected from the power supply.

- This equipment produces output that can produce a physiological effect.
- Medical electrical equipment needs special precautions regarding Electro Magnetic Compatibility (EMC) and needs to be installed and serviced according to the EMC information provided in this manual.
- This device generates, uses, and can radiate radio frequency energy that may cause harmful interference to other devices in the vicinity if not installed and used in accordance with the instructions. However, there is no guarantee that interference will not occur during operation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
  - **a.** Reorient or relocate the receiving device.
  - **b.** Increase the separation between the equipment .
  - **c.** Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected,
  - **d.** Consult the manufacturer's service technician for help.
  - **e.** Reorient or relocate the device receiving interference.
  - **f.** Increase the separation between the equipment by consulting the EMC Table. If distance cannot be determined, the minimum distance should be no less than 40 feet (12.2 meters).
  - **g.** Ensure that this equipment and the device receiving interference are connected to different circuits.
- **This equipment is to be used by, and sold to, a trained clinician only under the prescription and supervision of a licensed practitioner.**

## ⚠ WARNINGS

- Relatively high powers are used on this device and there is the possibility of producing localized burns, and cataracts if the patient is unaware of the heat, due to reduced thermal sensation, or if the patient does not know what to expect during treatment. Please inform the patient of expected heating perception for each thermal dose used.
- Improper installation, operation or maintenance of the shortwave diathermy system may result in malfunctions of this device or other devices. Please read all warning, cautions and safety instructions, as well as user installation to ensure proper installation.
- In case of display failure or other obvious defects, switch the device off immediately by means of the power switch, disconnect the power cord from the power outlet, and notify a certified service technician or the company where the device was purchased.
- Be aware that some synthetics and plastics, though assumed to be non-conductive, may be heated by shortwave diathermy.
- When adjusting or replacing components, please observe the beginning of installation instructions as if assembling for the first time to ensure the device does not fail to meet the requirements for interface suppression.
- If the device cannot be installed immediately after delivery, the device and its accessory elements must be stored in their original packaging in a dry place.
- Do not store or operate the device in a dusty environment.
- Do not cross power cord cable with coaxial cable cord.
- Keep all accessories, and their cords separated during treatment. Cords in contact with each other during treatment could result in improper stimulation, skin burns, or damage to the cord.

# SAFETY INSTRUCTIONS

- Do not lean on or hold mechanical arm, drum applicator or coaxial cable during treatment. In addition to the possibility of strong heating effect, it could expose the user and/or operator to high voltages, and/or damage the mechanical arm.
- Keep all power cords away from the diathermy device cables. Do not store or coil line cords where they can come close to the cables on an operating shortwave diathermy device.
- This equipment is not designed to prevent the ingress of water or 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.
- Care must be taken when operating this device adjacent to other equipment. If adjacent use is necessary, the TheraTouch® DX2 should be observed to verify normal operation in the configuration in which it will be used. Potential electromagnetic or other interference could occur to this or other equipment. To avoid interference, do not use other equipment in conjunction with shortwave diathermy.
- Use only accessories that are specially designed for this device. Do not use accessories manufactured by other companies on this device. Manufacturer is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables (other than those specified) may result in increased emissions or decreased immunity of this device.
- Metal in treatment area will provide low impedance paths to the induced radio frequency current, producing local heating and the possibility of burning. Treatment should never be given in the area of metal implants, and all metal jewelry, buckles, cell phones, etc. must be removed prior to starting treatment.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to shortwave diathermy energy.
- To avoid risk of electric shock, make certain that the device is electrically grounded by connecting only to a grounded electrical service receptacle, conforming to the applicable national and local electrical codes by consulting the website of the National Institute of Standards and Technology of the U.S. Department of Commerce regarding radio frequency devices.
- Induction field drums that are operated without a patient could be destroyed due to overheating.
- Make certain that the mechanical arm is locked firmly into place during shortwave diathermy therapy using the three joints adjustments to prevent unintentional movement. If movement occurs after fully tightening any of the three joint, please contact the company where you purchased the device. Keep in mind, the joint attached to the cart will still sway back and forth but should not move up and down once fully tightened.
- Do not leave patient unattended during shortwave diathermy therapy.
- This device should be kept out of the reach of children.
- Remove the electrode applicator by pulling the cable connector only. DO NOT remove by pulling the cable.
- To remove the cable from the applicator, make certain the power is off. While the drum applicator is being supported by the mechanical arm, hold the drum while removing the cable to prevent the drum from dropping to the floor.
- Observe the patient and the position of the arms at all times during therapy.
- Inform the patient that the mechanical arm is not supposed to move during therapy.

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# SAFETY INSTRUCTIONS

- Before using the device, verify the patient is not touching the device, the coaxial cable, the monode drum, or other devices or metal objects.
- Do not position medical equipment to where it is difficult to operate or disconnect the power supply.
- Check the insulation of coaxial cable for drum applicator regularly.

## DANGERS

- Do not administer shortwave diathermy on a patient who has had an implant in the past unless you are certain that the implant and all leads in their entirety have been removed. Note that the leads are often left implanted after the implant is removed.
- This device generates non-ionizing radiation. Patients with implanted electronic devices, such as cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators, must not be treated or in the treatment area of shortwave diathermy, even if the device has been turned off.
- The function of certain implanted devices (e.g. pacemakers) may be adversely affected during treatment with shortwave diathermy. In case of doubt, the advice of a licensed practitioner in charge of the patient should be sought.
- Shortwave diathermy should not be used on patients who have any implanted metallic lead or any implanted system that may contain a lead. Both the heating and non-heating modes of operation pose a risk of tissue destruction. If you are a licensed practitioner who implants or monitors patients with leads or implanted systems with leads, explain to the patient what diathermy is and stress that they should not receive shortwave diathermy treatment. If you are a licensed practitioner who uses diathermy in your practice, be sure to ask patients about possible implants before deciding to administer shortwave diathermy.
- Other equipment, including patient connected devices, may be adversely affected when near shortwave diathermy equipment.
- Patients should not be treated with shortwave diathermy when they have reduced thermal sensitivity over the proposed area of treatment, unless the physician in charge of the patient is notified.
- Treatment should not be given through clothing, although it is permissible to administer treatment through a dressing or plaster in pulsed modes.
- At average power levels above 5 W, patients should not be allowed to come into contact with conductive parts which are grounded or that may provide unwanted pathways for the radio frequency current. Treatment must never be given with the patient on metal framed couches, chairs, or beds. Do not use conductive mattresses or mattress covers.
- Before increasing the output in response to a report of inadequate patient heating, verify that the cables are properly routed and away from metal or grounded objects. The heating effect may be misdirected, and heating may be occurring in an unwanted area.
- Before each use, check the condition of the housing and the insulation of the drum applicator, drum applicator connection cable, and the power supply cable.
- If the device is not safe for operation, then it must be repaired by certified service personnel and the operators must be informed of the dangers posed by the device.
- The device, drum applicator, and cables may not be sterilized using steam or gas.
- Never clean the device with abrasives, disinfectants or solvents that could scratch the housing or damage the device.
- To prevent electrical shock, unplug the power plug from the wall outlet before cleaning or disinfecting the device. Under no circumstances may liquid penetrate the openings on the device. Therefore, do not use cleaning or disinfectant sprays.

# SAFETY INSTRUCTIONS

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- Internal and/or external burns can occur with the incorrect application of shortwave diathermy due to excessive intensity or excessive exposure time.
- Do not perform unauthorized repairs under any circumstances.
- The device must be positioned so that there is no danger of personal injury. Therefore, you must read and observe the safety instructions and the list of contraindications before putting the device into operation.
- Explosion hazard if the TheraTouch® DX2 is used in the presence of flammable anesthetics mixed with air, oxygen, or nitrous oxide.
- Shortwave diathermy should not be used over the heart in order to prevent theoretical cardiac signal interference.
- Keep all unnecessary persons out of the treatment location. No other person should be located within 10 feet of the device.
- Adhere to rules, regulations, and ordinances that may vary from location to location concerning the appropriate use of high powered radio frequency fields.
- Since the effects of high-frequency fields on unborn life has not yet been sufficiently researched, we recommend that pregnant women are not within 50 feet of the applicator when the device is activated.
- Any persons (whom are not patients) with pacemakers or implants must remain outside of the treatment area during shortwave diathermy. No one wearing a cardiac pacemaker should be within 50 feet of an operating device.

## PERSONAL SAFETY

**In case of improper or unauthorized use of the device, the operator, the patient or other persons may be subjected to the danger of electric shock due to high voltage produced by the device, the danger of influence on active implantations by magnetic fields produced by the device or false parameters such as the duration of treatment, power output or operating mode.**

**Before operating the device, please read this instruction manual carefully and observe the information contained therein. Pay special attention to the list of contraindications.**

Before operating the device each time, verify that:

- **The patient to be treated (and the personnel) have removed all electric devices (e.g. hearing aids, electrotherapy electrodes, mobile telephones) and all conductive objects (e.g. rings, chains, watches, earrings or other jewelry, eyeglasses) and that they are not in the immediate vicinity of the device, the patient is in a composed state and the bodily areas to be treated are dry on the exterior.**
- The device has been correctly connected to the power supply.
- The patient has the patient interrupt chord around their wrist.
- The device has been set up so that it is free-standing, and the patient is not in direct contact with metal objects such as heating radiators, metal beds, or other equipment.
- The insulation of the RF output jack and drum applicator coaxial cable are not damaged. In addition to a stronger heating effect, a deteriorated cable could break down and expose the user to high voltages.
- Only accessories (cables) approved by the manufacturer are connected.
- The drum applicator is positioned according to the doctor's instructions (to be checked by the doctor or physiotherapist if applied by assisting personnel).
- There is no unneeded personnel in the room or within 40 feet of the device other than the operator and the patient.
- There is no danger of unwanted local warming due to drum applicator constrictions.
- Safety instructions are reviewed and met.

Before using the device, speak with the patient to verify:

- The patient is in a comfortable position during the entire treatment.
- The patient is not in contact with the device, the drum applicator cable, the drum applicator, or other devices or metal objects.
- The patient understands the effects of treatment.

At regular intervals during the treatment, verify:

- The device is functioning properly
- There is no moisture development* (perspiration) in the treatment area.
- The patient feels well.

After the treatment, ask the patient about the tolerance of the treatment. The treatment environment should be inspected by a licensed practitioner.

## PROTECTION OF THE DEVICE

Observe the following instructions in order to prevent malfunctions:

- In order to prevent electromagnetic disturbances, place the device at least 40 feet (see the Caution Section for more information) from any other devices. Also make sure that there is sufficient distance between the device and power supply or data cables in walls, ceilings and floors, because the electromagnetic radiation from the device can pass through these, essentially without hindrance.
- When selecting the placement of the device, ensure the patient has contact during the treatment to the non-grounded application element and due to equalizing currents in case of differing potentials, that the patient is never in contact with metal elements (especially if they are grounded), such as heating radiators, metal beds, metal chairs/wheelchairs or other grounded devices.
- Before connecting the device, make sure that:
- The voltage rating on the safety label corresponds to the available system voltage.
- The frequency rating on the rating plate corresponds to the system frequency.
- A grounding socket outlet with grounding contact is available for connecting the device.
- The routing of the power cable from the device to the socket outlet with earthing contact does not pose a danger for personnel or the patient.

Do not connect the device to the power supply until the following requirements have been met:

- Before putting the device into operation, check to make sure that the drum applicator cable and the drum is undamaged and has been connected correctly to the device.
- Never operate the device with open outputs, (i.e. without drum applicator).
- Do not operate the device for an extended period with no load (without a patient), especially in induction field mode. When operating the device without power output, induction field accessories could be destroyed due to overheating.
- Other than equipment supplied by the manufacturer, keep chip cards, magnetic cards, audio and video cassettes, credit cards, key fob's, and other data media susceptible to interference away from the device.
- Clean and disinfect the device only when the power supply is deactivated (power switch off, power plug disconnected).
- Clean and disinfect the device only by means of disinfection by wiping. Disinfecting by spraying can damage the device due to penetrating moisture.
- Never perform unauthorized service work. All service work must be performed only by service technicians who have been authorized by the manufacturer.

# CONTRAINDICATIONS

The TheraTouch® DX2 device is contraindicated for the following:

- Any patient with an implanted electronic device such as a cardiac pacemaker, bladder stimulator, spinal cord stimulator for a myoelectric prosthesis, or implanted metallic leads, must not be treated with shortwave diathermy. The effects of applied high frequency on the pacemaker could cause ventricular fibrillation as well as any other people with pacemakers within the treatment area.
- Diathermy must not be applied over areas of the body which may contain metal (implants, surgical staples, etc.) as heat will become concentrated in that area increasing the possibility of tissue damage and deep burns.
- Do not treat on a metal treatment table, mattress with metal springs, wheel chair or a metal stool. Make sure that the patient cannot come into any contact with metal during treatment.
- Metal objects within the treatment area should be removed and placed outside the electromagnetic field and avoided. These include, but are not limited to:
- Within 2 feet of beds, treatment tables, standard chairs, wheelchairs, swivel stools, step stools, splints, braces, scissors, forceps, and scalpels.
- Within 4 feet (see the Cautions Section for more information) of electronically controlled medical devices such as, CPM devices, electric wheelchairs, electrotherapy devices or other electrical systems, computers, etc.
- Remove any clothing from the treatment area containing metal in the clothing, such as zippers, bra hooks or rivets that may cause burning.
- Remove hearing aids and watches during treatment to prevent interference with or damage to these devices.
- Do not treat over the pelvic or low back area when an IUD is present.
- Do not treat patients with external metal such as, orthodontic braces, dental fillings, staples, or external fixation devices. Shunts may contain a valve rather than a pump.
- Internal metal: valves, joint replacements, metal IUDs, shrapnel, metal implants, internal fixation devices-rods, plates, screws, wires, etc. NOTE: If there is a scar in or near the treatment area, check with the patient and/or the patient's chart to determine if there is metal under the scar.
- Remove metal near or on the patient, such as:
- Jewelry, body piercing earrings, watches, keys, coins, belt buckles, underwire bra, hearing aids, zipper in clothing or pillow cases.
- Do not apply treatment over exposed spinal cord (i.e. following laminectomy, spinal fusion, etc.).
- Shortwave diathermy should not be applied over the pregnant or potentially pregnant uterus. Therefore, shortwave diathermy should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant. Due to irradiation of the abdomen, shortwave therapy could cause teratogenous damage due to alterations of blood circulation and diffusion over the pregnant or potentially pregnant uterus.
- When treating small children, special care is required due to the low body weight. Very careful dosing and constant observation (manual checks of the skin temperature while the unit is switched off) are necessary. Shortwave diathermy should not be applied over the epiphyseal areas (bone growth centers) of the bones of growing children because shortwave diathermy therapy may enhance or inhibit bone growth.
- Shortwave diathermy should not be applied to the eye, swellings that still feel warm, acute inflammations, over reproductive organs.
- Neoplastic tissues or space occupying lesions should not be exposed to shortwave diathermy.
- Shortwave diathermy should not be applied to the testes to avoid increases in temperature.

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# CONTRAINDICATIONS

- Do not treat ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
- Patients whose condition could be negatively affected by heat.
- Patients with hemorrhages or risk of hemorrhage, septic conditions, empyemas, malignant tumors and undiagnosed tumors.
- Implants, areas where implants have been removed, damaged implants, and metal inclusions or that could be impaired by shortwave diathermy irradiation. Implants that could be impaired by shortwave diathermy irradiation.
- Swellings that still feel warm.
- Patients with thermohypesthesia (diminished perception of temperature differences) or thermohyperesthesia (exaggerated perception of hot and cold).
- Acute inflammations.
- Severe arterial obstructions (stage III and IV).
- Gynecological disorders involving acute inflammation.
- Wetness, perspiration, or damp bandages.
- Permeating irradiation of the thorax in cases of severe heart diseases (heart valve diseases, myocardial insufficiency, myocardial infarct, severe coronary sclerosis).
- During the menstrual cycle.
- Sudeck's syndrome (Chronic Regional Pain Syndrome; which occurs after a fracture or distortion), Stage I and Stage II.
- Basedow's disease/Graves' disease (autoimmune disease that affects the thyroid) as irradiation could cause serious states of agitation.
- Particular care must be taken if the patient's clothing is wet or damp, since the garments may heat up faster and more intensely than the patient's body.
- Any synthetic fibers (e.g. perlon, nylon, etc.) are characterized by low absorbency, which can cause the skin beneath such fabrics to quickly become moist. Therefore, it is recommended that the body areas to be treated be completely unclothed and the patient's skin dried, particularly where perspiration accumulates in folds of the skin. This applies especially when a higher dosage is being applied. There is no danger, however, when applying shortwave diathermy irradiation to bandaged areas if the bandages are completely dry.
- Since the effects of high-frequency fields on unborn life have not yet been sufficiently researched, we recommend that operators who are pregnant are not within 50 feet of the applicator when the device is activated.
- The output power must always be set according to the subjective response of the patient. Therefore, special care must be taken in case of patients with a diminished capacity for perception of heat.
- Cardiac conditions.
- Do not apply directly over or in close proximity to Deep Vein Thrombosis (DVT). Thermal agents should be avoided in early phases of a DVT. Therapists should follow the guidelines provided by the referring physician on recommended activity level and modality use.
- Arterial disease, circulatory insufficiency.
- Over cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators.
- Over open lamina (after laminectomy; spina bifida).
- Over superficial endoprosthesis (artificial hip joint) or metal implants.
- Directly over the carotid sinuses, cervical stellate ganglion, or Vagus nerve located in the anterior neck triangle.

# CONTRAINDICATIONS

- Direct application over cancerous tumors or lesions due to its potential to increase blood flow to the area of malignancy.
- Neoplastic tissues or space occupying lesions (including post-op lesions).
- Occlusive vascular disease, such as arteriosclerosis obliterans and thromboangiitis obliterans (Buerger disease), in which organic occlusion and ischemia are evident.
- In the presence of systemic or local infection (sepsis, osteomyelitis, tuberculosis) or if the patient has an elevated temperature.

# PRECAUTIONS

When administering shortwave diathermy, keep in mind the following:

- Caution is advised in patients who lack normal sensation or report pain or heat sensation accurately. Absent or diminished sensation should be avoided or, if unavoidable, treated with caution. Establishment of acceptable intensity levels for desensitized areas may be related to the intensity levels tolerated on normal skin in opposite or related body parts.
- Frequent monitoring of intensity level and skin response should occur during all treatments.
- Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic shortwave diathermy who have bleeding disorders.
- Heating of the joint capsule in acute or sub-acute arthritis should be avoided & over bone with minimal or no soft tissue present.
- Use a single layer of toweling to absorb moisture during treatment with the inductive drum applicators.
- Shortwave diathermy may interfere with other electronic therapeutic devices such as neuromuscular stimulators and therapeutic ultrasound devices. Never use another electronic device on the same patient when shortwave diathermy is being applied.
- Caution should be exercised when treating over adipose tissue. Excessive superficial heating can occur due to the high electrical resistance of subcutaneous fat to shortwave diathermy.
- Caution is suggested when using shortwave diathermy immediately after the application of superficial and deep heat or cold modalities. The application of thermal modalities prior to shortwave diathermy can alter the patient's perception of warmth and pain.
- Caution is advised when applying thermal shortwave diathermy directly to an area with impaired arterial blood supply because the compromised blood flow may not meet the increased metabolic demand placed on the tissues by the thermal energy dose. Always start with a low dose and observe patient response. Increase in dose may be made in subsequent treatments if the patient can tolerate the dosage given.
- The function of other patient connected equipment WILL adversely affect the operation of the pulsed shortwave diathermy equipment. Maintain maximum distance between devices to reduce any tendencies of interference.

# PRODUCT DESCRIPTION

The TheraTouch® DX2, Shortwave Diathermy device, is part of a family of clinical therapy devices which offers practitioners a wider range of treatment options. Shortwave Diathermy generates deep heat within body tissues to increase circulation, decrease pain, decrease inflammation, increase range of motion (ROM), influence muscle tone and facilitate the sub-acute healing phase. The TheraTouch® DX2 shares the same type of user interface as our CX4 and EX4 clinical devices, a full color touch screen with four quick start buttons, making treatment set-up easier than ever. A few simple key presses are all you need to set up a treatment. The User Interface intuitively groups and displays Thermal Dosimetry and Quick Links by Indications for a modality setup that ensures treatment parameters can be easily selected and fully adjustable.

## GENERAL INFORMATION

The TheraTouch® DX2 device and the accompanying components, together, fulfill the currently valid safety standards and comply with the stipulations of IEC 60601-1 and the medical products regulations.

The TheraTouch® DX2 utilizes a monode drum to administer the clinical application of oscillating electromagnetic energy to increase the temperature of tissues to treat a wide variety of orthopedic and physiotherapeutic conditions such as:

- Pain, Acute and Chronic
- Muscle Tightness
- Poor Circulation
- Joint Stiffness
- Contractures
- Inflammation, Acute and Chronic
- Inhibited Microcirculation
- Chronic Muscle Spasms

Please read and observe all safety instructions in this operating manual.

The TheraTouch® DX2 has the following features available:

**Clear Touch Screen LCD**

Allows the operator to select an option by simply touching the screen to guide them through the set-up process while providing information regarding treatment settings during attended procedures.

**Thermal Dosimetry**

Allows the operator to set up a treatment using the six treatment dosages (the four standard diathermy dosages, in addition to two proprietary dosages) to provide outputs capable of producing thermal effects. Higher dosages result in greater thermal effects in the tissue.

**Scientific Dosage Control (S.D.C.)**

The technology incorporated into the TheraTouch® DX2 that creates tighter titration of shortwave output, allowing for the additional proprietary dosimetry protocols, which provide increased thermal effect with decreased risk of patient discomfort.

**Quick Link Indications**

The TheraTouch® DX2 device incorporates a unique Quick Link Indications sub menu which allows the user to select specific clinical indications to apply the most common therapy for the indication selected. All underlying parameters can be adjusted, and saved to Favorite Protocols if desired.

**Favorite Protocols**

Favorite protocols allow the operator to set, change, and save the parameters of any treatment to easily recall at a later time. Up to 100 Favorite Protocols can be saved.

**High Efficiency Automatic Tuning (H.E.A.T.)**

The TheraTouch® DX2 device has been programmed to automatically regulate the power between the monode drum and the patient to maximize tissue heating efficiency.

# UNPACKING & INSPECTION

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### UNPACKING THE DEVICE

The TheraTouch® DX2 device weighs approximately 90 lbs. and will need to be unpacked by, at least, 2 people.

Proceed as follows:

- Position the shipping carton with the arrows pointing up.
- Cut the yellow safety straps from the shipping carton
- Pull the top part of the shipping carton upward to remove the top.
- Remove the surrounding foam.
- Using at least 2 people, remove the device from the bottom shipping carton being careful to realize the device is heavy and may need extra care when removing.

### INSPECTION

Immediately upon unpacking the device, perform the following steps:

- Verify the delivery documents to make sure that the delivery is complete.
- Check the external components and accessories for possible damage due to transport.
- In case of damage from transport that could endanger personal safety, the device must not be connected to the Mains Power Supply before inspection is complete.
- Verify that the packaging contains all of the Package Contents, listed in the section below.

# PACKAGE CONTENTS

The TheraTouch® DX2 includes the necessary components to perform shortwave diathermy.

Below is a list of items that are included in the shipping carton.

### PACKAGE CONTENTS

| REF | DESCRIPTION | QTY |
|---|---|---|
| DQSWD2 | The TheraTouch® DX2 Main Device & Cart | 1 |
| DQSWDX | The TheraTouch® DX2 Medical Grade Power Cord | 1 |
| DQSWD2-MAN | The TheraTouch® DX2 User Manual | 1 |
| DQSWD-D | Monode Drum (14cm diameter) | 1 |
| DQSWD2-MA | Mechanical Arm | 1 |
| DQSWD2-C | Coaxial Cable | 1 |
| N/A | Wrench (10mm) | 1 |
| N/A | Test Report | 1 |

## POWER CONNECTION

- Connect the top power cord to the back of the shortwave diathermy as shown in **Figure 1** .
- The bottom power cord comes equipped with a standard 3—prong plug. This plug provides grounding for the TheraTouch® DX2. Do not use a 3-to-2 prong adapter or any other non-grounded means of attaching to a wall outlet.
- Attach the female end of the included Power Cord to the male power connector on the bottom of the device seen in **Figure 2**. Plug the male end of the Power Cord into a grounded wall outlet that is rated a 100 to 240Volt AC 50/60Hz. The power supply must match the voltage requirements listed on the serial number label of your device. Do not connect the TheraTouch® DX2 to power supply rated differently than described above.

**WARNING:** The TheraTouch® DX2 may emit radio interference. Avoid operating other electrical devices adjacent to and simultaneously with the TheraTouch® DX2 Shortwave Diathermy device.

## MECHANICAL ARM INSTALLATION

1. Slip the mechanical arm connection over the two screws on the side of the cart to sit as shown in **Figure 3**.
2. Use the 10mm wrench provided in the packaging to tighten the screws.

**Figure 1. Connect Top Power Cord**

**Figure 2. Bottom Male Power Connector**

**Figure 3. Slip the Mechanical Arm Over the Two Screws**

# INSTALLATION

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## INSTALLING THE MONODE DRUM

1. Insert the monode drum into the mechanical arm, as shown in **Figure 1**, by pulling down to open the gray clamps, insert the handle and let go once completely inserted.
2. Plug the coaxial cable into the output port on the back of the cart as shown in **Figure 2**, by aligning the notches to the output port and then turning clockwise, to lock into place.
3. Connect the other end of the coaxial cable to the back of the monode drum as shown in Figure 3. Align the connector notches, push in, then twist clockwise to lock in place.

**Figure 1. Insert the Monode Drum**

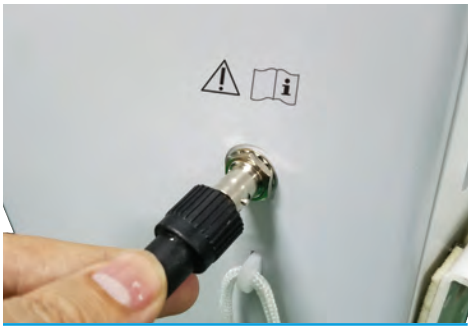

**Figure 2. Connecting Coaxial Cable to the Cart**

**Figure 2. Connecting Coaxial Cable to Monode Drum**

## REQUIREMENTS OF OPERATING LOCATION

Keep in mind the following:

- Before the device can be installed and operable, certain requirements must be fulfilled throughout the building where there the device will be used.
- By selecting a suitable location for setting up the device or by means of structural measures, contact during the treatment by the personnel or the patient with conductive materials that are grounded or have a high capacity to ground, must be prevented (e.g. heating pipes, water faucets, metal chairs, metal beds or other grounded devices).
- The device must be set up so that the (normal) release of electromagnetic radiation during operation does not hinder the function of other devices or data media. The minimum distance to other devices or their power supplies or data transfer lines is 40 feet (see the Caution Section for more information). Please note that the radiation can easily pass through walls, ceilings and floors.
- The room and the installation location must be large enough so that the device can be operated from the front even if the monode drum is positioned inconveniently.
- If the device cannot be installed immediately after delivery, the device and its external components or accessory elements must be stored in their original packaging in a dry place.
- Do not store or operate the device in a dusty environment. The device must be installed so that there is no danger to the patient, the operator, or other people. Therefore, you must read the Safety Instructions.

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# INSTALLATION

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- Do not store or operate the device in a dusty environment. The device must be installed so that there is no danger to the patient, the operator, or other people. Therefore, you must read the Safety Instructions.

### MONODE DRUM

This monode drum uses high frequency magnetic field by the inductive coil of an electrical resonant circuit for therapy. The TheraTouch® DX2 Monode drum is electrically shielded and connected to the device via a removable, shielded coaxial cable. Use only the cable, designed for this application. Failure to do so may result in damage to the device or potential abnormal output.

# APPLICATION INFORMATION

### PREPARING THE PATIENT

**WARNING: PLEASE READ ALL PREPARATIONS BELOW BEFORE PROCEEDING WITH PATIENT THERAPY**

- For best therapy practices, ensure the patient is in a comfortable and relaxed position. To accomplish this either have the patient in a seated or supine position. Patients should never be treated on metal chairs, tables or beds.
- For safety reasons, remove all hearing aids, watches, rings, chains, bracelets and other metal objects before starting the treatment. The clinician should also take care to remove metallic objects while operating the TheraTouch® DX2.
- Do not treat patients through their clothing. Remove clothing from the treatment area (including undergarments with metal parts) and provide a clinic room gown for the patient during therapy. Clothes made of synthetic materials should especially be removed because they insufficiently absorb moisture, allowing moisture to pool on the skin causing local overheating.
- Use a single layer of absorbent toweling between the patient and the applicator to absorb any perspiration produced during the treatment, and to prevent the development of hot spots due to pooling of perspiration on the skin's surface.

# APPLICATION INFORMATION



- Do not leave children or patients who cannot pull the patient interrupt cord, unattended while operating this device.

## HEAT EFFECT OF THE MONODE DRUM

Evaluating the heat effect of the monode drum is based on the heat felt by the patient. This is strongly influenced by many factors, (e.g. the thickness of fat layers, treatment through clothes or bandages, blood circulation, temperature of the skin, etc.). Therefore, the following section explain the operation of the monode drum used with the TheraTouch® DX2.

## MONODE DRUM OPERATION

- The shortwave magnetic field of inductive coil applicator generates eddy currents that are transformed to heat the bodies tissues. These currents increase with increasing electric conductivity of the corresponding tissue region (e.g. tissues with good blood circulation, muscle tissue and inner organs, etc.).
- To reach these deeper tissues, the monode drum of the TheraTouch® DX2 is provided with an electrostatic shielding that prevents the electric field of the monode drum from heating the upper-skin adipose tissue and may take several minutes to realize desired heating sensation. Therefore, heat sensation by the patient is basically delayed when using the drum applicator. Dosage should be applied based on the nature and location of injury and whether it is an acute or chronic condition. Start with a lower intensity level first and then increase, after several minutes, to the patients desired heating sensation. The intensity and treatment time values given in the application screen should be observed. For maximum deep effects, apply the monode drum directly to the body through a single layer of toweling.

### Setting the Monode Drum-Skin Distance

The full power required for successful depth therapy is provided by the unit by using a large Monode Drum.

For treatment near the surface, in which the power must be limited, in accordance with the respective therapy, a small Monode drum-Skin Distance is required.

This adjustment changes the distance of the metal plate that is built into the monode drum for determining the penetration depth of the HF field; (i.e. the distance between the metal plate and the body is increased or decreased.)

The desired Monode Drum-Skin Distance can be achieved by placing a towel between the patient and the monode drum.

## DESCRIPTION OF APPLICATION

The TheraTouch® DX2 is suitable for nearly all heat therapy processes for use in clinics and private practices. Classic therapy applications can be administered with the monode drum in continuous or pulsed mode.

The application of high-frequency energy in heat therapy has the advantage of greater depth penetration as opposed to simpler methods, such as packs, baths, infrared light, and heat cushions. The endogenous heat that is formed triggers a series of physiological processes, producing a spasmolytic effect on muscles, tendons, and other structures containing connective tissue, increasing the cell metabolism and the enzyme reaction speed and stimulating perfusion in the treated zone.

The capability of applying the high-frequency energy in short, intense pulses (PSWD) can further increase the depth effectiveness, especially the stimulation of perfusion, while the heat generation is hardly felt in the skin, which is more sensitive to heat.

The applications for the high-frequency therapy are diverse. This therapy is especially effective in treating rheumatic disorders of the joints and muscles, inflammatory disorders of the respiratory organs, the kidneys and bile ducts, and disorders related to insufficient perfusion.

The pulsed mode is advantageous in the treatment of acute conditions.

# DEVICE DESCRIPTION DETAILS

## THERATOUCH® DX2, FRONT


## THERATOUCH® DX2, REAR


1. Monode Drum
2. Mechanical Arm
3. Emergency Stop Button
4. Manual Treatment Screen Button
5. Power LED Indicator
6. Touch Screen Display
7. Quick Link by Indications Button
8. Favorites Button
9. Central Controller Dial
10. Handle
11. Storage Baskets
12. Therapy Cart Base
13. Front Swivel, Locking Casters
14. Power Button
15. USB updating port (only used by authorized personnel)
16. Top Power Cord
17. Patient Interrupt Cord
18. On/Off Switch
19. Bottom Power Cord
20. Output Port
21. Coaxial cable

# DEVICE USER INTERFACE

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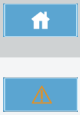
## SHORTCUT BUTTONS

| ICON | NAME | DETAILS |
|---|---|---|
|   | Stop | Press this button to stop treatment at immediately. |
|  | Clinical Protocols | Press this button can enter Quick Link By Indication interface when device is in standby. |
|  | Favorites | Press this button can enter favorites interface when device is in standby. |
|  | Manual Operation | Press this button can enter treatment interface when device is in standby. |

## NAVIGATION

Below is a list of software symbols you will notice throughout the device. Please make yourself familiar with each symbol and its definition before operating the TheraTouch® DX2.

## SOFTWARE SYMBOLS

| ICON | NAME | DETAILS |
|---|---|---|
|  | Back | Return to previous screen. |
|  | Home | Return to Home screen. |
|  | Stop | Stop Treatment |
|  | Favorite | Store favorite protocols/treatments |
|  | Start | Start power output |
|  | Pause | Pauses power output |
|  | Delete | Delete Favorite |
|  | Save | Save favorites protocol |
|   | Drum Applicator Indicator | Type of applicator (Fixed) |
|   | Pulse Rate | Pulsed Rate Indicator |

## SOFTWARE SYMBOLS (CONTINUED)

| ICON | NAME | DETAILS |
|---|---|---|
|   | Pulse Duration | Pulsed Duration Indicator |
|   | Mode Indicator: Pulse | Pulse Mode Indicator |
|   | Mode Indicator: Continuous | Continuous Mode Indicator |
|  | Pairing Status | Pairing Status Indicator Bar |
|   | Start Pairing | Start to Pair/Standby Indicator |
|   | Ready Indicator | Pairing Success Indicator |
|   | Timer | Treatment Time Indicator |
|   | Power Output | Power Output Indicator |

## SYSTEM STARTUP

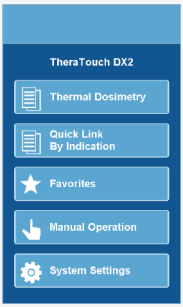
**Startup Screen**

- Once power supply is connected, turn the On/Off Switch on the back of the device to the On position.
- The Home Screen will appear in approximately 5 seconds.


**Home Screen**

The Home Screen includes the following functions:

- Thermal Dosimetry
- Quick Link by Indication
- Favorites
- Manual Operation
- System Settings



# DEVICE USER INTERFACE

## THERMAL DOSIMETRY

### Home Screen

- Press **Thermal Dosimetry**.


### Thermal Dosimetry Screen

- For Treatment Information, such as parameters for a specific dosage, press i on the left side of desired dose.

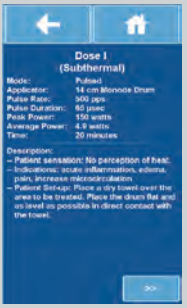
Note: To go directly to the Treatment Screen, press desired dose button (i.e. Dose I (Subthermal)).


### Treatment Information Screen

This screen shows the parameters of treatment and descriptions for treatment.

- Touch >> to enter the Treatment Screen.

Note: To return to the Thermal Dosimetry Screen, touch ←.




### Treatment Screen

To change a parameter, touch the corresponding button and adjust accordingly with the Central Controller Dial.

- To prepare the device for therapy, touch **Press to start**. The text will change to read **Please wait** and the Pairing Status bars will fill in with color. When the device is paired, the text will read **Ready**.

## THERMAL DOSIMETRY (CONTINUED)

- Press ▶ to begin treatment.

Note: According to level of pairing, the indicator will display different colors. **The more bars filled with color, the better the device is paired with the patient. Recommendation is to only use when more than 3 lights are showing in the vertical bar.**


## QUICK LINK BY INDICATION

The TheraTouch® DX2 device incorporates a unique Quick Link Indications section which allows the user to select specific clinical indications and apply the most common therapy for the indication selected. All presets are editable, and can be saved to Favorites for later use.


### Home Screen

- Press Quick Link By Indication by touching the button.

### Quick Link By Indication Screen

- For Treatment Information, touch the i to the left of the desired indication.

Note: There are 9 protocols under Quick Link By Indication which have been divided into 2 pages. Press >> to advance to the next page.

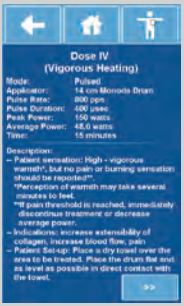
Note: To go directly to an Indication Treatment Screen, just press the corresponding indication (i.e. Contractures).


### Treatment Information Screen

This interface shows the parameters of treatment and descriptions for treatment.

- Press 🚹 to view Drum Position Suggestions based on the specified body part to be treated.

Note: To go directly to the Treatment Screen, touch >>.



# DEVICE USER INTERFACE

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## QUICK LINK BY INDICATION (CONTINUED)

### Drum Position Suggestions Screen

- Touch the specified body part to be treated in order to see the drum applicator placement suggestions.

For example, touch  , and the relevant position will appear.

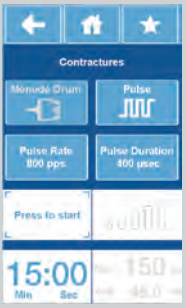

### Position Selection Screen

- Position the monode drum according to the Positioning Guide shown.
- To go to the Treatment Screen, first press ←, then press ».

### Treatment Screen

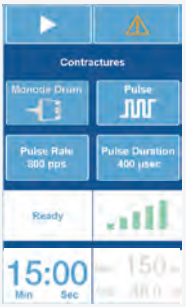
In this screen users can change the parameter by touching the button and changing the value with the central controller.

- To prepare the device for therapy, touch **Press to start**. The text will change to read **Please wait** and the Pairing Status bars will fill in with color. When the device is paired, the text will read **Ready** and the Output Power Indicator will become highlighted.




- Press ▶ to begin treatment.

Note: According to level of pairing, the indicator will display different colors. **The more bars filled with color, the better the device is paired with the patient. Recommendation is to only use when more than 3 lights are showing in the vertical bar.**



## MANUAL OPERATION

Manual Operation allows the user to select customizable parameters specific to the patient based on their experience.

**Home**

- Press Manual Operation to navigate directly to the Treatment Screen.


**Treatment Screen**

To change a specific parameter, press the button on the screen and use the central controller dial to adjust to desired setting.

- Press Pulse and rotate the Central Controller Dial to the left or right to select which mode of output preferred (Pulsed or Continuous).

Note: When selecting Continuous, the Pulse Rate and Pulse Duration cannot be adjusted.


- Press **Pulse Rate** to adjust the Pulse Rate within the range of 10 to 800 pulses per second.


- Press **Pulse Duration** to adjust the Pulse Duration within the range of 20 µs to 400µs.

# DEVICE USER INTERFACE

## MANUAL OPERATION (CONTINUED)

- To adjust the Treatment Timer, press 15:00.
- With the Treatment Timer highlighted, you may adjust the Treatment Time with the Central Controller Dial.

Note: It is recommended that treatment not exceed 20 minutes per session.

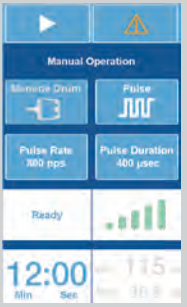

- To adjust output power setting, press 0.00, and rotate the Central Controller Dial until desired output power is reached.
- To prepare the device for therapy, touch **Press to start**. The text will change to read **Please wait** and the Pairing Status bars will fill in with color. When the device is paired, the text will read **Ready** and the Output Power Indicator will become highlighted.


- Press ▶ to begin treatment.

Note: Output power can also be adjusted during treatment by pressing the Output Power Indicator and rotating the Central Controller Dial until the Output Power Indicator reaches the desired output.

Note: The Output Power Indicator will only display power in Watts (W) when Output Mode is set to Continuous.

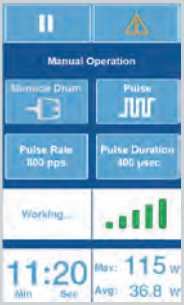
Note: According to level of pairing, the indicator will display different colors. **The more bars filled with color, the better the device is paired with the patient. Recommendation is to only use when more than 3 lights are showing in the vertical bar.**



## MANUAL OPERATION (CONTINUED)

- When the power is outputting, press ⏸. The power output will cease and the Treatment Timer will pause.

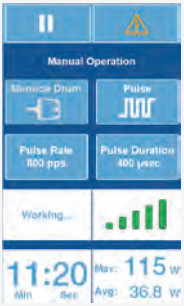
Note: To resume the treatment and outputting of power, press ▶.




- Press ⚠, the treatment will be stopped at once.

Note: The STOP shortcut button will also immediately stop treatment.

Note: You can also adjust the Output Power to "0W" to stop treatment.




## SAVING FAVORITES

In order to save a set of parameters to your Favorites, the treatment must not yet be started.

**Treatment Screen**

- To begin saving a Favorite from the Treatment Screen, press ★.


**Save Favorite Screen**

- Enter the name of your favorite using the keyboard.

Note: Per HIPPA Guidelines, you should not store favorites under a patient's name. We recommend saving under a general treatment description or the patient's chart number.

- Press ☑ to save the name chosen, under favorites.

Note: Once saved, you can view saved Favorites, and recall them to be used in treatment.

# DEVICE USER INTERFACE

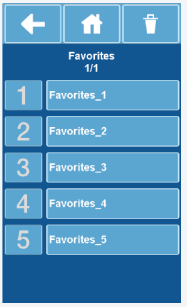
## DELETING FAVORITES

**Home**

- Press **Favorites**.


**Favorites**

- Press . With the icon highlighted, any Favorite from the list can be deleted by simply pressing the corresponding button.




## SYSTEM SETTINGS

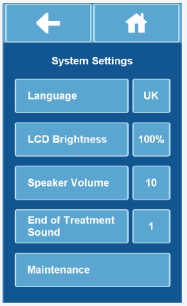
**Home**

- Press System Settings.


**System Settings**

In this screen you can personalize some features on the device such as:

- Language
- LCD Brightness
- Speaker Volume
- End of Treatment Sound



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# DEVICE USER INTERFACE

### EMERGENCY SHUTOFF

The output of the TheraTouch® DX2 can be ended immediately in the following ways:

- Pull the Patient Interrupt Cord.
- Pressing ⚠.
- Pressing the stop shortcut button.
- Pressing **Ready** when treating.
- Turn off power switch on the rear of the device.

In addition, output can also be ended by:

- Adjust the intensity to 0W.
- Adjust the treatment time to "0".

# CLEANING INSTRUCTIONS

### CLEANING & DISINFECTING

When cleaning the device, keep in mind the following:

- Press the Power On/Off button so that the device is off.
- Unplug the power plug from the power outlet before cleaning or disinfecting the device.
- After each patient use, clean the accessories using a soft, clean cloth dampened with water and a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.
- Wait until the device is completely dry before operating it again.

### DANGER

- Under no circumstances may liquid penetrate the openings on the device (e.g. the connecting sockets of the coaxial cable). Therefore, do not use cleaning or disinfectant sprays.
- The device, monode drum, and coaxial cable may not be sterilized using steam or gas.
- Never clean the device with abrasives, disinfectants, or solvents that could scratch the housing or LCD or otherwise damage the device.
- To prevent electrical shock, unplug the power plug from the power outlet before cleaning or disinfecting the device.

# SAFETY INSPECTIONS

The following safety inspections must be performed on this device. This must be done by clinicians, who based on training, knowledge or practical experience, can conduct the inspections correctly and independently.

### VISUAL INSPECTION (DAILY)

When performing daily inspections of the device, pay attention the following areas of potential damage:

- Deformation of unit housing
- Power cable damage
- Coaxial cable damage
- Monode Drum damage

### FUNCTION TEST (DAILY)

When performing daily inspections of the device, pay attention to the following areas of potential damage:

- Correct function of indicators
- Display of operating modes
- Verify power output by observing the brightness of the green LED on back of monode drum.
- Patient Interrupt Button

NOTE: It is the responsibility of the health care facility to verify that the device complies with the facility, local, and national Earth Leakage limits.

# TROUBLESHOOTING

We have found that most problems occur because of inadvertent operating errors. Therefore, when the TheraTouch® DX2 displays an error code, please check whether the operating instructions have been correctly followed.

- If the Power indicator light does not light when the device is turned on, check whether the device is correctly connected to an active wall outlet and the power cord is connected to the device.
- If the device displays “Tuning Failure”, check the connection of monode drum and confirm the patient does not have any metal in the treatment area.
- In order to prevent excessive warming of tissue, the maximum and average output power must not be exceeded

## SYMBOLS GLOSSARY

| SYMBOL | DESCRIPTION |
|---|---|
|  | Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions. |
|  | Type BF Applied Part |
|  | Refer to instruction manual |
|  | This symbol means that this device emits non-ionizing radiation. All devices with RF transmitters or that use RF electromagnetic energy must have a label with this symbol. |
|  | Caution |
|  | Operating instructions |
|  | Date of Manufacture |

## SOFTWARE ERROR MESSAGES

| ERROR CODE | ERROR MESSAGE | RECOMMENDED STEP |
|---|---|---|
| 218 | SD card read failure | Please contact manufacturer tech support at techcsr@compasshealthbrands.com or (800) 376-7263 |
| 219 | Favorites is full, add failure | Delete unnecessary favorites. The maximum allowed is 99. |
| 224 | Communicate invalid | Please contact manufacturer tech support at techcsr@compasshealthbrands.com or (800) 376-7263 |
| 227 | The board temperature is too high | Check whether the cooling fan work normally. You should be able to hear the fan running. |
| 228 | Font file fails to load, use the default settings | Please contact manufacturer tech support at techcsr@compasshealthbrands.com or (800) 376-7263 |
| 802 | Power correction data has been saved successfully | Power device on and off with power button to resume operation. |
| 805 | Tuning failure | Check whether monode drum is placed correctly and that coaxial cable is installed and locked into place on both ends. |
| 811 | The temperature sensor of function board is invalid | Please contact manufacturer tech support at techcsr@compasshealthbrands.com or (800) 376-7263 |
| 812 | The password is not correct | Password function is only used by authorized personnel. |
| 817 | The temperature of function board is too high | Check whether the air fan work normally. You should be able to hear the fan running. |
| 818 | Fail to save the power correction data | Please contact manufacturer tech support at techcsr@compasshealthbrands.com or (800) 376-7263 |
| 819 | Power data initialization failure. Please recalibrate | Recalibrate the output power |

## TROUBLESHOOTING

| PROBLEM | PROBABLE CAUSES | POSSIBLE REMEDIES |
|---|---|---|
| LCD display fails to light | Adapter contact failure | Ensure power cord is connected to back of device, completely. |
| Stop output and Tuning failure | Coaxial Cable contact failure | Ensure Coaxial Cable is connected & locked into place. |

# OPERATING DATA & RATINGS

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## SPECIFICATIONS

| | |
|---|---|
| Width* | 455 mm (17.91") |
| Depth* | 555 mm (21.85") |
| Height* | 1075 mm (42.32") |
| Standard Net Weight | 32.3 kg (71.21 lbs) |
| Ambient temperature | +5 °C to 40 °C (41 °F to 104 °F) |
| Relative Humidity | 10% to 85% |
| Air Pressure | 700 hPa to 1060 hPa |
| Power Consumption | 450 VA |
| Power Supply | 100-240 V, 50/60 Hz, 2.5-5.0 A |
| Output Frequency | 27.12 MHz ± 0.6% |
| Mode | Pulsed or Continuous |
| HF output:<br>Continuous Mode<br>Pulsed Mode | <br>100W Average Power at 50Ω<br>200W Peak Power at 50Ω |
| Power Increment Settings | 5 W |
| Power Indication | Maximum and Average Power |
| Pulse Width | 20 - 400 µsec in 20 µsec increments |
| Pulse Frequencies | 10 - 800 Hz in 10 Hz increments |
| Treatment Duration | 1 - 30 minutes in 1 minute increments |
| Storage/Shipping Conditions:<br>Temperature<br>Relative Humidity<br>Air Pressure | <br>-4 - 131 °F (-20 - 55°C)<br>10% to 93%<br>700 hPa to 1060 hPa |
| Electrical Class | CLASS I |
| Electrical Type (Degree of Protection) | TYPE BF |

* without electrodes, electrode arm, and electrode cables

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# APPENDIX A - EMC TABLES

## IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

This medical conforms to t IEC60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories other than those specified by the manufacturer, with the exception of the ones sold by the manufacturer as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- This device should not be used adjacent to or stacked with other equipment.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## TABLE 1: GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS

The TheraTouch® DX2 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraTouch® DX2 should assure that it is used in such an environment.

| Emission test | Compliance | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 2 | The TheraTouch® DX2 must emit RF energy to perform its internal function. Nearby electronic equipment may be affected. |
| RF emissions CISPR11 | Class A | The TheraTouch® DX2 device is equipment suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

# APPENDIX A - EMC TABLES

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## TABLE 2: GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

| **Guidance and manufacturer's declaration — electromagnetic immunity** | | | |
|---|---|---|---|
| The TheraTouch® DX2 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraTouch® DX2 should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 0.5kV, ± 1 kV line(s) to lines<br>± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth | ± 0.5kV, ± 1 kV line(s) to lines<br>± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°<br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°<br>0 % UT; 250/300 cycles | 0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°<br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°<br>0 % UT; 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is needed that the device be powered from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: UT is the main power voltage prior to application of the test level. | | | |

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# APPENDIX A - EMC TABLES

## TABLE 3: GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

| Guidance and- manufacturer's declaration. Electromagnetic immunity | | | |
|---|---|---|---|
| The TheraTouch® DX2 device is intended for use in. the electromagnetic environment specified below. The customer or the user of the TheraTouch® DX2 should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF IEC 61000-4-6<br>Radiated RF IEC 61000-4-3 | 3 V<br>0.15 MHz to 80 MHz<br>6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br><br>3 V/m<br>80 MHz to 2.7 GHz | 3 V<br>0.15 MHz to 80 MHz<br>6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the TheraTouch® DX2 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d=([3.5]\sqrt{P})/V_1$ , 80 MHz to 150 KHz<br>$d=([3.5]\sqrt{P})/E_1$ , 80 MHz to 800 MHz<br>$d=([7]\sqrt{P})/E_1$ , 800 MHz to 2.7 GHz<br>Where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)b.<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range b .<br>Interference may occur In the vicinity of equipment marked with the following symbol: |
| NOTE 1 : At 80 MHz ends 800 MHz. the higher frequency range applies.<br>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

**a.** Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TheraTouch® DX2 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TheraTouch® DX2.

**b.** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# APPENDIX A - EMC TABLES

### TABLE 4: RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THERATOUCH® DX2

**Recommended separation distances between portable and mobile RF communications equipment and the TheraTouch® DX2 device**

The TheraTouch® DX2 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TheraTouch® DX2 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TheraTouch® DX2 as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output Power of transmitter W** | **Separation distance according to frequency of transmitter m** | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d=([3.5]\sqrt{P})/V_1$ | 80 MHz to 800MHz $d=([3.5]\sqrt{P})/E_1$ | 800 MHz to 2.7GHz $d=([7]\sqrt{P})/E_1$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz. The separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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