PHOTOBIOMODULATION THERAPY

BIOFLEX

MiniPort Professional

User Manual

Meditech International Inc
411 Horner Ave Unit 1
Toronto, ON M8W 4W3
Canada

Toll Free: 1-844-770-0177 (North America Only)
Phone: 1-416-251-1055 or 1-888-557-4004 Ext: 117 & 137
Email: service@bioflexlaser.com
Website: www.bioflexlaser.com

Family: BIOFLEX® MiniPort Professional
Models: Main Controller Unit I Professional (MCU I-P), DUO+ 180 (LS-B 2250+), DUO+ 240 (LS-B 3000+), DUOFLEX+ 120 (LS-B 3270), DUOFLEX+ 180 (LS-B 4890), LD-R 100+, LD-I 200+
Date: April 2026

Regulatory Representatives		
Region	**Representative**	**Contact**
Europe	EU REP Authorized Representative	CMC Medical Devices & Drugs SL C/ Horacio Lengo N18 29006, Málaga, Spain
United Kingdom	UK REP UK Responsible Person	CMC Medical Devices Ltd Office 32, 19-21 Crawford St London, W1H 1PJ United Kingdom
Australia	Australian Sponsor	RQSolutions Pty Ltd 44 Del Monte Pl Copacabana NSW 2251 Australia

Table of Contents

Intended Use and Indications for Use

The BIOFLEX® MiniPort Professional is used by trained healthcare professionals and is indicated for use to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness, promoting relaxation of muscle tissue and temporary increase in local blood circulation.

Target Population

Adults (18+)

Contraindications

The use of BIOFLEX® systems is contraindicated for patients with lupus and other diseases which may be stimulated by light, history of keloids, recent excessive sun exposure and/or artificial tanning at the treatment area, recent patients using photosensitive medications or herbs, and patients who are pregnant. For additional advice consult your personal physician or consultants at Meditech.

Side Effects

The following may be experienced: pain; bruising and swelling; redness and inflammation; herpes simplex outbreaks and bacterial infections; temporary skin lightening or darkening; darkening/lightening of tattoos; freckle loss or lightening of moles; permanent skin pigment changes; exacerbation of preexisting skin conditions; and hair loss at the treatment area.

Important Information

- It is appropriate to read and understand the user manual. Failure to follow the instructions may result in complications and void the product warranty.
- Ensure that the system is electrically rated to operate with the alternating current power available in your location. Call BIOFLEX® Service for additional assistance.
- Connecting electrical equipment to a power bar effectively leads to creating a Medical Electrical System and the result can be a reduced level of safety (see IEC 60601-1).
- Use of accessories, detachable parts, and materials other than those provided with the system is not allowed and may be unsafe. Do not connect equipment other than what is provided with the system.
- Warning: Do not attempt to modify or open any part of the system. No modification of this equipment is allowed.

- The system is intended to be used externally over the skin only. Do not treat over compromised skin, mucous membranes, or over the eyes.
- Do not use the system over the eyes. It is inappropriate to do this as it may irritate or even damage the eyes.
- Avoid looking directly into the LED beam or staring at its bright reflections.
- Use dark glasses if your eyes are sensitive to the light emanating from the LED array or while treating upper body areas.
- Keep the system away from radiators and heat sources. Do not block any ports or cooling vents.
- Prolonged exposure to direct sunlight or excessive exposure to lint or dust is not recommended and may accelerate deterioration of the system components.
- The device must be used in a dry environment and be kept away from moisture at all times.
- The system is not waterproof. Do not allow it to become wet, do not rinse under water, or use while bathing.
- The system will produce an audible signal when powered on. Ensure the audible signal is heard before operating the system.
- Do not cover the LED array during treatment. The top surface removes excess heat into the surrounding environment.
- All system cables should be periodically inspected for signs of deterioration. Do not use the system if any cables are damaged.
- Do not exert excessive pressure or twisting motions on the LED array as this may damage the system circuitry.
- Do not pull or wrap cables around the LED array too tightly.
- Do not use the system while operating a vehicle or machinery.
- Do not use the system as a passenger in a vehicle. The bright light may distract the driver.
- Do not leave the device unattended while in operational mode.
- Keep out of reach of pets, pests, and children. Do not let young children use the system unattended.
- The system is designed for a service life of 10 years assuming that recommendations for annual calibration and maintenance are followed.
- Follow applicable local medical and electronic equipment disposal regulations and acts, including the Waste Electrical and Electronic Equipment Directive (WEEE Directive), if applicable.
- Do not run any other applications on the system except for BIOFLEX® Practitioner+.
- Always activate the Software Lock in BIOFLEX® Practitioner+ when the system is not in use.
- In Canada, the subject device should be installed and operated in accordance with CAN/CSA-Z386: Laser Safety in Health Care Facilities.

- Warning: Wear safety glasses when using the laser probes.
- Position the controller unit such that the Laser Stop button is easily accessible.
- In case of emergency, press the Laser Stop button on the front of the controller unit. This action immediately stops the treatment and emission of light radiation.
- Caution: Use of controls or adjustments to performance of procedures, other than those specified herein may result in hazardous radiation exposure.

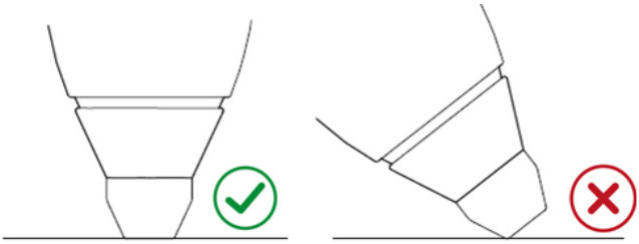
Laser Safety Rules

These laser probes are Class 3B lasers that produce a very intense beam of light that is potentially hazardous if a direct beam and/or specular reflection is viewed by the unprotected eye. The following precautions should be taken to avoid direct beam viewing and to control specular reflections:

- Read the Laser Safety Guide from the Laser Institute of America before using the system.
- Warning: Designate a Laser Safety Officer (LSO) in accordance with the Laser Safety Guide. Ensure an effective laser safety program is in place.
- Warning: Make sure that the system is located and operated in a controlled area. The purpose of a controlled area is to confine laser hazards to a well-defined space that is under the control of the laser operator. An example of a controlled area would be a room with a closed door.
- Remove all shiny objects from the area where you will be working. This includes rings, watches, metal bands, tools, and glass. Reflections from the beam can be nearly as intense as the beam itself.
- The entrances to the controlled area should be posted with a provided laser warning sign.
- Warning: Never look directly into the laser beam or stare at their bright reflections. Permanent eye damage could result.
- Never use magnifiers (such as binoculars or telescopes) to look at the beam.
- Never point the laser at the eyes directly.
- If you are applying the laser to a region of the face, please ensure that the patient is wearing the safety eye shields which protect against possible exposure of the eye to the laser beam.
- Never leave the laser unattended while it is turned on.
- Warning: Wear safety glasses! Every person within the enclosed area must wear safety glasses or eye shields when using a laser probe.
- The laser probe is equipped with a “body switch” that will start the laser beam only when the tip of the laser probe is in direct contact with the skin. The “body switch” was designed to help prevent direct ocular exposure to

the laser beam.

- Specific labeling is required on all laser products. For your safety and that of others, do not remove any of the labels.
- Caution: For your own safety, ensure that the entire flat surface of the nosecone tip (also called the "body switch") has complete contact with the skin and is not applied at an angle. Failure to do so will allow potentially harmful laser light to irradiate the surrounding areas.



Safety Glasses and Eye Shield Use

- Warning: Failure to follow these instructions may result in serious injury and/or blindness.
- Warning: Read the Laser Safety Guide and all instructions and warnings before using the system.
- Warning: Never use the safety glasses for any purpose other than for eye protection for the system.
- Never use other manufacturer's safety glasses with the system.
- Always avoid direct eye exposure to direct or reflected laser light.
- Ensure the eyewear fits securely at all times.
- Warning: Always check your eyewear before use to assure that it has not become pitted, cracked, crazed, scratched, discoloured, or otherwise damaged. Exposure to or contact with chemical vapors or liquids may also cause surface cracks or other damage. Do not use if you observe any type of damage to your eyewear and replace your eyewear immediately.
- Always keep your eyewear in the protective casing provided when not in use.
- Warning: Use the provided eye shields when administering laser therapy in the facial region. Do not treat near the eyes.

Safety Glasses Cleaning Instructions

Warning: Do not use ammonia, alkaline cleaners, abrasive cleaning compounds, or solvents when cleaning the safety glasses. Certain solvents may lower the impact resistance of the lenses.

1. Wash in mild soap and water.
2. Rinse in clean water.
3. Air dry or pat dry with a clean, soft tissue.

LED Array Cooling

Surfaces of the LED arrays may get hot and may reach temperatures as high as 51°C at 40° ambient temperature. Caution must be exercised. This is particularly applicable to treatment steps running in infrared light. The higher the power and/or duty cycle, the higher the temperature. Hotter surfaces are also expected if treatments are run consecutively without sufficient time for the LED array to cool down.

If the administering person is different than the person receiving the treatment, they should be warned that the LED array may become uncomfortable and that they should notify the administering individual if so especially for young children, elderly patients and/or patients who are sensitive to heat. Common sense must prevail. If an individual leans back against the LED array placed on the spine, there may be lack of ventilation and overheating may occur. The LED array must be properly ventilated.

Cool the LED array for a minimum of 15 minutes at room temperature in case it gets too hot. Note that the internal temperature sensor will prevent the LED array from operating if the LED array gets very hot.

Essential Performance

According to IEC 60601-1 Ed. 3.2, Essential Performance is performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. The Essential Performance of the BIOFLEX® MiniPort Professional according to IEC 60601-1 Ed. 3.2, is to not radiate harmful levels of light to shine in the eyes of the patients, operators or bystanders.

System Components

Image	Name and Model
System components are intended to be used with the BIOFLEX® MiniPort Professional only. Parts may appear visually different than as displayed.	

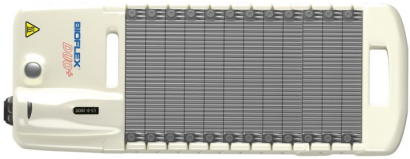
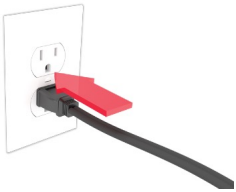
Image	Name and Model
	Main Controller Unit I Professional MCU I-P
	DUO+ 240 LS-B 3000+
	DUOFLEX+ 180 LS-B 4890
	LD-R 100+
	LD-I 200+
	Power Supply

Image	Name and Model
	Power Cable
	Treatment Head Cable
	Safety Glasses
	Eye Shields
	Straps

Image	Name and Model
	Carrying Case

System Setup

Instruction	Image
1. Connect the power supply into the socket in the back of the device.	
2. Connect the power cable to the power supply.	
3. Connect the power cable to a wall socket.	

Instruction	Image
4. Connect the treatment head cable into the port in the MCU I-P.	
5. Connect the treatment head cable to the LED array.	
6. Connect the treatment head cable to the laser probe. The system is now ready for use.	

System Features

Port

The MCU I-P has one port available on the side. The port is used to connect any LED array compatible with the MCU I-P. The plug and socket are keyed, thus they must be correctly orientated before they will mate. Recognition of the LED array will come through the software.

Treatment

Treatments are controlled via BIOFLEX® Practitioner+; however, there is a Laser Stop button which can be used to stop all treatments in an emergency.

Power Supply

A power supply is provided with your system and is connected to the MCU I-P to provide the power needed for operation. Only use the supplied power supply with your system. Do not connect any other power supply to your MCU I-P.

Power Cord

Use a Meditech-supplied power cord to connect the power supply to a power socket.

On/Off Button

The MCU I-P also has an on/off switch located on the front panel (illuminated). This button will turn BIOFLEX® Practitioner and the screen on and off once the power to the unit is available.

External USBs

The MCU I-P has two USB ports located on the back of the unit. The primary use of these ports is to connect a flash drive for backup. This USB port is also available to connect external accessories, such as a keyboard or mouse.

Software Installation

The BIOFLEX® MiniPort Professional uses BIOFLEX® MiniPort Professional Practitioner+, which is pre-installed on the MCU I-P. This new innovative way of treating patients makes prescribing easier and faster, as well as being able to view all treatments as they progress. If updates are required, instructions will be provided by Meditech.

LED Array

The LED array is capable of emitting red or infrared light. The system will automatically progress from a red to an infrared step without pause for a single placement of the LED array. The system will pause automatically between infrared and red steps to allow for repositioning of the LED array.

System Operation, Indicators, and Controls

This section describes the system's audible and visual warnings for the LED arrays. It also explains how to stop the system in an emergency situation.

DUO+ 240

- Once enabled, two beeps will sound, one short and one long. The green indicator LED on the LED array will start blinking, indicating that the LED array is ready to start.
- Once started by quickly double tapping the button on the LED array

or tapping Play, two long beeps will sound. Both the green and amber indicator LEDs will turn solid. The LED array will turn on and light will be radiated.

- Once paused by tapping the button on the LED array or tapping Pause, a long beep will sound and the amber indicator LED will turn off. The green indicator LED will start blinking and the light from the LED array will stop radiating.
- Once stopped by tapping Stop, a long beep will be heard and the amber indicator LED will turn off. The green indicator LED will start blinking. After confirmation to stop the prescription is made, another long beep will sound, and the green indicator LED on the will turn off.

DUOFLEX+ 180

- Once enabled, two beeps will sound, one short and one long. The green indicator LED on the LED array Start/Stop button will start blinking, indicating that the LED array is ready to start.
- Once started by quickly double tapping the button on the LED array or tapping Play, two long beeps will sound. The green indicator LED will turn solid. The LED array will turn on, and light will be radiated from the LED array.
- Once paused by tapping the button on the LED array or tapping Pause, a long beep will sound. The green indicator LED will start blinking, and light from the LED array will stop radiating.
- Once stopped by tapping Stop, a long beep will be heard. The green indicator LED will start blinking. After confirmation to stop the prescription is made, another long beep will sound, and the green indicator LED on the will turn off.

Laser Probes

- Once enabled, two beeps will sound, one short and one long. The green indicator on the probe will turn solid, indicating that it is ready to start.
- Note: The probe must not contact the skin until the indicator on the probe is green.
- Once started by applying the surface of the nosecone tip flat against the skin, two long beeps will sound. The green indicator on the probe will turn amber. The probe will turn on and light will be radiated.
- Once paused by removing the nosecone from the skin, a single beep will sound. The amber indicator will turn green. The light from the probe will stop radiating.

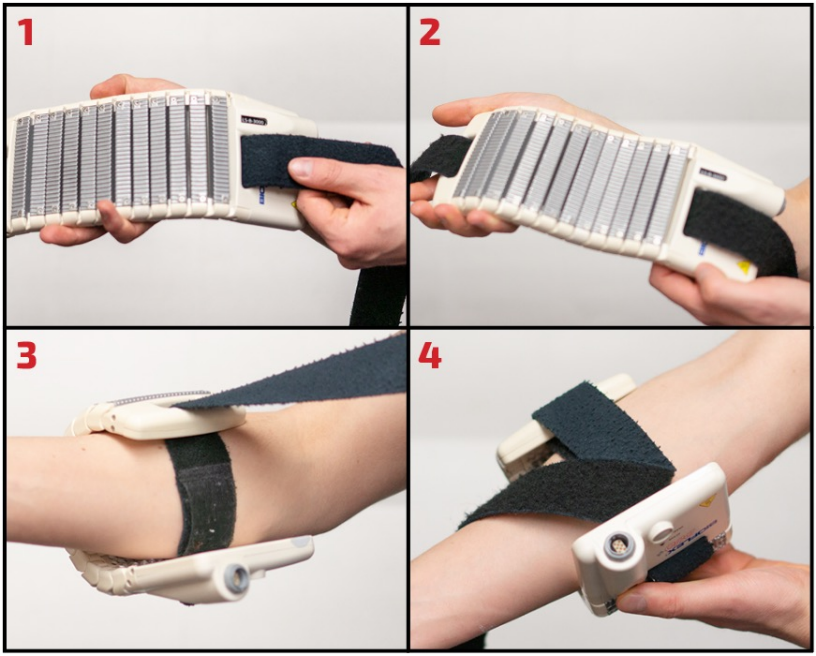
- Once stopped by using the software, one long beep will sound. The green indicator will turn off.

Emergency Stop

In an emergency, press the Red button on the front of the MCU I-P. This immediately stops the emission of light from the LED array. Beeps will be heard and active treatment will be stopped. Treatment can only be resumed after confirmation on BIOFLEX® Practitioner+.

Placement of LED Arrays

The LED arrays may be secured directly to the body with the provided strap. This is done by feeding the strap through the end loop of the LED array and then mating the strap.



- Do not bend the LED array beyond its normal curvature, as this may break the LED array.
- The LED array must be secured while allowing air circulation around the top surfaces of the LED array.

Laser Probes

These laser probes are equipped with a “body switch” that will start the laser light only when the tip is in direct contact with the skin without an angle. After enabling the treatment or continuing from a previous step, the practitioner must wait for the indicators on the laser probe to turn green before applying probe or making contact with the nosecone tip.

Application of Treatment

1. Local: Apply the LED array to the painful area.
2. Treating a joint: When treating a joint, place the LED array over the most symptomatic area and if possible, surround the entire joint. For example, if treating hand arthritis, place the LED array on the palm and back of the hand.
3. Good contact between the LED array and skin should always be maintained. This may require gentle application of pressure keeping in mind that ventilation for proper cooling must continue. When strapping an LED array, good contact without excessive pressure is important.
4. Maintaining cleanliness: Ensure the skin is free of oil, lotions, creams, etc. before applying the LED array. LED arrays should be carefully cleaned between use.
5. Frequency of use: Initially treat once per day, but not exceeding twice a day. As symptoms improve, treatment can be reduced to every other day until symptoms resolve. For progressive conditions like osteoarthritis, ongoing treatment 2 - 3 times a week may be helpful in managing ongoing symptoms of pain and stiffness.

Treatment Protocols and Levels

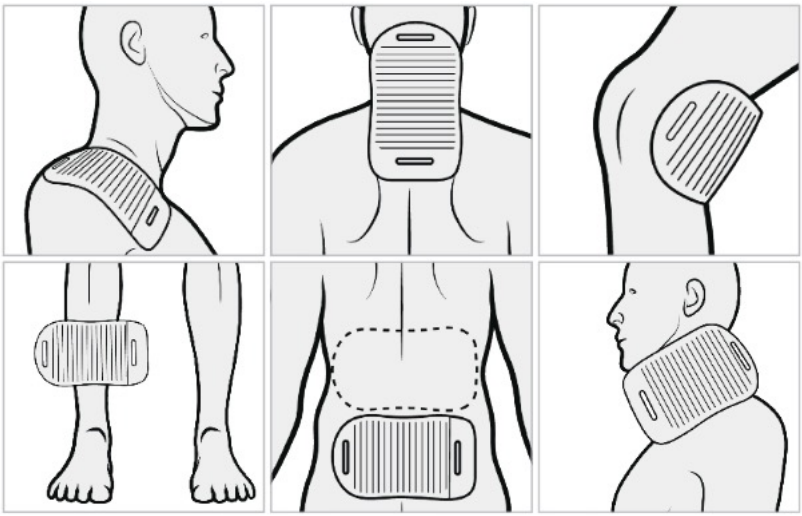
The preprogrammed protocols provide optimal parameters depending on the condition being treated. Levels of protocols reference increasing dosage of light and stimulation. It is recommended to start with Level 1 and only increase to the next level if symptoms are not improving or are no longer improving.

LED Arrays

Your BIOFLEX® MiniPort Professional is provided with a DUO+ 240 by default; however, an optional DUOFLEX+ 180 is available. Both of these LED arrays provide the same dosage. Thus, any LED array can be used for any specific protocol. LED array selection depends on user preference.

Placement

The system is primarily utilized to treat localized pathologies characterized by pain and other symptoms. It may also be placed over the area of the spine innervating the area that is symptomatic. The following illustrations demonstrate typical ways to place the array over a treatment area:

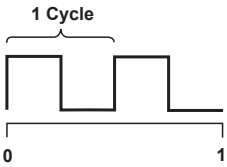


Parameters

Waveform: When the system is used in “Modulation” (Mode of Operation) the waveform controls the output intensity of the laser diode and LEDs. The system uses square waveforms.

Frequency (Hz): Describes how many times (cycles) per second the waveform repeats.

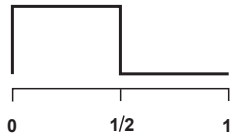
For example, the figure below shows a square wave repeating two times in one second.



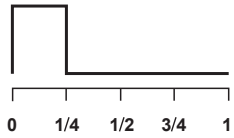
Therefore, the frequency of the above waveform is 2 cycles per second (c/s) or 2 Hertz (Hz).

Duty Cycle (%): When the system is used in “Modulation” (Mode of Operation), duty cycle describes the percentage of time the light is on compared to the time

it is off in each cycle. The figure below shows a square waveform with a duty cycle of 50% because it is on for half of its full cycle (1/2 x 100% = 50%).



The figure below shows a square waveform with a duty cycle of 25% because it is on for 1/4 of its full cycle (1/4 x 100% = 25%).



Power Density (mW/cm²): Describes the amount of light delivered over the treatment area. For example, if a 60 W (equals 60,000 mW) light delivers all its light to a 10 cm² area, the power density is:

$$60{,}000 \div 10 = 6{,}000 \text{ mW/cm}^2$$

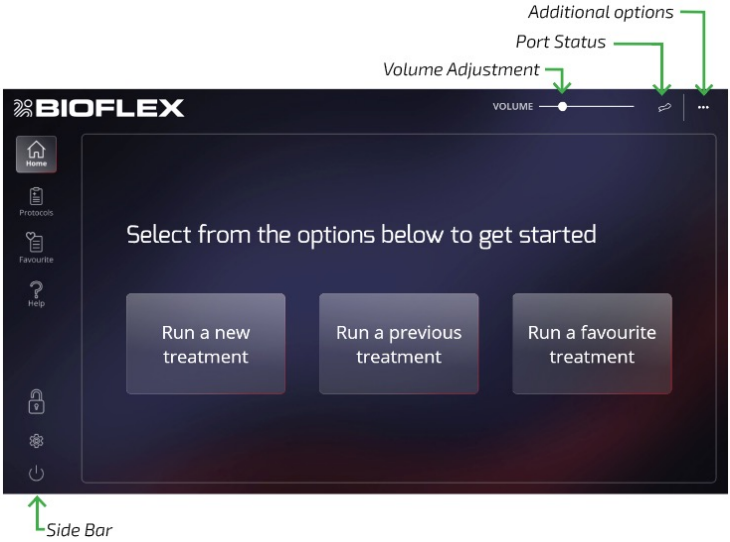
Energy Density (J/cm²): Indicates the amount of power divided by the area (power density) multiplied by time (duration). For example, if a 60 W light delivers all its light to a 10 cm² area for 10 seconds, the power density is:

$$60 \div 10 \times 10 = 60 \text{ J/cm}^2$$

Duration (s): The length of time for the treatment.

BIOFLEX Practitioner+

BIOFLEX® MiniPort Professional Practitioner+ (i.e. BIOFLEX® Practitioner+) is a software application developed by Meditech and designed to work with the BIOFLEX® MiniPort Professional. It is an intuitive and easy to use application. The following sections describe the use of the application and its features.



From the Home screen, choose to run a quick treatment or go to View Patients to assign a treatment to an existing or a new patient. Running a quick treatment allows a treatment to be run without choosing a patient first (for a quick start). At the end of a quick treatment, there is an option to save to an existing patient or to a new patient.

On the side bar choose to go to Patients, Protocols, Help, Lock Laser, Settings, or the On/Off button (to turn the application off).

On the top right is a slider for adjusting the speaker volume, a button for viewing the port status, and a button for additional options.

Side Bar

The side bar is located on the left of the screen. It enables the following actions:

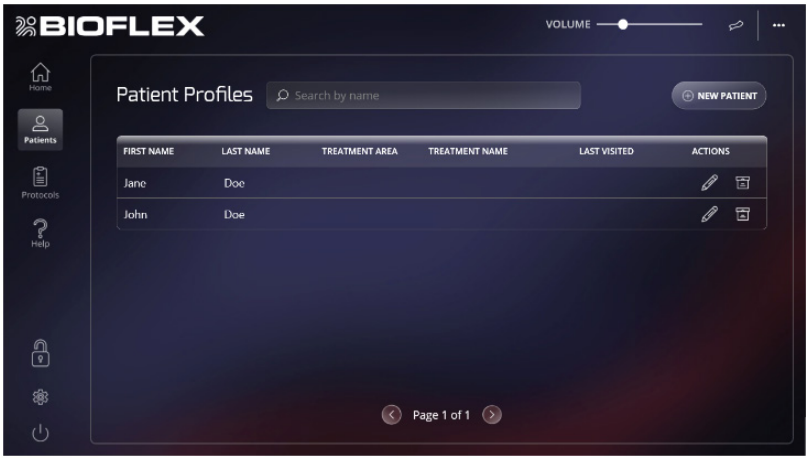
- The Home button can be clicked at any time to go back to the Home screen.
- The Protocols button can be clicked at anytime to go to the Select Protocol screen. From the Protocol screen, select a protocol.
- The Favourite button can be clicked at anytime to go to the Favourite Protocols screen. From the list of favourite protocols, choose a protocol to run.
- The Help button can be clicked at any time to access the Help screens. The Help screens contain the information of this chapter as well as a link to the treatment tutorials, links to the frequently asked questions,

and information pertaining to the software name, software version, and software region.

- The Lockup button provides a way to lock the system in case the operator needs to step away. This eliminates the risk of an unauthorized person using the device. Once the system is locked, a password is required to unlock the system. The Lockup factory setting password is locklaser. This password can be changed by choosing the Settings button from the side bar in the Home screen and following the steps for changing the password.
- The Settings button can be used to change settings, such as passwords, volume, brightness, etc.
- The On/Off button allows the user to shut down the application. Note that the device is still powered on. To fully turn the MCU I-P off, unplug the power supply located at the back of the unit.

Patient Profiles

Selecting View Patients from the Home screen or the Patients button on the side bar will navigate to the Patient Profiles screen.



In the Patient Profiles screen:

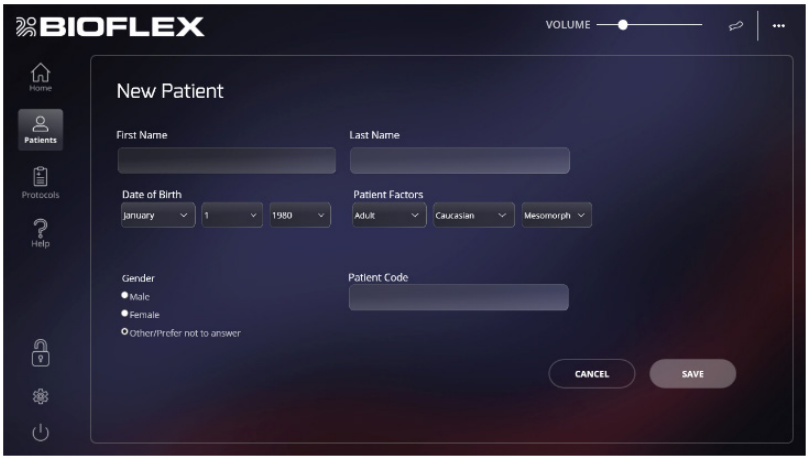
- Choose an existing patient from the list or create a new one by clicking on the New Patient button.
- Search for an existing patient by typing in the Search by Name box. Any text will narrow down the list to include only patients whose name includes the text entered in the search box.
- The list can be sorted by clicking on any column header to sort by that

column.

- In the Actions column, a selection can be made to either edit the patient's profile or archive the patient. Click to edit and to archive.
- When archiving, a password is required. This is the Administrator password and the default factory setting password is newadmin. This password can be changed by choosing the Settings button from the side bar in the Home screen and following the steps for changing the password.

Creating/Editing a Patient

After selecting to create a new patient from the Patient Profiles screen, the New Patient screen is shown.



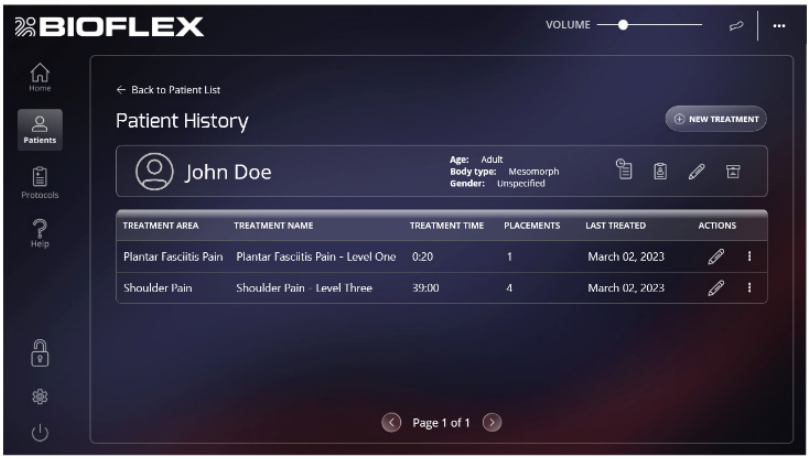
In the New Patient screen:

- Fill in the details, first and last name, date of birth, and gender.
- Enter a patient code. Patient codes are not generated automatically, but the application will not allow duplicate codes. The patient code can only include alphanumeric characters and the '-' sign with a 24-character limit.
- Patient factors can also be edited or left as default. Patient factors fields will be shown and available only if the Patient Factors feature is enabled in Settings.
- Press the Save button to save the newly created patient profile or Cancel to cancel.
- Saving the newly created patient profile will bring up an option to prescribe a new treatment to this patient or go back to the Patient Profiles screen.
- Note: When editing a patient, a similar window will show, but the options

are the same.

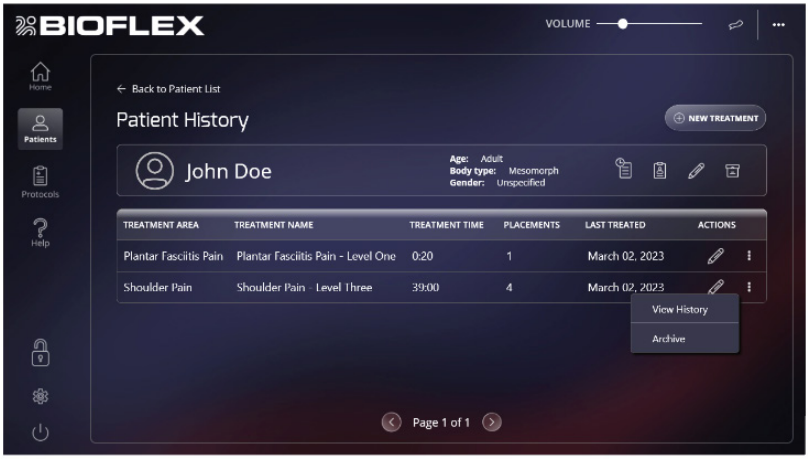
Patient History

After selecting an existing patient from the Patient Profiles screen, the Patient History screen is shown.



In the Patient History screen:

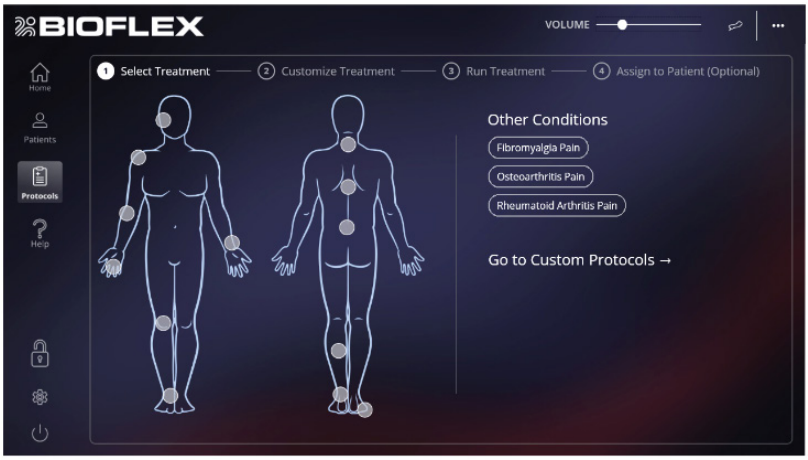
- A list of previously prescribed treatments is shown as well as the patient's details.
- Choose an existing treatment from the list to run it again.
- Press the New Treatment button to prescribe a new treatment.
- The patient's profile can also be edited from this screen or be archived. In the patient's details area (above the list of previously prescribed treatment), click ✎ to edit and 🗄 to archive the patient.
- When archiving, the Administrator password is required.
- In the Patient History screen, a list of previously prescribed treatments is shown in a table. Each row corresponds to a previously prescribed treatment for the patient. The Actions column in this table contains two buttons - an Edit button ✎ and an Options button ⋮.
- Choose the Edit button ✎ to modify (customize) the treatment.
- Choose the Options button ⋮ to view the treatment's revision history or to archive the treatment.



Archiving a treatment removes that treatment from the patient's treatment history list (i.e. removes the row from the list).

Selecting a Protocol

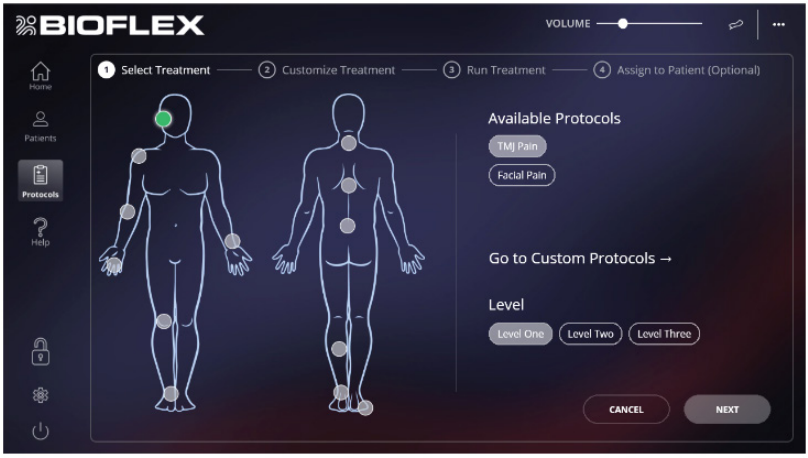
A protocol can be selected after choosing to run a new treatment for an existing patient or after selecting to run a quick treatment. The Select Protocol screen shows up.



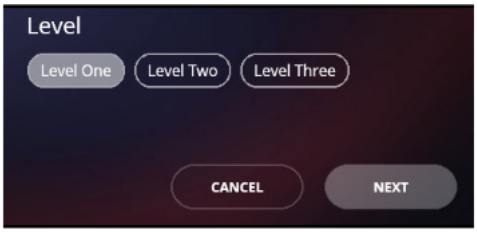
In the Select Protocol screen:

- Choose one of the body locations (dots on the body figures) or a protocol under other conditions.

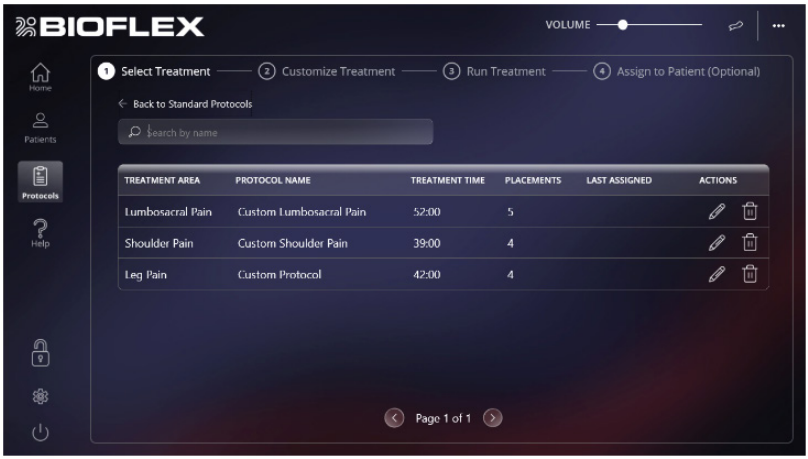
- If there is more than one protocol associated with a body location, select the most applicable protocol under Available Protocols.



- Make sure to select the desired level before selecting Next. There are no set rules or set levels for protocol treatments. It is recommended to start at Level 1 for treatments and evaluate their success. In this way, the levels can be raised or lowered based on treatment performance.



- To run a custom protocol or create a new custom protocol go to Custom Protocols.
- After going into custom protocols, a list of custom protocols will show in the screen.
- Existing custom protocols can be reviewed, edited, or archived by clicking the corresponding button in the Actions tab.
- Choose an existing custom protocol from the list to run it. In the next screen, click Run Treatment to start. Parameters can be edited before running the protocol.



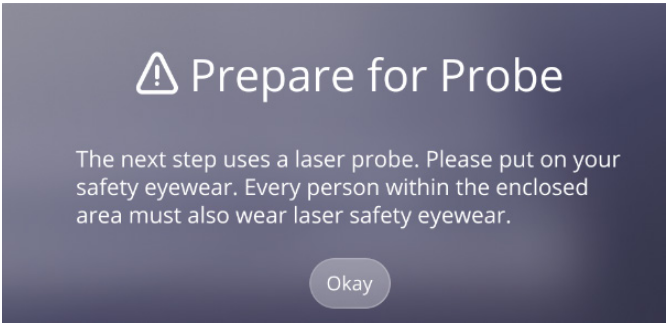
Running a Treatment

After selecting a protocol (standard or custom), a new screen opens showing the protocol parameters and steps.

- The parameters and steps can be edited prior to running the protocol.
- Additionally, the edited protocol can be saved to the Custom Protocol List from this window by clicking the Save to Custom Protocols List button.
- To start the treatment, click the Run Treatment button. The treatment head will activate (a message will come up if no head is connected) and the Running a Treatment screen will be shown.

The Running a Treatment screen shows cascading steps (placements) as well as the progress of the treatment.

- To start the treatment, click the Play button ⊙.
- Treatment can be paused and resumed by clicking the Pause button ⊙ and the Play button ⊙.
- To skip a step, pause the treatment first and then click on the desired step.
- Information about the energy density applied is shown as the treatment progresses.
- If the treatment started from the Quick Treatment option, a button will be available on the screen to assign this treatment to a new or existing patient. Simply click on the button and follow the on-screen instructions.
- The pictures at the bottom of the screen show typical placements of the treatment being run (for standard protocols only). However, the exact position (and the number of placements) is determined by the practitioner and based on the location and extent of the pathology being treated.
- Not all placements are necessary. Actual placements are determined by the practitioner and based on the location and extent of the pathology being treated. Skip step(s) as necessary. Placements can be skipped by clicking on any step in the cascading list of steps (current running step must be paused before being able to skip to a different step).
- Once the array steps (placements) are finished and prior to starting a laser step, a warning message will come up to make sure that every person in the enclosed (laser enclosed) area is wearing safety eyewear.



- Click Okay to acknowledge that a laser step is about to start and that everybody in the enclosed area is wearing safety eyewear. The laser probe is now enabled and the LED indicator will turn green.
- Note: Do not touch the nosecone of the laser probe while the laser step is being enabled. Doing so will interfere with the initial calibration of the laser probe and cause an error.
- The screen is now back to the Running a Treatment screen and showing

the progress of the treatment.

- When running a laser step, the laser probe will go in and out of running and pausing. When the laser probe is making contact with skin the laser light goes on and as soon as skin contact is removed, the laser probe will pause and laser light will be disabled. The practitioner should move the laser probe from spot to spot as the step progresses. The actual location and number of spots will be determined by the practitioner based on the location and the extent of the pathology being treated.
- Always follow laser safety rules when treating with a laser probe.

Customization

Treatments and/or protocols can be customized. The actions are the same for both. Customizing a treatment means customizing a treatment that was already assigned to a patient while customizing a protocol means to customize an existing standard protocol or any existing protocol in the Custom Protocol List.

When customizing the existing steps of a treatment or a protocol, the parameters are displayed. Steps can be added, deleted, or moved in order, and the following parameters can be changed for each step:

1. Duration (0 - 60 min): Length of time the treatment head is to be applied.
2. Power (0 - 100%): Setting for the % of maximum power to be used.
3. Waveform: Square or continuous.
4. Frequency (1 Hz – 10 kHz): Frequency of operation (square wave).
5. Duty Cycle (1 - 99%): Effective cycle of the full period (square wave).
6. Laser Diode Placement Duration (s): The dwell time for each acupoint. By default, it is set to 7 sec and can be changed to calculate the dosage for

other dwell times.

7. Dosage (J/cm²): Calculated dosage for the parameter set.
8. # of Repeats: Number of times to repeat this step for different placements.

If the treatment only requires one light, then the practitioner can set the duration for the other light to zero seconds, thus, turning off that portion of the treatment. The Waveform box will be highlighted in black when a duration is set to zero to indicate that this light is not used.

When going to custom protocols from the Protocol Selection window, there is an option to start a new custom protocol from the beginning where no existing steps will be populated.

Dosage

Dosage is calculated for the setting in each step (row). The practitioner can see the energy density that will be delivered and is able to make changes based on their professional judgment to achieve higher or lower dosages.

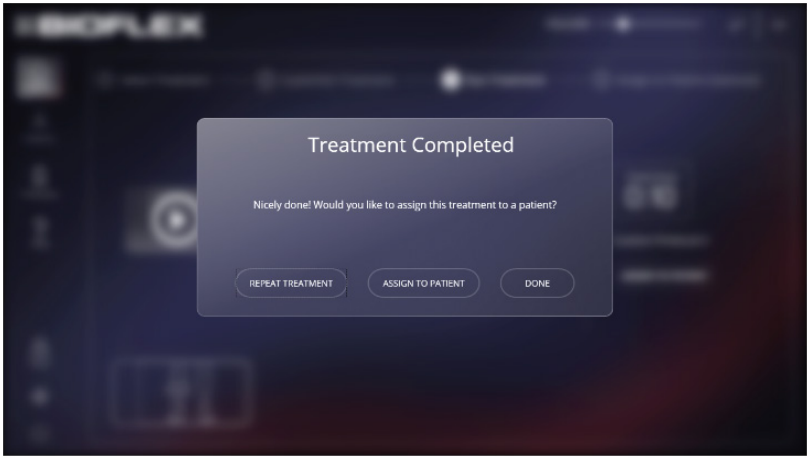
At the end of customizing, choose to either run the treatment or save it to a new custom protocol (to go on the Custom Protocol List). When saving to the Custom Protocol List, a name needs to be entered in the Treatment Name field.

Running a Quick Treatment

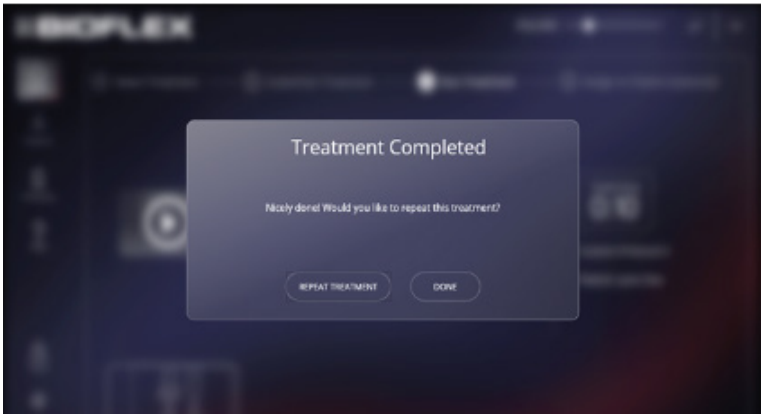
Running a quick treatment is an option from the Home screen without choosing an existing patient or creating a new patient first. This feature enables starting a treatment quickly and then later assigning it to an existing or new patient. It can also be used to run a treatment without assigning it to a patient.

After clicking on the Quick Treatment button on the Home screen, you will be taken to the Selecting Protocol screen. All steps from this point on for running or customizing the protocol are the same as if a patient was already assigned.

At the end of running a quick treatment, options will be available to assign the treatment to a patient (existing or new), repeat the treatment, or go back to the Home screen.



By clicking the Assign to Patient button you will be taken to the Assign to Patient screen where you can select a patient or create a new one and then continue to assign the treatment to that patient. A message will come up with an option to repeat the treatment or to go to the assigned patient's treatment history.



Port Status

A port's status can be seen at any point by clicking the Port Status button. The Port Controller Status window will show.

The Port Controller Status window shows the port status, serial number, and firmware version. To see the port data, click the Refresh Port Data button. To reset the port, click the Reset Port button.

The Port Controller Status window will also show the model of any treatment head that is connected to the port together with its output specifications. The internal temperature inside an LED array and if a treatment is running or paused, the remaining time for that treatment, are also displayed.

The port status indicates the state of the port. Some states of the treatment port can be:

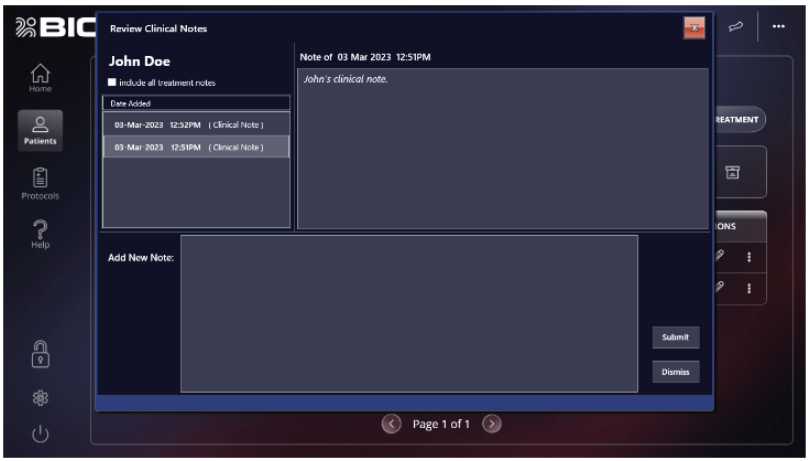
- N/A: A treatment head is not connected to the port.
- Idle: A treatment head is connected to the port, but no protocol is selected.
- Linked: A treatment head is connected to the port and a treatment protocol is selected.
- Enabled: A treatment head is connected to the port and is enabled (treatment head is fully powered and ready to be started).
- Running: The port is running a treatment protocol.
- Paused: The port is paused in the middle of treatment.
- Error (e.g. overheat)

If the port is in an error state, the user needs to click the Get Error Code button and proceed as instructed. The error may be cleared by clicking the Clear Error button in the Port Controller Status window.

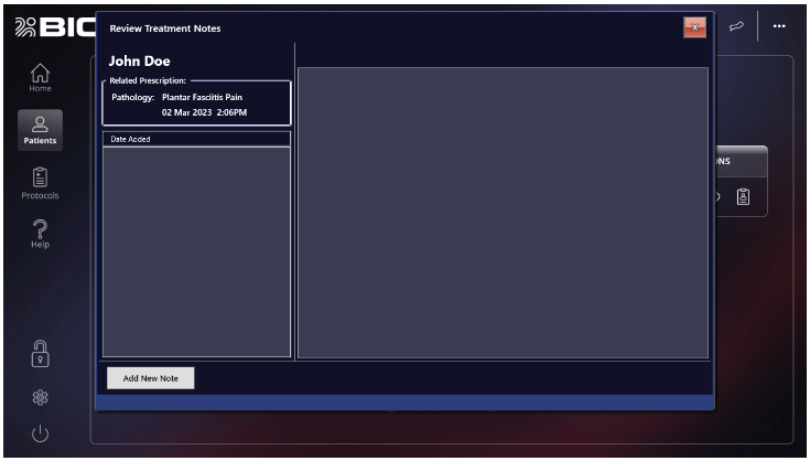
Patient and Treatment Notes

There are two note options in the BIOFLEX® Practitioner+ - Patient Clinical Notes

and Treatment Notes. Patient Clinical Notes are clinical notes that can be added by the practitioner to a patient by clicking the Patient Clinical Notes button in the Patient History screen. The Clinical Notes area is an optional field. This is where the practitioner can document information on the patient. The clinical notes are considered a historical field, and old notes cannot be deleted; however, notes can always be added. Clicking on the Patient Clinical Notes button opens the Review Clinical Notes window.

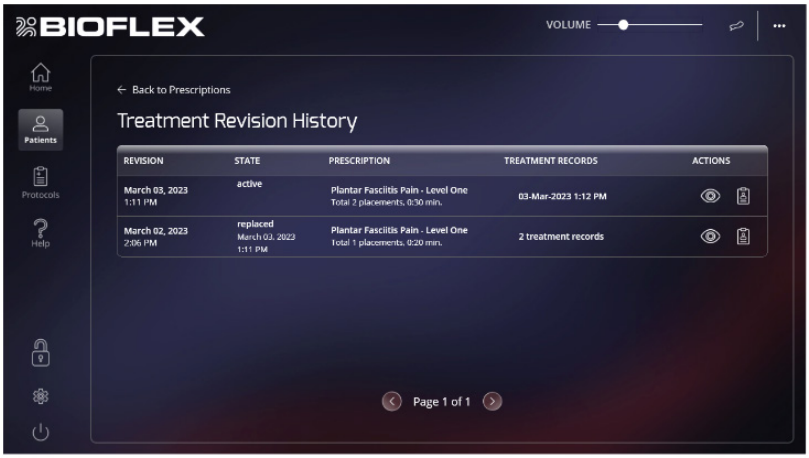


Treatment Notes are notes specific to a treatment in a patient's treatment history. To add or review treatment notes, click on the Notes button, which is located in the Actions column in the Patient History screen. The Review Treatment Notes screen will then be displayed.



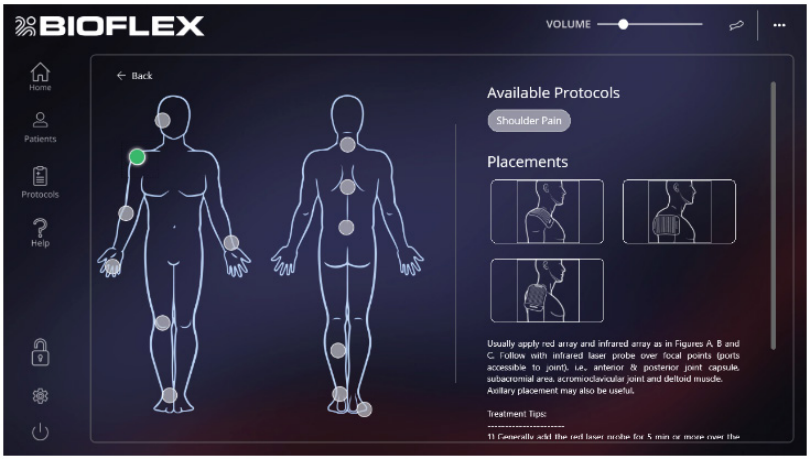
Treatment History

The Patient History screen shows a list of previously prescribed treatments. The list shows the last treated date for any treatment on the list. In order to see a treatment's (revision) history, click on the three dots in the Actions column and then choose View History. The Treatment History screen will open.



Treatment Tutorials

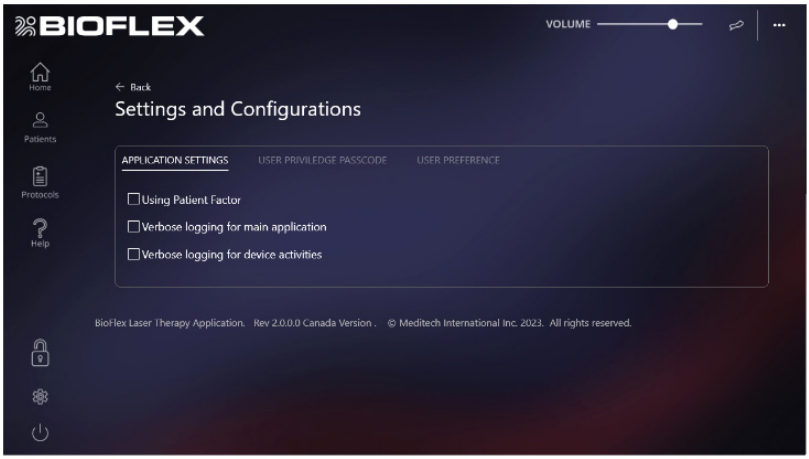
Tutorial support for treatments is available from Help in the side bar or from the Additional Options button in the Home screen. Similar to selecting a protocol for a treatment, the Tutorial screen has body locations and other protocols to choose from. Once a protocol is selected, the corresponding tutorial will be displayed.



If there are multiple protocols associated with an anatomy (body location), the first tutorial will be shown automatically. Click the other available protocols to view their tutorial.

Settings and Configuration

Settings and configurations are available by clicking on the Settings button ⚙ in the side bar. Click on one of Application Settings, User Privilege Passcode, or User Preference to access the setting that is required.



Application Settings

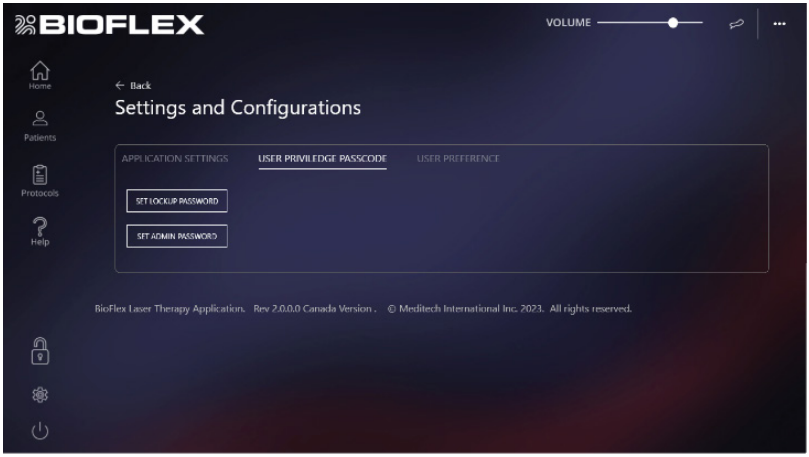
The Application Settings tab is used to enable or disable the following settings:

- Using Patient Factor: Used to switch the patient factor on and off. By default, this setting is off. Once enabled, the patient factors can be set when creating a new patient or editing an existing patient. This will adjust the duration to account for different body types and skin colours.
- Verbose logging for main application: Logs the database communications for diagnostic purposes.
- Verbose logging for device activities: Logs the hardware communications for diagnostic purposes.

User Privilege Passcode

The User Privilege Passcode tab is used to set or change the two passcodes in the system:

- Lockup Passcode: Used to set up a password for locking the system. The factory passcode is locklaser.
- Admin Passcode: Used to set up the Administrator password for archiving or restoring archived patients. The factory password is newadmin.

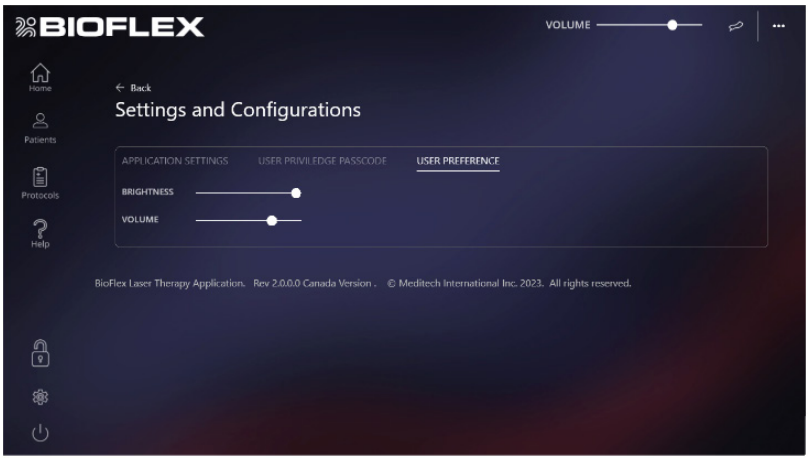


User Preference

The User Preference tab is used to change the following settings:

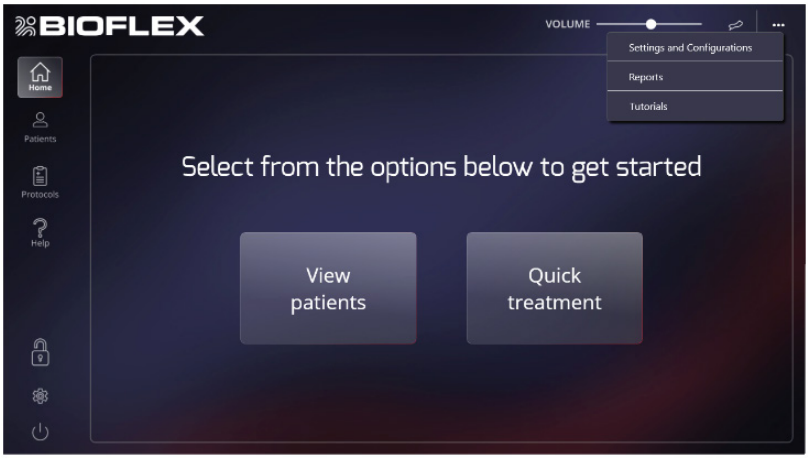
- Brightness: Change the brightness of the screen.
- Speaker Volume: Change the volume of the internal speakers (used when playing tutorial videos). Note this is not the volume of the audible beeps when treatments are started, paused, or stopped. The audible beeps are a safety mechanism that cannot be changed.

- Dark Mode: To toggle dark mode on or off. Dark mode lowers the screen and feature brightness. For user comfort, it may be preferable in dark environments.



Additional Options

The Additional Options button is on the top right of the screen, and can be used to access the settings and configurations or treatment tutorials and navigate to reports:



Database Reports

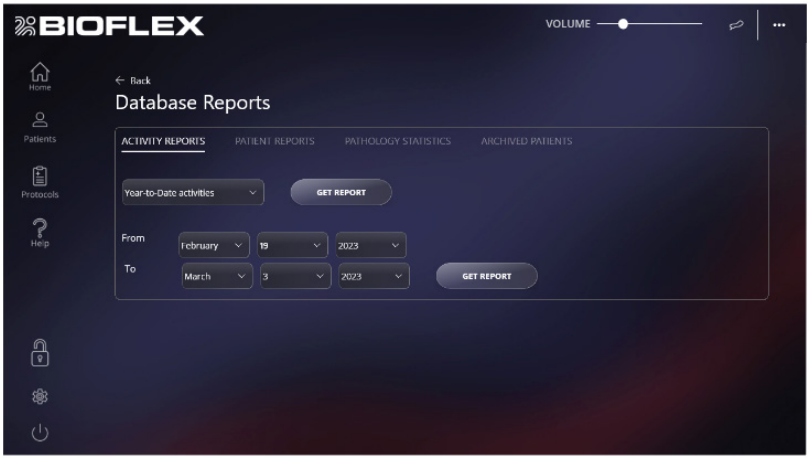
BIOFLEX® Practitioner+ offers four types of database reports:

- Activity Reports
- Patient Reports
- Pathology Statistics
- Archived Patients

These reports can be accessed from the Additional Options button. To generate a report, fill in the corresponding fields and follow the on-screen instructions. Reports can be downloaded to an external USB drive as a PDF file.

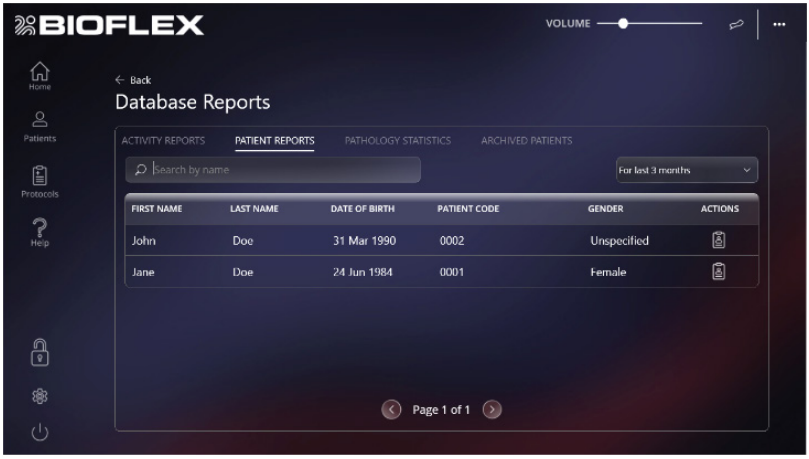
Activity Reports

Activity reports can be generated for a specific range of dates. The report will show the number of new patients, the number of treatments prescribed, the total time, and the total laser time treated on the dates that were selected. The report can be summarized daily, weekly, or monthly. To generate a report, fill in a date range or select a range from the dropdown list and click Get Report.



Patient Reports

Patients reports can be generated for a specific patient. To generate a report, select the date range from the dropdown list and then search and select a patient by name. The report will show details of all treatments for the patient in the date range.



Pathology Statistics

The Pathology Statistics report shows a summary of the pathologies treated and the number of treatments for each pathology. To generate the report, select the Pathology Statistics tab.

Archived Patients

The Archived Patients report shows a list of all archived patients. To generate the report, select the Archived Patients tab.

Restoring an Archived Patient

Patients can be restored from within the Archived Patients report by clicking on the icon in the Actions column of the report. When restoring an archived patient, the Administrator password is required.

Calibration, Maintenance, and Service

Warning: Do not modify this equipment without Meditech's authorization. If the BIOFLEX® MiniPort Professional gives repeated errors it might need calibration. Please contact BIOFLEX® Service. To ensure that the system runs at optimum performance, it is strongly recommended that the treatment heads are checked annually by BIOFLEX® Service.

Attention: Only Meditech authorized service personnel may calibrate or service the system. Unauthorized changes to the system may be subject to the immediate termination of warranty (at Meditech's discretion). Unauthorized changes to the system-specific parameters will also cause the immediate termination of warranty (at Meditech's discretion).

To reduce the risk of electric shock, do not remove the cover from any part of the system. There are no serviceable parts inside. All system cables should be periodically inspected for signs of deterioration. If damaged, contact BIOFLEX® Service immediately to fix or replace the cable(s). On request, Meditech will make available circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Meditech authorized service personnel to repair the system.

Cleaning

- The MCU I-P may be cleaned using a damp soft cloth or a soft disinfectant cloth.
- The treatment heads may be cleaned with alcohol wipes, a soft disinfectant cloth, a soft damp cloth, and/or alcohol and cotton swab combination. Meditech recommends using PDI Sani-Cloth Plus disinfecting wipes.
- A soft bristle brush can be used to remove particles from the treatment heads.
- It is recommended that the treatment heads be cleaned after each treatment.

Follow the instructions below to clean your system:

- To clean the MCU I-P, gently wipe surfaces as necessary.
- To clean the treatment heads, use clean wipes, cloth, and/or cotton swab. If present, remove heavy soil loads with a soft bristle brush prior to cleaning. Unfold a clean wipe (or cloth) and thoroughly wipe the surfaces of the treatment heads. Make sure to thoroughly wipe the LED surfaces, laser lens, and nosecone tip. Make sure to wet all surfaces and not backtrack after wiping. If necessary, use a cotton swab and alcohol to get into smaller surfaces. Allow treatment heads to air dry prior to use.

Note: Do not spray or immerse the treatment heads with water/disinfectants/cleaning solutions or wrap them with disinfectant-soaked towels. Excessive disinfecting or cleaning solutions can penetrate the equipment housings and will likely cause corrosion of the electronic circuitry, causing treatment head failure.

System Damage

If part or all of the system is dropped or damaged, check it to make sure it still functions properly. To troubleshoot a damaged system, perform the following steps:

1. Check all power and interface cable connections. Make sure all cables are secure and properly connected.
2. Turn on all components of the system. If the system does not work, contact BIOFLEX® Service.

Liquids from spills, splashes, and excessive humidity can also damage your system. If the system becomes wet, perform the following steps:

1. Immediately unplug all system components from the electrical outlet.
2. Contact BIOFLEX ® Service.

System Troubleshooting

Contact BIOFLEX® Service if you are unable to solve the problem with the information below:

Error Code	Problem	Solution
D01, D02, D03	The laser probe connected to this port has failed.	Contact BIOFLEX® Service.
E10, E11, E12, E13, E14	This port controller board has failed.	1. Disconnect and reconnect the treatment head cable. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
L01	This port controller or the laser probe has failed.	1. Disconnect and reconnect the treatment head cable. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
L02	The optical power for the laser probe connected to the port is critically low.	1. Disconnect and reconnect the treatment head cable. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
L03	The laser probe connected to the port has failed.	1. Disconnect and reconnect the treatment head cable. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
L10	Laser probe nosecone tip was touched while enabling the laser probe.	Re-enable the laser probe without touching the nosecone tip.
S01, S02	LED array cannot switch light source or color.	Contact BIOFLEX® Service.
S04	Unable to turn on the treatment head on the port.	1. Disconnect and reconnect the treatment head cable. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
S06	Temperature sensor for the LED array connected to the port has failed.	1. Wait until the LED array cools to a safe temperature. 2. Resume treatment.

Error Code	Problem	Solution
S07	LED array connected to the port has a factory calibration error.	Contact BIOFLEX® Service.
S12	The LED array ran into a communication error.	1. Reset the system by unplugging the power supply, waiting 10 sec, and then replugging it in. 2. Disconnect and reconnect the treatment head cable. 3. Connect the LED array to a known working system. 4. Replace the treatment head cable. 5. Contact BIOFLEX® Service.

System Specifications

Electrical Specifications	
Rated Voltage	100 to 240 V
Rated Frequency	50 to 60 Hz
Operating Conditions (Note: Also applies to treatment heads.)	
Temperature	+5 to +40°C
Relative Humidity	15 to 93% non-condensing
Atmospheric Pressure	700 to 1,060 hPa
Storage Conditions (Note: Also applies to treatment heads.)	
Temperature/Humidity	-25 to +70°C
Relative Humidity	Up to 93% non-condensing
Functional Specifications	
Waveform	Square
Percent of Total Power	0 to 100% (1% steps)
Duration	0 to 3,600 sec (60 min)
Frequency (Modulation Mode)	1 to 10,000 Hz (5 µs)
Duty Cycle	1 to 99% (1% steps, 5 µs)
Classification	

The system is classified as a medical device. In accordance to IEC 60601-1:2005+A2:2020 (3.2 Edition):
Class II equipment, according to the type of protection against electric shock;
Type BF applied parts, according to the degree of protection against electric shock;
Classified IP21, according to the degree of protection against harmful ingress of water or particulate matter;
Continuous operation, according to the mode of operation;
None of the parts or the system is sterilized.

LED Array Specifications

Parameter	DUO+ 240	DUOFLEX+ 180
Model	LS-B 3000+	LS-B 4890
LED Maximum Optical Power (mW)	R: 4.2 IR: 8.5	R: 9.3 IR: 18.5
Array Optical Power (mW)	R: 1000 IR: 2000	R: 1630 IR: 3260
Effective Surface Area (cm²)	100	163
Maximum Power Density (mW/cm²)	R: 10.0 IR: 20.0	
Number of LEDs	240	176
Medium	R: AlGaInP IR: AlGaAs	
Wavelength (nm)	R: 660 IR: 840	
Spectral Width (nm)	R: 32 IR: 80	

Laser Probe Specifications

Parameter	Red Laser Probe	Infrared Laser
Model	LD-R 100+	LD-I 200+
Laser Class	3B	
Laser Optical Power (mW)	75	180
Effective Surface Area (cm²)	0.10	
Maximum Power Density (mW/cm²)	750	1800
Optical Density (OD)	1.87	2.42
Medium	AlGaInP	AlGaAs

Parameter	Red Laser Probe	Infrared Laser
Wavelength (nm)	660	825
Spectral Width (nm)	Not Available	3.0
Divergence (°)	10, 14	8, 16
Maximum Permissible Exposure (MPE)	6.36 J/m²	17.8 W/m²
NOHD (cm)	30	58

Symbols Glossary

Symbol	Title and Description	Standard
	Refer to instruction manual/booklet	ISO 7010
	Manufacturer Indicates the medical device manufacturer.	ISO 15223-1
	Date of manufacture Indicates the date when the medical device was manufactured.	ISO 15223-1
	Authorized representative in the European Community Indicates the Authorized representative in the European Community.	ISO 15223-1
	Authorized representative in the UK Indicates the Authorized representative in the United Kingdom.	-
	Medical device Indicates the item is a medical device.	ISO 15223-1
	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1
	Warning; Hot surface	ISO 7010
	Waste Electrical and Electronic Equipment This electrical and electronic equipment is subject to separate waste collection.	EN 50419

Symbol	Title and Description	Standard
	Type BF applied part To identify a type BF applied part complying with IEC 60601-1.	IEC 60417
	ETL listed mark Indicates that the product has been tested by Intertek and found in compliance with accepted national standards.	-
IP21	Degrees of protection provided by enclosures (IP Code)	IEC 60529
	Laser stop Indicates which button to press to stop the laser treatment in case of emergency	IEC 60417
	Warning; Laser beam To warn of a laser beam	ISO 7010
	Aperture Indicates the location of the aperture through which laser radiation is emitted.	IEC 60825-1
	Warning for invisible laser radiation Indicates a device which outputs electromagnetic radiation outside the wavelength range from 400 nm to 700 nm.	IEC 60825-1
	Warning for visible laser radiation Indicates a device which outputs electromagnetic radiation within the wavelength range of 400 nm to 700 nm.	IEC 60825-1

Safety Standards

This product is medical equipment and is in compliance with the following standards:

General Basic Safety:

- IEC 60601-1:2005+A2:2020 (3.2 Edition). Canada and USA national deviations:
  - CAN/CSA-C22.2 No. 60601-1:2014+A2:2022 (3.2 Edition)
  - ANSI/AAMI ES60601-1:2005+A2:2021 (3.2 Edition)
- IEC 60601-1-6:2010+A1:2013+A2:2020 (3.2 Edition)
- 21 CFR 1040 - Performance Standards for Light-Emitting Products

EMC:

- IEC 60601-1-2:2014+A1:2020 (4.1 Edition)

LED and Laser Safety:

- IEC 60601-2-22:2019 (4th Edition)
- IEC 60601-2-57:2011 (1st Edition)
- IEC 60825-1:2014 (3rd Edition)
- IEC 62471:2006 (1st Edition) including European deviations

Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

List of Cables, Transducers, and Accessories			
Cable	Length	Connected From	Connected To
Power Cord, CT402.019	1.83 m	Power Supply	Power Outlet

Warning: The use of accessories and cables other than those specified in this manual, with the exception of accessories and cables qualified and sold by Meditech International Inc may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2014+A1:2020.

Warning: The BIOFLEX® MiniPort Professional should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Example Emission Class and Group Compliance		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
The BIOFLEX® MiniPort Professional is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.		

Example Emission Class and Group Compliance		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	This system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The emissions characteristics of this equipment make it suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Example Immunity and Test Level Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
The BIOFLEX® MiniPort Professional is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line to line	± 0.5 kV, ± 1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.

Example Immunity and Test Level Compliance			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) 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.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].

Example Immunity and Test Level Compliance			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Note 1: U_T is the AC mains voltage prior to application of the test level. Note 2: At 80 MHz and 800 MHz, the higher frequency range applies. Note 3: 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 system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BIOFLEX® MiniPort Professional

The BIOFLEX® MiniPort Professional is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
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 metres (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.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of these systems, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Contact Us

Please contact BIOFLEX® Service and the competent authority of the EU member state in which you or the patient is established if any serious incident has occurred in relation to the device.

Meditech International Inc
411 Horner Ave Unit 1
Toronto, ON M8W 4W3
Canada

Toll Free: 1-844-770-0177
info@bioflexlaser.com
www.bioflexlaser.com