PHOTOBIOMODULATION THERAPY

BIOFLEX

DualPort System
MultiPort System

User Manual

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Families: BIOFLEX® DualPort System, BIOFLEX® MultiPort System
Models: Main Controller Unit III (MCU III), Main Controller Unit IV (MCU IV), 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

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Intended Use and Indications for Use

The BIOFLEX® DualPort System and BIOFLEX® MultiPort System are used by trained healthcare professionals and are 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.
- The system requires AC power of 100 - 240 VAC, 50 - 60 Hz, 3.3 A, and 1 Ph. Never remove the ground pin of the AC power cord. To help prevent electric shock, plug the controller unit power cable into a properly grounded

power source. For the best grounding, use hospital grade receptacles.

- **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.

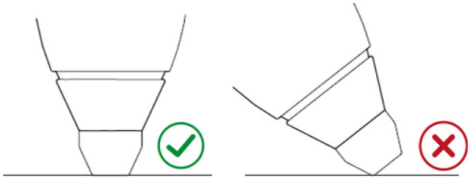
Laser Safety Rules

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. 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. The practitioner must pay attention to the patient and check from time to time that surfaces are not getting too hot. Especially for young children, elderly patients and/or patients who are sensitive to heat. Common sense must prevail.

Do not customize long continuous wave steps in the infrared light at 100% power without paying extra attention to the patient. If a patient leans back against the array placed on the spine, there may be lack of ventilation and over-heating may occur. The LED array must be properly ventilated. Do not cover the array during treatment. Patients must be aware that temperatures may get hot and to notify the practitioner in case they do. One should also alert patients that if the LED array should become too warm during treatment they should advise the practitioner.

Cool the LED array for a minimum of 6 min 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 that 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® DualPort System and the BIOFLEX® MultiPort System 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® DualPort System or BIOFLEX® MultiPort System only.	
	Main Controller Unit IV MCU IV
	Main Controller Unit III MCU III
	MCU III Laptop
	LD-R 100+
	LD-I 200+

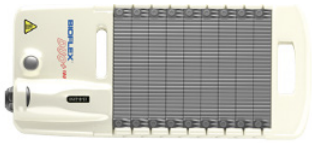
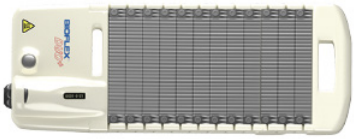
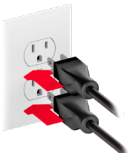
Image	Name and Model
	DUO+ 180 LS-B 2250+
	DUO+ 240 LS-B 3000+
	DUOFLEX+ 120 LS-B 3270
	DUOFLEX+ 180 LS-B 4890
	Laptop Power Cable
	System Power Cable

Image	Name and Model
	MCU III Laptop Cable
	Treatment Head Cable
	Safety Glasses
	Eye Shields
	Strap
	Weight Set

Image	Name and Model
	Carrying case

BIOFLEX® DualPort System Setup

Instruction	Image
1. Connect the System Power Cable, MCU III Laptop Cable, and Treatment Head Cable(s) to the back of the BIOFLEX® DualPort System Controller Unit.	
2. Connect the MCU III Laptop Cable to any USB port in the BIOFLEX® DualPort System Laptop.	

Instruction	Image
3. Connect the Treatment Head Cable(s) to the treatment heads.	
4. Connect the System Power Cable and the Laptop Power Cable to the wall socket.	
5. The system is now ready for use.	

BIOFLEX® MultiPort System Setup

Instruction	Image
1. Connect the System Power Cable to the back of the BIOFLEX® MultiPort System Controller Unit.	

Instruction	Image
2. Connect the System Power Cable to the wall socket.	
3. Connect the Treatment Head Cable(s) to the ports on the BIOFLEX® MultiPort System Controller Unit.	
4. Connect the Treatment Head Cable(s) to the treatment heads.	
5. The system is now ready for use.	

System Features

Ports

The MCU III has two treatment ports available while the MCU IV has four treatment ports available. The ports can be used to connect any compatible treatment head. Plugs and sockets are keyed, thus, they must be correctly oriented before they will mate. Recognition of the treatment head 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 Cord

Use the supplied power cord to connect the power module to a power socket. For best grounding, plug into a power socket marked “Hospital Grade.”

Power Switch

- Power to the controller units is controlled with the power switch located directly over the power cord socket.
- Press the power switch to turn the power on or off.
- The MCU IV also has an On/Off switch located on the front panel (illuminated blue). This button will turn the system on once power to the unit is available.

MCU III Laptop

The MCU III is designed to function with the provided MCU III Laptop. The minimum hardware requirements for the laptop are:

- IEC 60950-1 compliant
- Windows 10 Pro
- Intel i3 with 500 GB HDD or 128 GB SSD
- 4 GB RAM

External USBs

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

The MCU III has a USB port located on the back of the unit for connection to the

MCU III laptop. This port cannot be used for any other purpose.

Other Ports

An ethernet port is available to make an ethernet connection; however, this feature is not supported.

BIOFLEX® Practitioner+

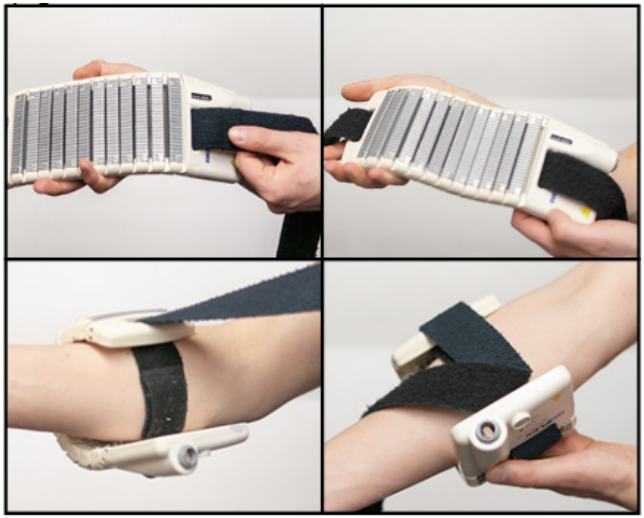
The system comes pre-installed with BIOFLEX® Practitioner+. If updates are required, instructions will be provided by email. Support and training is available by visiting the BIOFLEX® website.

LED Arrays

These LED arrays are 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 treatment head. The system will pause automatically between infrared and red steps to allow for repositioning of the treatment head. If desired, the practitioner can override the automatic pause settings when customizing protocols in the software.

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

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

System Operation

DUO+ 180 and DUO+ 240

- Once enabled, two beeps will sound, one short and one long. The green indicator on the array will blink, indicating that it is ready to start.
- Once started either by double pressing the array button or using the software, two long beeps will sound. The green indicator on the array will turn solid, and the amber indicator on the array will turn solid as well. The array will turn on and light will be radiated.
- Once paused by pressing the array button or using the software, one long beep will sound. The amber indicator on the array will turn off and the green indicator on the array will blink. The light from the array will stop radiating.
- Once stopped by using the software, one long beep will sound. The amber indicator on the array will turn off and the green indicator on the array will blink. The light from the array will stop radiating. After confirmation in the software to stop the prescription, another long beep will be heard and the green indicator on the array will turn off.

DUOFLEX+ 120 and DUOFLEX+ 180

- Once enabled, two beeps will sound, one short and one long. The green indicator on the array will blink, indicating that it is ready to start.
- Once started either by double pressing the array button or using the software, two long beeps will sound. The green indicator on the array will turn solid. The array will turn on and light will be radiated.
- Once paused by pressing the array button or using the software, one long beep will sound. The green indicator on the array will blink. The light from the array will stop radiating.
- Once stopped by using the software, one long beep will sound. The green indicator on the array will blink. The light from the array will stop radiating. After confirmation in the software to stop the prescription, another long beep will be heard and the green indicator on the array will turn off.

Laser Probes

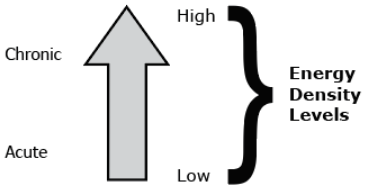
- Once enabled, two beeps will sound, one short and one long. The green indicator on the probe will turn solid, indicating that it is ready to start.
- **Note**: The probe must not contact the skin until the indicator on the probe is green.
- Once started by applying the surface of the nosecone tip flat 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, the red Laser Stop button on the front of the controller unit can be activated. This immediately stops the radiance of light on all ports and treatment heads. Beeps will sound and all active treatments will be stopped. Treatments can only be resumed after confirmation on BIOFLEX® Practitioner+.

Application of Treatment

Protocols provided should be effective for the majority of patients; however, some broad guidelines in treating the following categories of pathology prevail.



- **Local**: Apply probe to the primary area of pathology.
- **Nerve root** of relevant dermatome as it exits the spinal cord.
- **Peripheral Pain**: When treating areas of peripheral pain it is generally preferable to treat over the spinal cord and the nerve roots innervating the area where symptoms exist, as they exit the spinal canal, in addition to the area where the pain sensation is localized. If the initial treatment of the localized area is successful this may not be necessary. Therapeutic effectiveness is frequently enhanced when the nerve root origin is also treated. This is particularly valid with radiculitis where sciatic nerve pain is the subjective symptom but the appropriate application is over the nerve roots as they exit the spinal canal. Frequently, in treating localized lesions (i.e. carpal tunnel syndrome), it may be appropriate and extremely helpful to treat the cervical nerve roots in conjunction with local therapy particularly in problematic cases.
- **Sandwich Approach** (i.e. when treating the foot or wrist irradiate dorsal and plantar/palmar aspect during the same session): In areas such as the wrist, ankle, knee, and foot, applications of the LED array should generally surround the entire joint. With the bones of the foot, particularly the talo-navicular, cuneiform, and metatarsal regions, the “sandwich approach” is usually most effective with a portion of the therapy being applied dorsally, and similarly on the plantar aspect.
- **Trigger or Accupoint**: Apply the probe as directed over the area where the most severe pain is located. The total treatment time for using a probe varies according to the condition being treated. The probe should be held approximately for 7 seconds per point and then moved to as many points as required to cover the entire affected area.
- **Good contact** between the LED array and tissue should always be maintained. This may require the gentle application of pressure keeping in mind that ventilation for proper cooling must continue. When strapping arrays into place, be sensitive with regard to the tissues at all times. Good contact without excessive pressure is important. Bindings should be snug but not too tight as this may occlude venous flow and lead to thrombosis.
- **Tissues**: When treating any area, particularly a joint, attempt to irradiate all the tissues involved. For example, the shoulder should be irradiated from the superior, anterior, posterior, and lateral aspects with all arrays. The axillary approach is optional.
- **Maintaining Cleanliness**: Always wash hands between treating patients.

Use a biocompatible sterile transparent film (e.g. 3M TegadermTM Film) when treating inguinal/axillary areas where elevated bacterial counts exist. It is also advisable to clean and dry the skin before the application of the arrays. Additionally, arrays and probes should be carefully cleaned between use on patients.

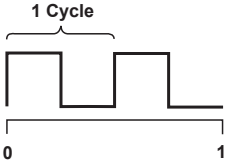
- **Red Laser Probe**:
  - Power can be set from 10% to 100%.
  - The red laser probe can be used in standalone configuration or in combination with any other arrays and probes.
  - The time utilized depends on the extent of the condition and the clinical response with previous applications.
  - It can be used as an add-on prior to the infrared laser probe application or in place of the same.
  - Time factor of application should be less than 10 min in all instances.

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.

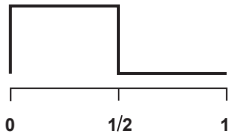
Frequency (Hz): Describes how many times (cycles) per second the waveform repeats.

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

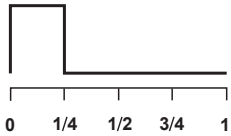


Therefore, the frequency of the above waveform is 2 cycles per second (c/s) or 2 Hertz (Hz).

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.

Treatment Stages

The pre-programmed protocols or prescriptions allow the practitioner to select the appropriate parameters (e.g. duration, duty cycle, frequency) depending on the needs of the patient.

For standard protocols (anatomic or condition), the practitioner may decide to change the protocol intensity by adjusting the treatment stage. It is recommended to start with stage 1 and evaluate after several treatments before advancing to stage 2 and then stage 3.

All LED arrays supported by these systems have the same energy density. Thus, any array can be used for any specific protocol. Array selection can depend on patient size, treatment location, array availability, or practitioner preference. The practitioner may select the preferred array before prescribing the treatment.

In this manual, protocols are referenced as a guideline with a range for each parameter. Recommended parameters are pre-programmed in the software for

each array type. The practitioner can customize the parameters of a protocol at their discretion based on their clinical judgment.

Treatment Tips

Fibromyalgia Pain

- Placement of arrays should correspond to the most symptomatic anatomical regions.
- The most common locations for fibromyalgia pain are the neck, posterior shoulders, gluteal region, hips, medial knees, and elbows.
- Apply the laser probe to the tender point associated with fibromyalgia pain.

Osteoarthritis Pain

- Placement of arrays should correspond to the entire circumference of the affected joint, if possible.
- Treat adjacent soft tissues if edematous or painful.
- This may require multiple placements to ensure adequate coverage.
- Ensure the joint is in an open packed position to allow for light to penetrate.

Rheumatoid Arthritis Pain

- Placement of arrays should correspond to the entire circumference of the affected joint, if possible.
- Treat adjacent soft tissues if edematous or painful.
- This may require multiple placements to ensure adequate coverage.
- Ensure the joint is in an open packed position to allow for light to penetrate.

BIOFLEX® Practitioner+

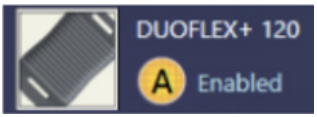
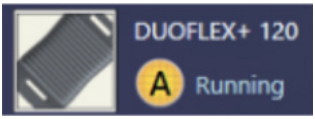
BIOFLEX® Practitioner+ is a Windows-based software package developed by Meditech. This software is a user interface for treatments, patient profiles, and clinical data management.

The system has two modes of operation: Kiosk mode and Admin mode. Kiosk mode is the day-to-day mode of operation. Admin mode has full access to the Microsoft Windows environment and all its settings and features (e.g. adding a printer). It also provides access for all administrative features of BIOFLEX® Practitioner+. Treatments cannot be run while in Admin mode.

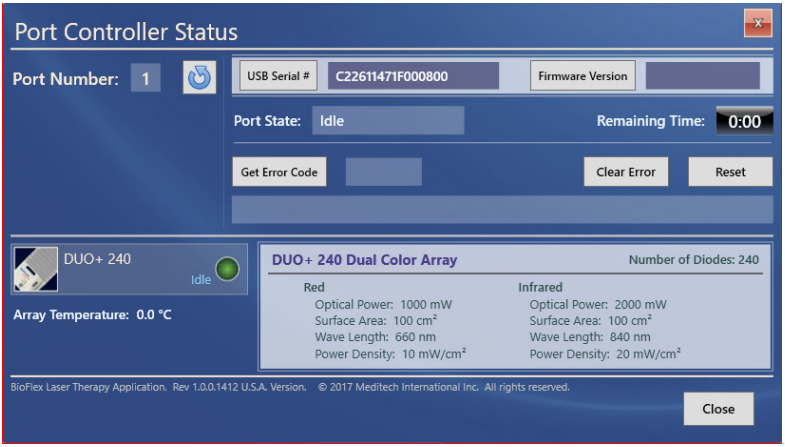
Port Identification

Each Port Status button displays the state and type of treatment head connected to the port. It is located on the bottom ribbon of BIOFLEX® Practitioner+:

The various states of a treatment port can be:

Image	Description
	Idle State The port is idle and no treatment panel is using it.
	Linked State A treatment head is linked to the port and the treatment protocol is uploaded into the device.
	Enabled State The treatment head to the port is enabled (fully powered on).
	Running State The port is running a treatment protocol.
	Paused State The port is paused in the middle of treatment.

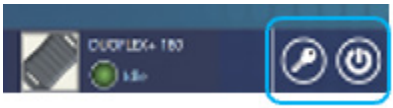
Each Port Status button displays a detailed window when clicked. If the port is in an Error state, the practitioner will need to click the Get Error Code button and proceed as instructed. The error may be cleared by clicking the Clear Error button.



The BIOFLEX® DualPort System supports two ports simultaneously while the BIOFLEX® MultiPort System supports four ports.

Lockup Button and Shutdown Button

The Lockup and Shutdown buttons are located on the right side of the bottom ribbon:



The Lockup button provides a quick way to lock the system in case the practitioner needs to step away. This eliminates the risk of an unauthorized person accessing the system.

The Shutdown button allows the user to shut down the computer. The practitioner may also use the Shutdown button in the Root Menu to achieve the same outcome.

Once the system is locked, a password is required to unlock it. There are two types of passwords in the system: one for lockup and one for Administrator. These passwords can be set by choosing Settings from the Root Menu on the main screen.

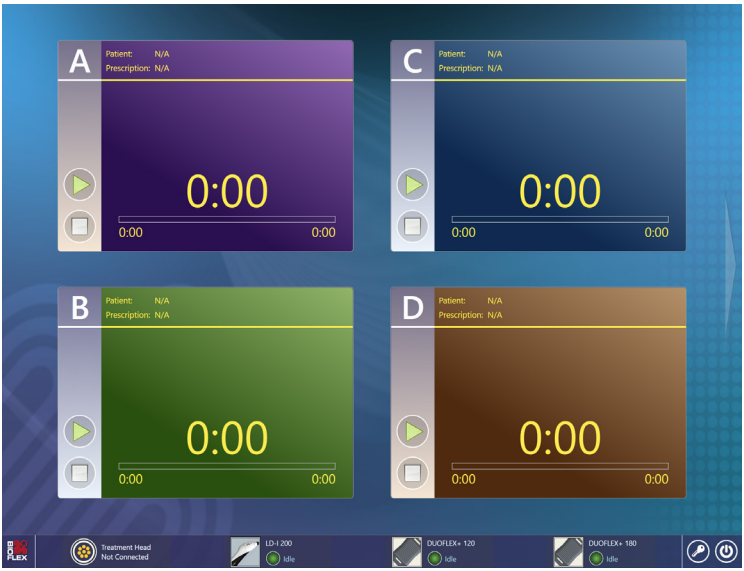
Default Administrator Password: **newadmin**
Default Lockup Password: **locklaser**

Two passwords are available for security reasons. The Administrator password is the main password which allows for access to all functionality of BIOFLEX®

Practitioner+. The Lockup password allows the user to lock the system when not in use to prevent unauthorized use.

Treatment Panel

The Treatment Panel is the core user interface element offering flexible treatment controls:



Only two treatment panels are simultaneously displayed when in Normal view. Each treatment panel can manage a therapeutic treatment for its respective treatment head. These therapeutic treatments can be applied to a single patient or multiple patients. Each treatment panel is identified by a letter from A to D. The BIOFLEX® DualPort System displays two treatment panels while the BIOFLEX® MultiPort System displays four. A swiping motion can be used on the BIOFLEX® MultiPort System to see the remaining two treatment panels. The touch screen allows for swiping either up and down or right and left, or by clicking on the dim triangle on the right side of the screen.

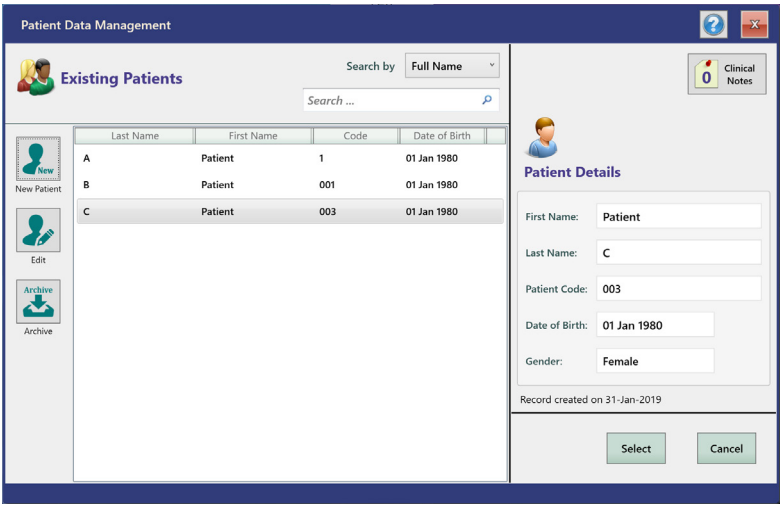
Simplified treatment panels can be viewed in a 2x2 format when in Snapshot view. These simplified panels only offer access to treatment controls. The practitioner must switch back to Normal view via the reversed dim triangle on the right side of the screen or by swiping horizontally from left to right to access more functionality.

Patient Data Management

Patient data management is performed by clicking the Patient button on any

treatment panel:

Doing so displays the Patient Data Management window:



The Patient Data Management window displays a patient list and details. The patient details will populate once a patient is chosen. Practitioners can use the tools in this window to create new patient profiles, edit existing profiles, and/or archive profiles which are no longer active.

The patient list may contain several patient profiles. A search and filter feature is available for searching patients and the patient list will automatically update based on the search terms.

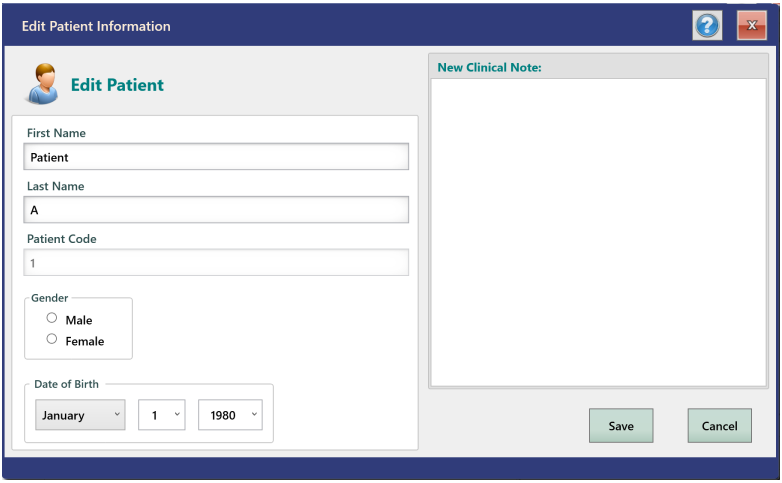
If a patient is no longer active, the practitioner may click the Archive button to hide the profile. The Archive function requires Administrator privileges to use.

Adding new patients is simply done by clicking the New Patient button.

When a patient profile is selected, the practitioner can click the Select button to upload the selected patient onto the treatment panel for therapeutic treatment.

Patient Details

Patient details can be viewed or edited by selecting the patient and clicking the Edit button, which displays the Edit Patient Information window:

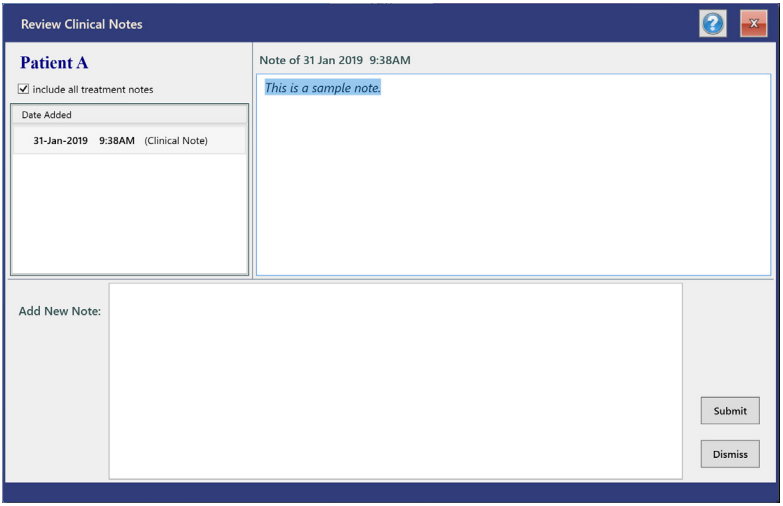


This window will be empty when a new patient profile is started. The Patient Code field is mandatory and will only accept alphanumeric characters and the '-' sign. There is a 24-character limit and if an invalid entry is made, the box will be highlighted with a red boundary. Patient codes cannot be duplicated and cannot be changed after the profile is created.

The New Clinical Note field is optional. This is where the practitioner can document other information on the patient. The clinical notes are considered a historical field, and old notes cannot be deleted; however notes can always be added.

Clinical Notes

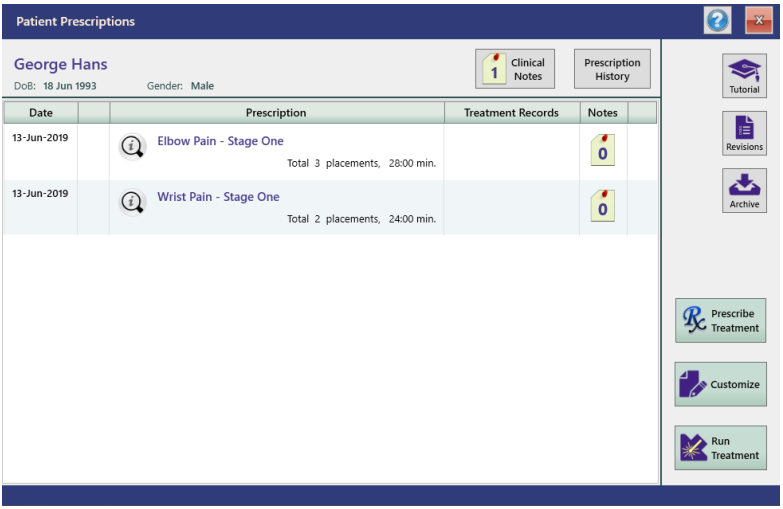
Clicking the Clinical Notes button will display the Review Clinical Notes window:



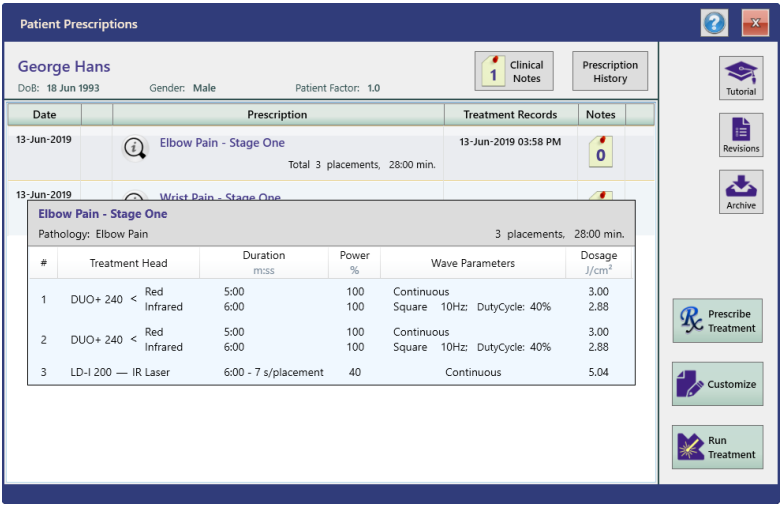
This provides the practitioner with an area to document any clinical notes. Enabling the "Include all treatment notes" option will populate the list with all treatment notes. These notes can later be accessed from the Patient Prescriptions window.

Patient Prescriptions

Selecting a patient from the patient list will automatically display the Patient Prescription window:

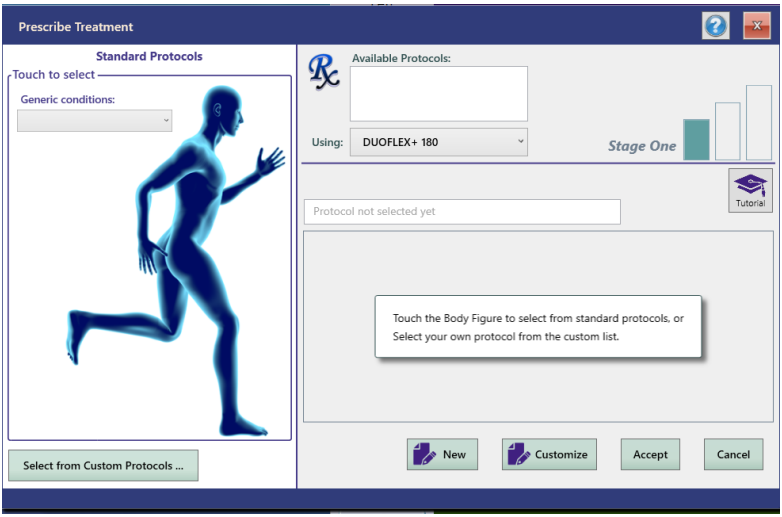


This displays a list of active prescriptions issued to the patient. The list contains information relevant to previous treatments, such as dates, treatment placements, treatment duration, and notes. Additional information is available by clicking the Info button for each prescription:



Prescribing Treatment

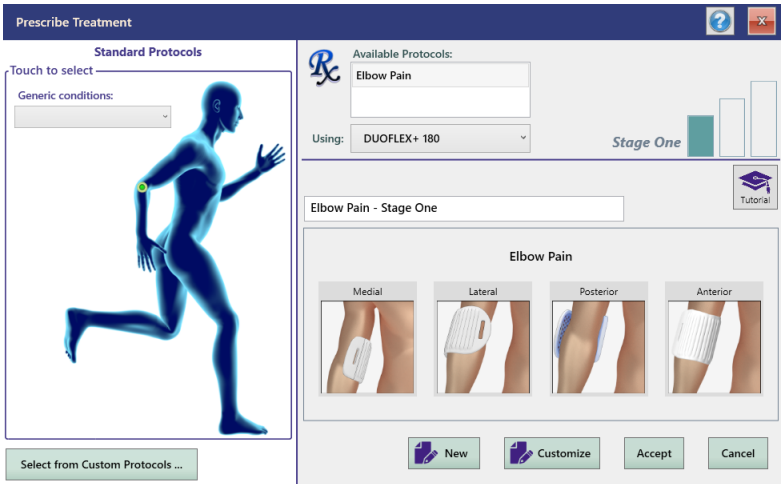
Treatments can be prescribed by clicking the Prescribe Treatment button, which displays the Prescribe Treatment window:



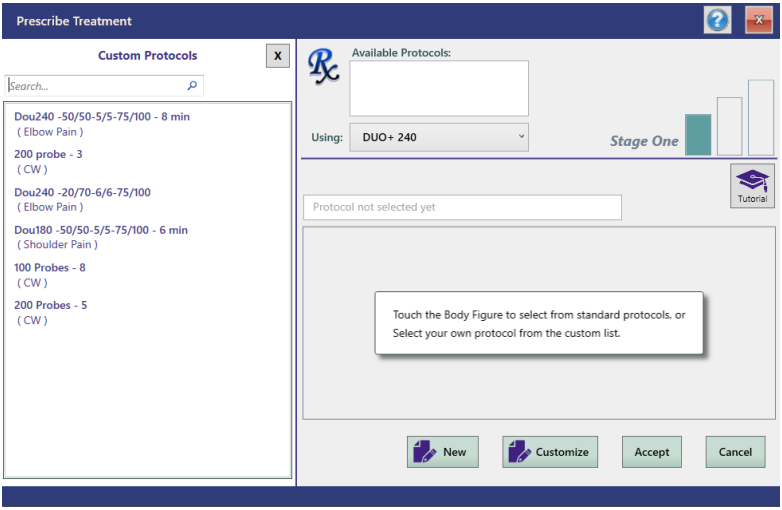
This window displays a body figure, which is used for selecting anatomy-related treatment protocols. The practitioner can hover over the body figure and select an anatomy hotspot represented by a circle corresponding to the ailment.

If the ailment is a condition, it can be selected from the Generic Conditions list. There is only one protocol associated with most anatomies. If, however, there are more, the practitioner must manually select the most applicable protocol for use.

The pre-programmed protocols or prescriptions allow the practitioner to select the appropriate parameters depending on the needs of the patient. For standard protocols (anatomic or conditions), the practitioner may have the choice to change the treatment strength by adjusting the treatment stage. For stages, there are no set rules or set stages for protocol treatments. It is recommended to start at stage 1 for treatments and evaluate their success. In this way, the stages can be raised or lowered based on treatment performance. Further modifications can be made by clicking the Customize button.



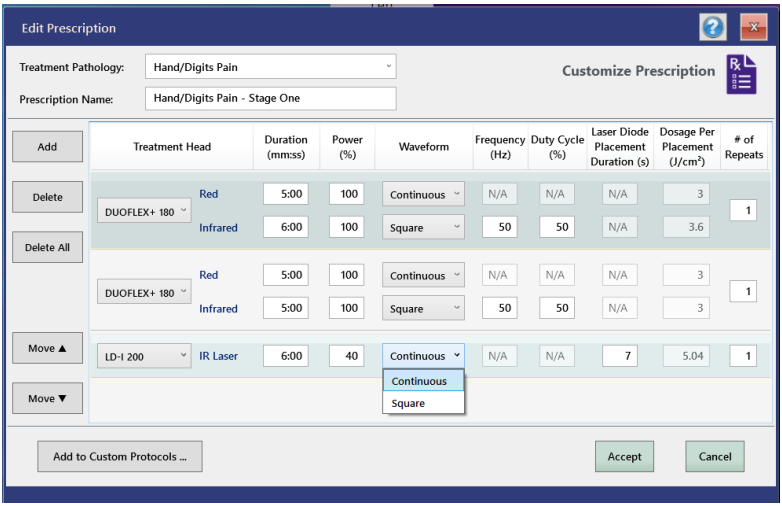
Advanced practitioners can create a new prescription by clicking the New button. These custom prescriptions can be accessed by selecting the Select from Custom Protocols button.

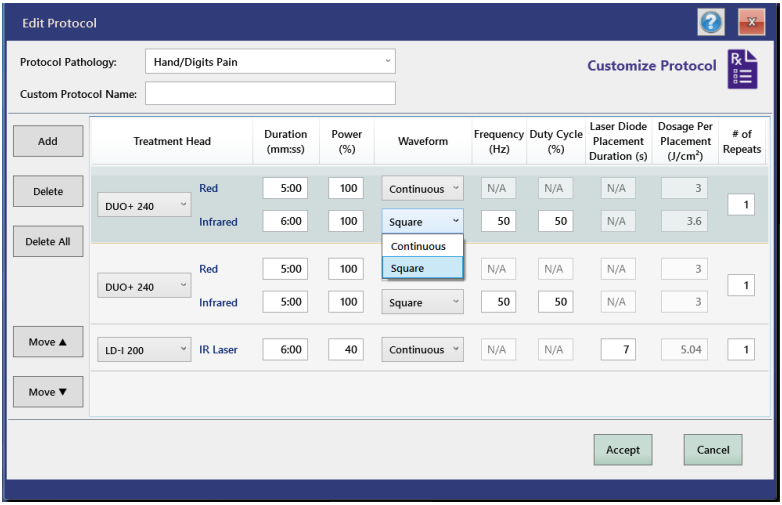


There are multiple ways to prescribe a treatment. After prescribing a treatment, there is an option to further customize and rename the treatment. Once accepted, the prescription can be uploaded to the treatment panel by clicking the Accept button.

Editing Prescriptions and Protocols

Prescriptions and protocols are edited in one of the Edit Prescription or Edit Protocol windows, respectively:





Both windows are list-based, allow steps or placements to be added as rows, and provide the dosage information in J/cm². The order of the rows can be changed by simply moving them up or down. The Edit Prescription window has the added feature of allowing the practitioner to save a custom protocol for future use.

Each field is further described below:

- **Treatment Head**: Displays a list of supported treatment heads. LED arrays display two sub-rows while laser probes display one sub-row.
- **Duration (0 - 60 min)**: Length of time for application of the treatment head.
- **Power (0 - 100%)**: Amount of maximum power.
- **Waveform**: Applicable wave form.
- **Frequency (1 Hz – 10 KHz)**: Frequency of operation, if applicable.
- **Duty Cycle (1 - 99%)**: Effective cycle of the full period.
- **Laser Diode Placement Duration (s)**: The dwell time for each acupoint. This is set to 7 sec by default and can be changed to calculate the dosage for other dwell times.
- **Dosage Per Placement (J/cm²)**: Calculated dosage for the parameter set.
- **# of Repeats**: Number of times to repeat this step for different placements.

If the treatment only requires one light type, then the practitioner can set the duration for the other light type to 0 sec, thus turning off that portion of the treatment. The box will be highlighted in orange when a duration is set to zero to indicate that the light type is not used.

Dosage

Dosage is calculated for the setting in each step. 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.

Preparing a Treatment

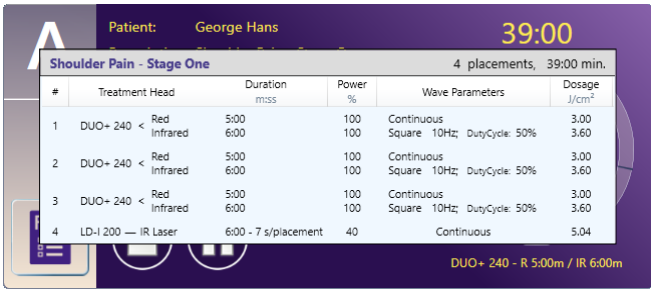
The treatment panel is the control center for running a therapeutic treatment. The panel allows the practitioner to load patients and prescriptions, review prescriptions, and start, pause, stop, or end a treatment.

The treatment panel will automatically connect to a port that has the appropriate treatment head attached to it. A port preference setting is available for the practitioner to have manual control over this feature. This feature is accessed by clicking the word (e.g. Right) under the port identification letter:

A treatment is executed by first selecting a patient with the Patient button and then loading a prescription. Information such as patient name, prescription, pathology, placement, duration, treatment head, color, and time are all available on the screen for monitoring.

Placement details are available by clicking the Placement button:

Doing so displays a pop-up that shows dual optical treatments with two rows and single optical treatments with one row:



After loading a prescription, the software will attempt to search for the correct treatment head for the first treatment step. If the treatment head is found, the corresponding port status will change from an Idle state to a Linked state. If it is not found, a warning message will appear. The practitioner can attach the correct treatment head to any available port and click the Enable button for the system to re-search and connect to the correct treatment head.

Enabling the Treatment Head

Once the applicable treatment head is linked, the practitioner can click the Enable button. Enabling is required on the first treatment step and on any laser treatment step.

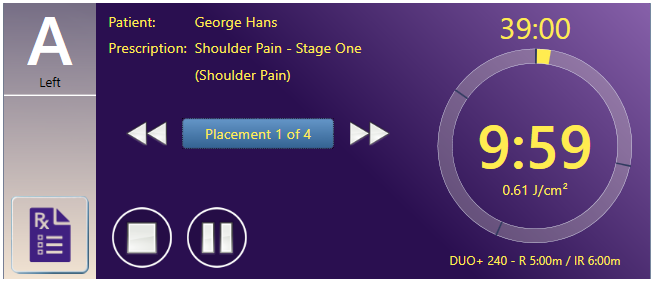
Note: Do not touch the nosecone of the laser probe while enabling the laser step. Doing so will interfere with the initial calibration of the probe and cause an error.

Initiating Treatment

Once the system is enabled, the Start button is displayed in place of the flashing Enable button. The remaining time flashes to indicate that the treatment is ready to start. The corresponding port status is changed from Linked to Enabled. The treatment will initiate when the Start button is clicked, when the array button is double-clicked, or when the probe nosecone touches the skin in a perpendicular manner.

The BIOFLEX® MultiPort System is capable of running any combination of four treatment heads at once (the BIOFLEX® DualPort System can run a combination of two). Each treatment head is assigned a port and can be identified on the main screen.

Note: The timer shows the cumulative time for all placements in the treatment.



Note: Continue to next step once all treatment heads are running.

Pausing or Stopping Treatment

The Start button will change to a Pause button once a treatment is started. The Stop button is also available for stopping the treatment entirely.

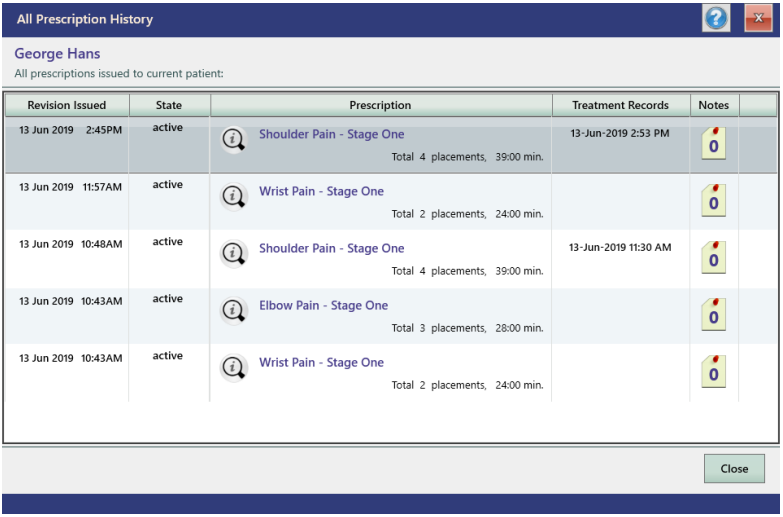
Port Identification During Treatment

To identify which treatment head is assigned to which port, the treatment must first be paused. The corresponding port will also display a Paused state and the Placement button can be clicked to display a window with the protocol name, steps, and parameters:

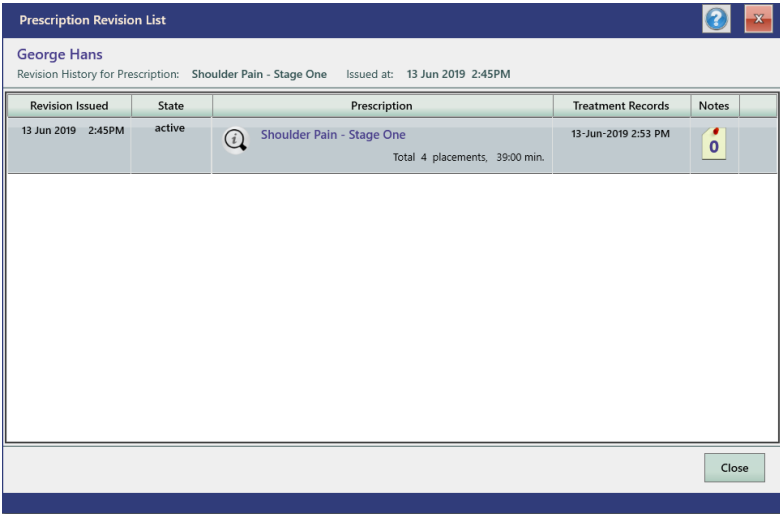
Treatment may be resumed by clicking the Start button. The treatment will resume from when it was paused.

Prescription History

The prescription history for a patient can be accessed using the Patient Prescriptions window. This is where practitioners can view all prescriptions issued to a patient. The Info button can be clicked for further details.



Each prescription has its own revision history that can be viewed by selecting the prescription and then selecting the Revisions button. The Prescription Revision List window shows all revisions of a prescription which led to the active prescription being used.

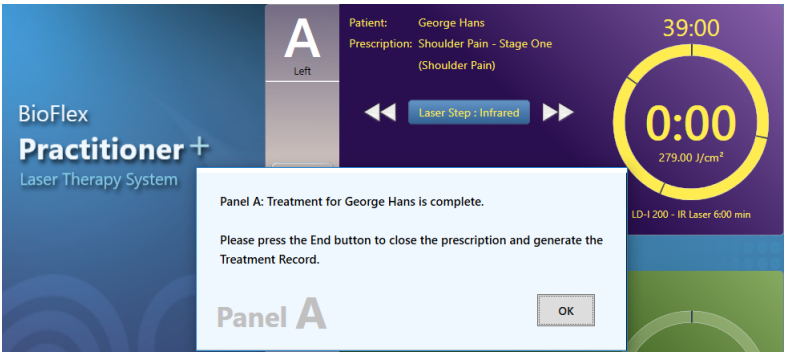


Treatment Transitions

While treatment is running and the progress timer is counting down, the practitioner may pause the treatment by clicking the Pause button. This will stop the timer, and the Start button will reappear. Restarting will resume the treatment and progress timer.

The Forward and Backward buttons are available to skip to the next or repeat the previous treatment placement. Skipping to the next placement is only permitted when the treatment is not running. If a placement needs to be changed during treatment, it must first be paused before the Forward or Backward buttons can be used.

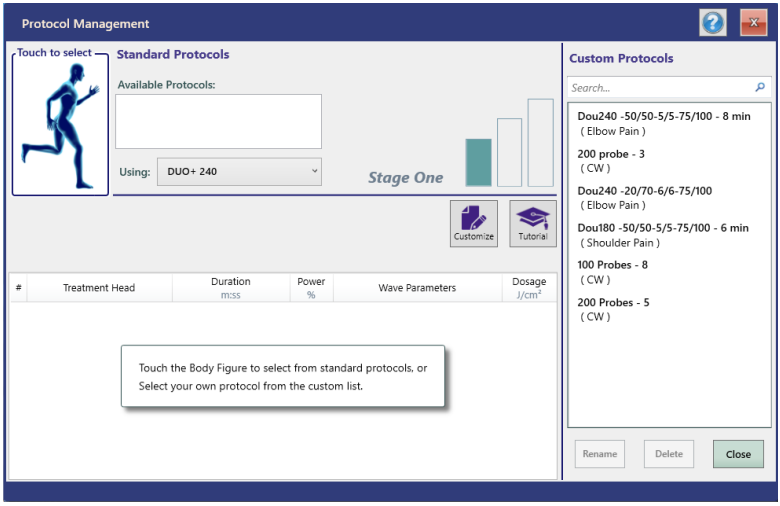
Once treatment is complete, the circular progress dial displays a full circle and the timer displays zero. The port used in the last treatment will remain linked (but not enabled) and the protocol for the last treatment step will remain uploaded. However, this does not mean the treatment has ended. The practitioner must click the Stop button to end the treatment and generate a treatment record. This is a feature that allows the practitioner to repeat the last step, if needed, or continue with another step.



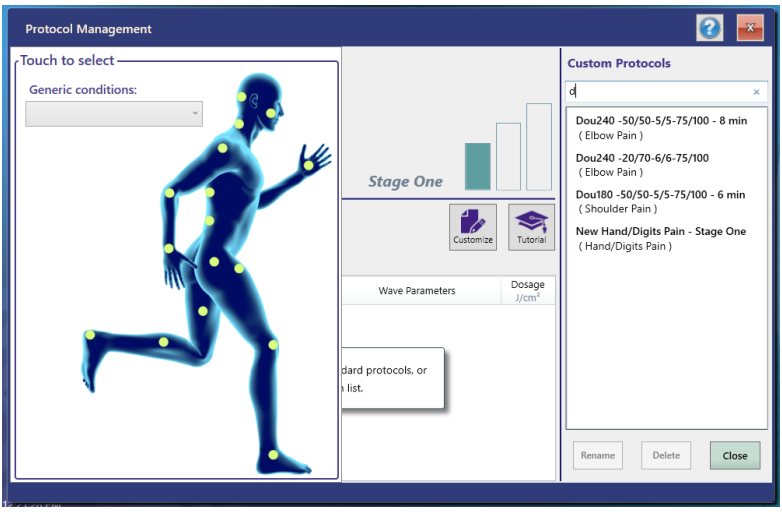
Clicking the Stop button is typically the last step for a normal treatment process. The button is used when the entire treatment is complete. If it is clicked before the treatment is fully complete, a warning message will appear to confirm cancellation. If it is confirmed, the treatment will be canceled and a treatment record will be generated. The prescription for that patient will be closed; however, the profile will remain active. This allows the practitioner to access other prescriptions for the same patient. Once the Close button is clicked, the patient profile will be closed and the Patient button will be displayed, allowing the practitioner to prepare for the next patient.

Protocol Management

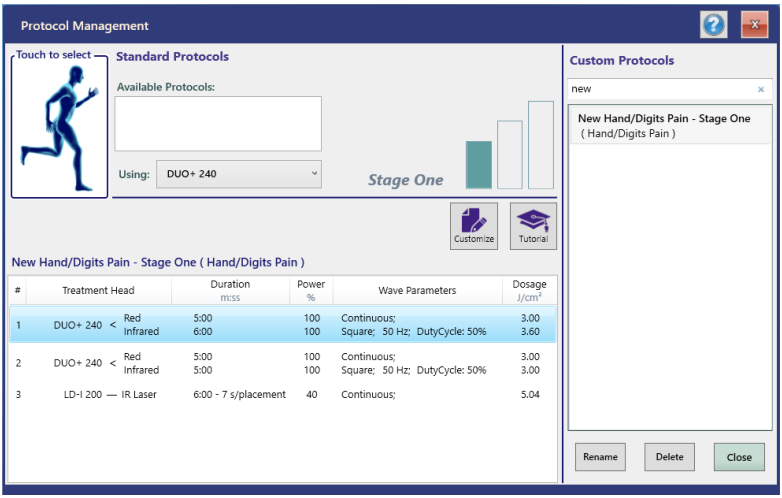
Protocols can be managed through the Root Menu on the Main Screen. All protocol management tasks can be carried out in the Protocol Management window. The body figure is used to select standard protocols along with treatment head and stage selectors.



On initial start, the protocol list will be empty. To start the selection process, the practitioner can click on the body figure to display the available hotspots for anatomy-related protocol selection:



To select a generic protocol, the practitioner can click the Generic Conditions dropdown menu and choose a protocol. Details are displayed once a standard protocol is selected. At this point, practitioners can change the treatment head and adjust the stage. If there is more than one protocol associated with a hotspot, the practitioner can select the desired one from the Available Protocols list.



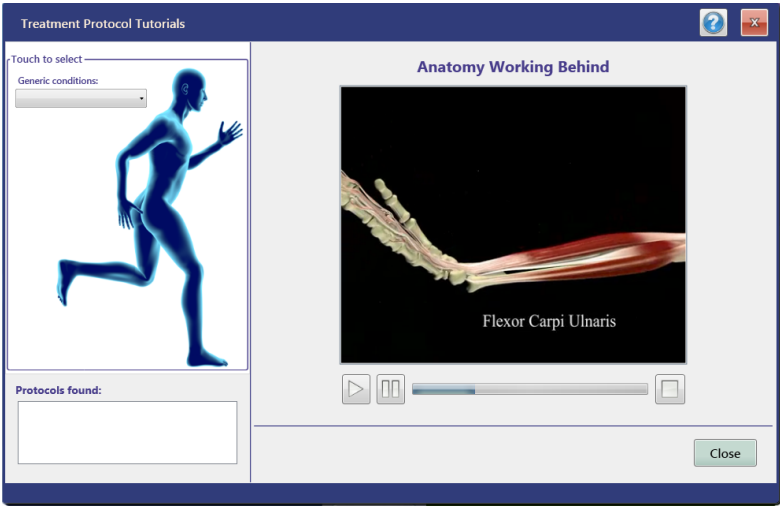
If available, custom protocols can be selected by double-clicking the specific protocol. A single click will only highlight the protocol. Once selected, the details will be shown in the window. It is also possible for the practitioner to rename or delete these protocols from the list.

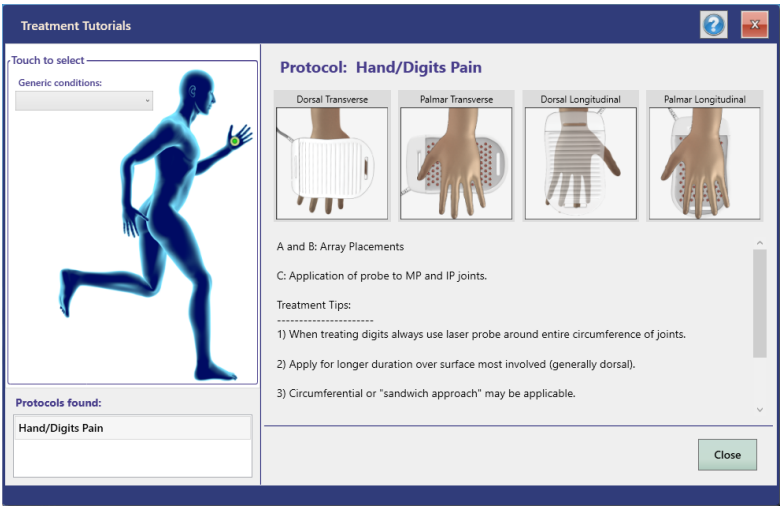
The search feature can be used to help find protocols. Fragmented strings can be used to filter the search for protocols. The Tutorial button provides treatment recommendations for selected protocols. For any protocol selected, the practitioner can customize it by clicking the Customize button.

Note: Modified protocols are saved in the Custom Protocols list. The original standard protocol will not be overwritten.

Tutorial Support

Tutorial support for the treatment protocols is available through the Root Menu on the Main Screen in addition to several other windows. Tutorials are organized by anatomy-related protocols. The practitioner can use the body figure selector or the dropdown menu to select the desired tutorial. If there are multiple protocols associated with an anatomy, the first tutorial will automatically load.



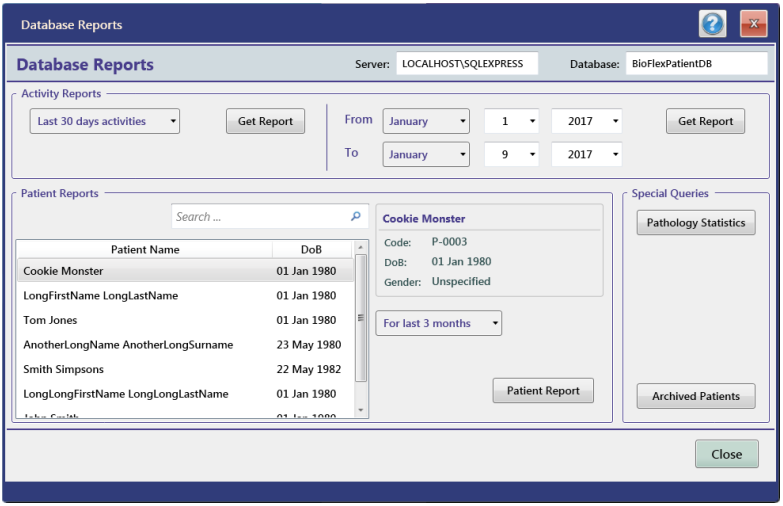


Database Reports

BIOFLEX® Practitioner+ offers four types of database reports:

- Daily Activity Reports
- Patient Reports
- Special Queries - Pathology Statistics
- Special Queries - Archived Patients

These reports can be displayed by selecting Reports from the Root Menu on the Main Screen.

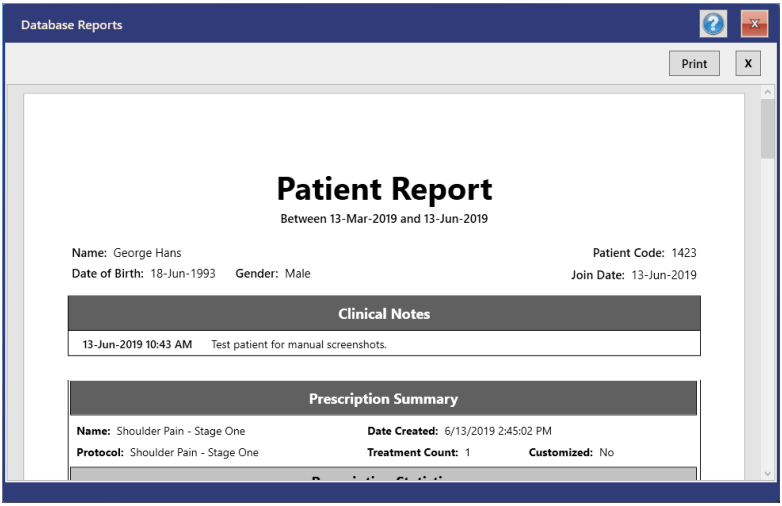


Daily Activity Reports

Daily Activity Reports provide information on the number of new patients, number of treatments prescribed, and the run time for the treatment devices. This report can be accessed using the Get Report button after selecting a timeframe in the dropdown menu.

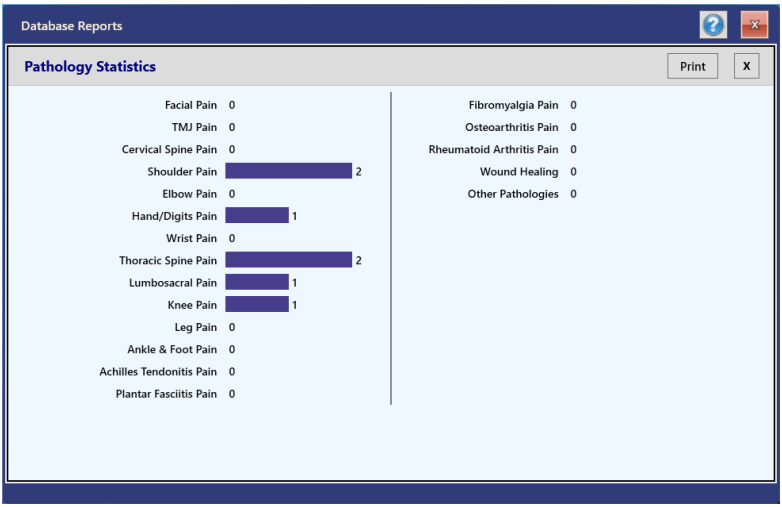
Patient Reports

The Patient Report is a summary of the recent treatment activities for a selected patient. This is displayed by selecting a patient, selecting a timeframe from the dropdown menu, and then clicking the Patient Report button.

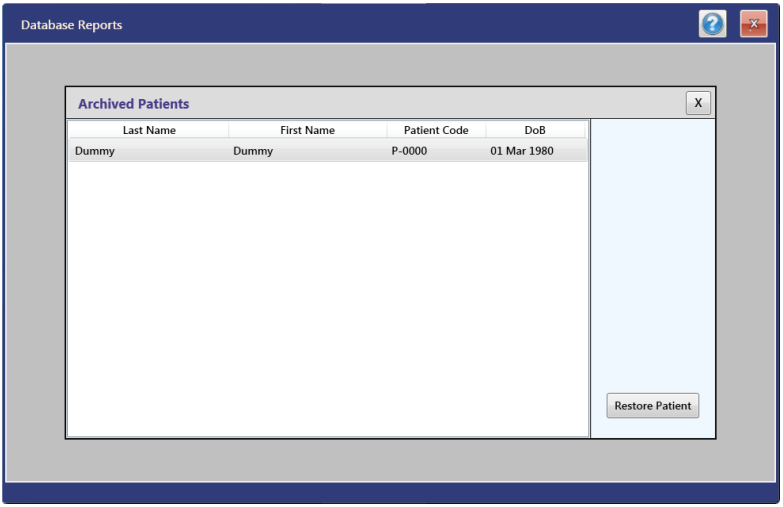


Special Queries

The Pathology Statistics Report summarizes the statistical distribution among pathologies. This data tracks the number of times a specific pathology was applied:

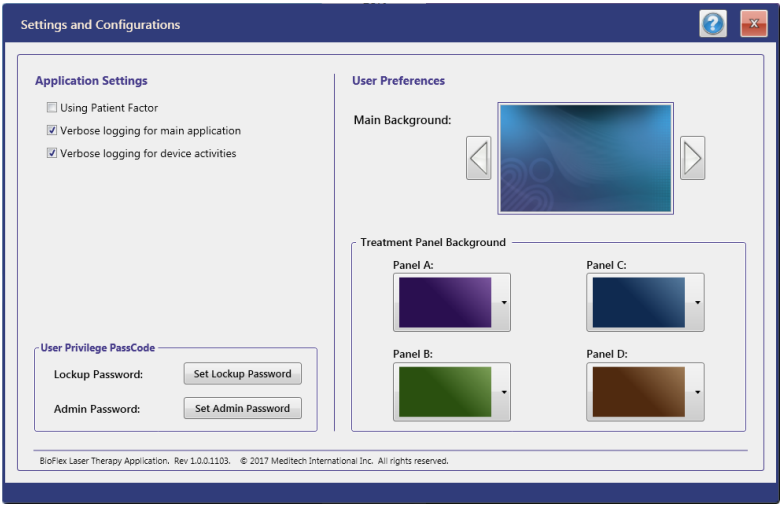


The Archived Patients Report provides a list of archived patient. An archived patient can be restored by selecting the Restore Patient button. This action requires Administrator privileges.



Application Settings

User settings can be accessed by selecting Settings from the Root Menu on the Main Screen:



- **Using Patient Factor**: Used to switch the patient factor on and off. By default, this setting is off. The patient factor, once switched on, is editable for each patient in their profile. It will adjust the duration to account for different body types and skin colors.
- **Verbose logging for main application**: Logs database communication for

diagnostic purposes.

- **Verbose logging for device activities**: Logs hardware communications for diagnostic purposes.

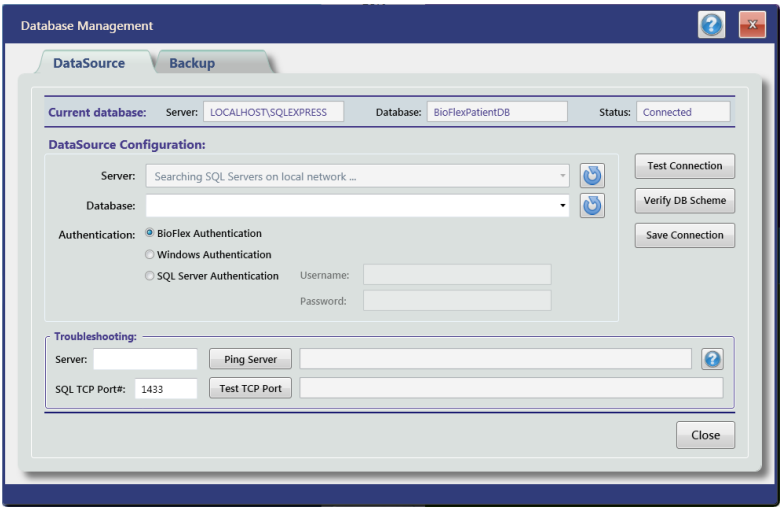
System Security

- **Lockup Password**: Used to set up a password for locking the system.
- **Admin Password**: Used to set up the administrator password for sensitive settings.
- **User Preferences**: Allows the practitioner to change the main background or the treatment panel backgrounds.

BIOFLEX® Practitioner+ Database Configuration

Note: Do not attempt to change any configuration settings or perform a backup or restore unless you have the knowledge to do so. Contact BIOFLEX® Service for support.

BIOFLEX® Practitioner+ is pre-configured with its database (BIOFLEXPatientDB). However, modifications can be made by selecting Database from the Root Menu on the Main Screen with Administrator privileges:



Upon display of the Database Management window, an automatic query over the local network will be made to find all SQL Server instances. The server will temporarily be disabled, and a message, “Searching SQL Servers on local network ...” will be displayed.

Note: Due to network latency, the query cannot guarantee that all database servers will be found during the search time. If a target server is not displayed in the list, refresh the screen by clicking the Circular Arrow button. When a server name is selected or entered, the database will query all database names on that server automatically.

Configuring a New Instance

To configure a new database, select the target server (BIOFLEXPatientDB) from the dropdown menu when the search is complete. Select an authentication method (BIOFLEX Authentication is recommended). If SQL Server Authentication is picked, the user will need to provide an account name and password for that SQL Server account. Once all required fields are entered, the connection can be tested by selecting the Test Connection button. If successful, select the Verify DB Scheme button and then the Save Connection button to save the new connection.

Database Backup

The database can be backed up by selecting the Backup tab.

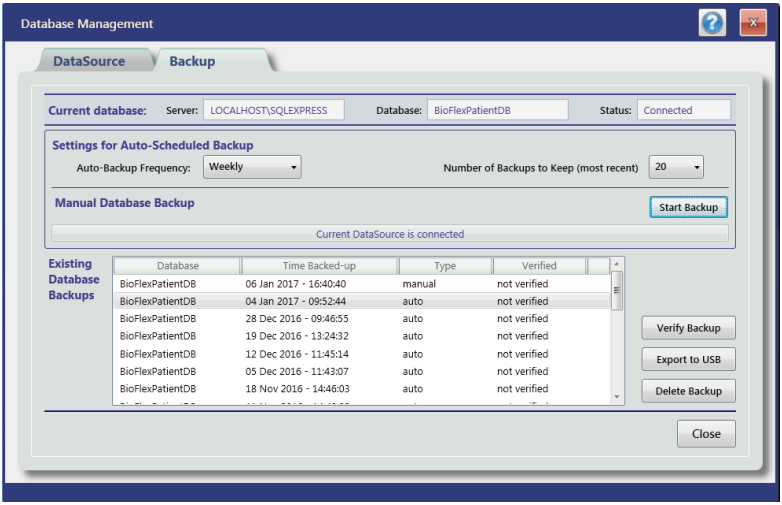
Note: The database connection must be local (LOCALHOST). Otherwise, this tab will not be displayed.

- **Auto-Backup Frequency**: Indicates how frequently the software should back up the database. It can be set to Daily, Weekly, or Bi-weekly.
- **Number of Backups to Keep**: Provides a setting to specify how many backup copies are to be kept. The oldest backups will be removed to keep the backup count to the specified limit.

A backup can also be performed manually by selecting the Start Backup button. Existing database backups are listed along with their details. Any backup can be verified and exported to a USB storage device. Only a corrupt backup can be deleted.

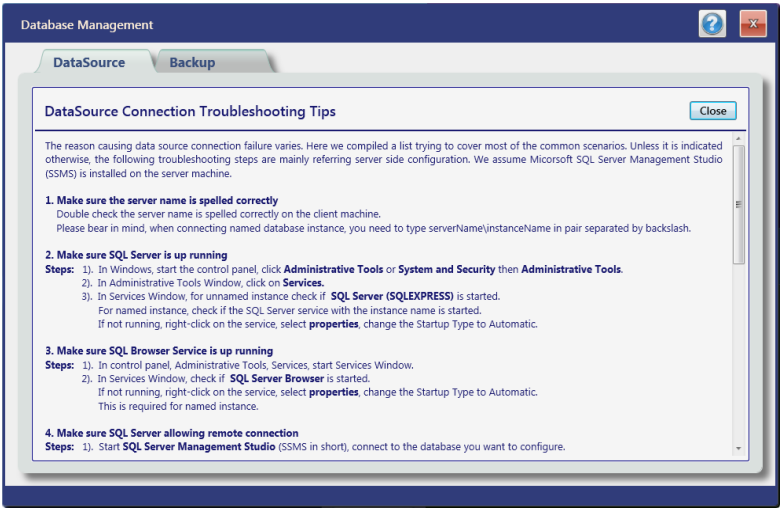
Database Restore

The provided Microsoft SQL Server Management Studio must be used in order to restore a backup.



Database Troubleshooting

Use the Help button to troubleshoot common communication errors:



Maintenance

Attention: Do not modify this equipment. Only Meditech authorized personnel may calibrate or service this equipment. Unauthorized change to the equipment may result in the immediate termination of the warranty. Contact BIOFLEX® Service for support.

Warning: To reduce the risk of electric shock, do not remove the cover from any part of the system. There are no serviceable parts inside. Contact BIOFLEX® Service for support.

Meditech recommends the following periodic activities to ensure that the system runs at optimal performance:

- Annual inspection and calibration of treatment heads by BIOFLEX® Service.
- Regular cleaning of all parts especially between treatments.
- Regular inspection of all system cables for signs of deterioration.

Cleaning

- The controller unit may be cleaned using a soft damp cloth or a soft disinfectant cloth.
- Treatment heads may be wiped with alcohol wipes, soft disinfectant cloth, soft damp cloth, or alcohol/cotton swab combination.
- Treatment heads may be cleaned with a soft bristle brush.
- Allow all parts to air dry prior to use.

Note: Do not spray or immerse the treatment heads with water, disinfectants, or 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.

Inspection

Perform the following steps if inspection reveals any damage or if any part of the system has been dropped or damaged (e.g. spill, splash, excessive humidity):

1. Check all power and cable connections. Ensure all cables are secure and properly connected.
2. Turn on all the parts of the system. If the system does not work, immediately unplug and disconnect all parts of the system.
3. Contact BIOFLEX® Service for support.

Frequently Asked Questions

Question	Solution
How do I add a new patient?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Click the New Patient button.

Question	Solution
How do I edit a patient profile?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient to edit. 3. Click the Edit button.
How do I archive a patient profile? **Note**: This action requires Administrator privileges.	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient to be archived. 3. Click the Archive button.
How do I restore an archived patient profile? **Note**: This action requires Administrator privileges.	1. Click the Root Menu on the Main Screen and select Reports. 2. Click the Archived Patients button. 3. Select the patient and click the Restore Patient Button.
How do I create a new prescription from a standard protocol?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Click the Prescribe Treatment button. 4. Select any protocol. Select the treatment head and stage. Customize the protocol as desired. 5. Click the Accept button.
How do I create a new prescription from a custom protocol?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Click the Prescribe Treatment button. 4. Click the Select from Custom Protocols button. Select the applicable custom protocol and customize the protocol as desired. 5. Click the Accept button.
How do I create a new prescription from scratch?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Click the Prescribe Treatment button. 4. Click the New button. Update the parameters as required. 5. Click the Accept button.

Question	Solution
How do I modify an existing prescription?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Select the prescription and click the Customize button. Update the parameters as required. 4. (Optional) Save the protocol as a customized protocol by clicking the Add to Custom Protocols button. 5. Click the Accept button.
How do I check a prescription's parameters?	• Navigate to the Patient Prescriptions window. Click the Info button beside the prescription; or • Click on the Placement text area in the treatment panel.
How do I check the previous revisions of a prescription?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Select the prescription and click the Revisions button.
How do I run a treatment?	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Click the Prescribe Treatment button. 4. Select the required protocol and click the Accept button.
How do I archive an active prescription? **Note**: Archived prescriptions are no longer active and will be hidden from view.	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Select the prescription and click the Archive button.
How do I add a treatment note to a prescription? **Note**: The Clinical Notes button above the prescription list is for patient-level notes, not treatment notes.	1. Click the Patient button from any treatment panel on the Main Screen. 2. Select the patient and click the Select button. 3. Click the Note button. 4. Click the Add Note button.

Question	Solution
How do I check protocol parameters?	1. Click the Root Menu on the Main Screen and select Protocols. 2. Select the protocol.
How do I modify a protocol? **Note**: Only custom protocols can be modified.	1. Click the Root Menu on the Main Screen and select Protocols. 2. Select the protocol. 3. Click the Customize button.
How do I rename a protocol? **Note**: Only custom protocols can be renamed.	1. Click the Root Menu on the Main Screen and select Protocols. 2. Select the protocol. 3. Click the Rename button.
How do I delete a protocol? **Note**: Only custom protocols can be deleted.	1. Click the Root Menu on the Main Screen and select Protocols. 2. Select the protocol. 3. Click the Delete button.
How do I get a database report?	1. Click the Root Menu on the Main Screen and select Reports. 2. Select the report type. 3. Click the appropriate button.

System Troubleshooting

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

Error Code	Screen Message	Solution
D01, D02, D03	The laser probe connected to this port has failed.	Contact BIOFLEX® Service.
E10, E11, E12, E13, E14	The port controller board has failed.	1. Replace treatment head cables. 2. Use a different port. 3. Contact BIOFLEX® Service.
L01	The port controller board or the laser probe has failed.	1. Use a different port. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.

Error Code	Screen Message	Solution
L02	The optical power for the laser probe connected to the port is critically low.	1. Use a different port. 2. Replace the treatment head cable. 3. Contact BIOFLEX® Service.
L03	The laser probe connected to the port has failed.	1. Use a different port. 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.	1. Use a different port. 2. Contact BIOFLEX® Service.
S04	Unable to turn on the treatment head on the port.	1. Replace the treatment head cable. 2. Use a different port. 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.
S07	LED array connected to the port has a factory calibration error.	Contact BIOFLEX® Service.
S12	The treatment head connected to the port ran into a communication error.	1. Reset the system by turning the power switch off and on. 2. Connect the treatment head to a known working system. 3. Replace the treatment head cable. 4. Use a different port. 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	-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 resolution)
Duty Cycle	10 to 90% (10% steps, 5 µs resolution)
Classification	
The system is classified as a medical device. In accordance with IEC 60601-1:2005+A2:2020 (3.2 Edition): Class I equipment, according to the type of protection against electric shock; Type BF applied part, according to the degree of protection against electric shock; Ordinary equipment, according to the degree of protection against harmful ingress of water; Continuous operation, according to the mode of operation; None of the parts of the system are sterilized.	

Laser Specifications

Parameter	Red Laser Probe	Infrared Laser
Model	LD-R 100+	LD-I 200+
Laser Class	3B	3B
Laser Optical Power (mW)	75	180
Effective Surface Area (cm^2)	0.10	0.10

Parameter	Red Laser Probe	Infrared Laser
Maximum Power Density (mW/cm²)	750	1800
Medium	AlGaInP	AlGaAs
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

LED Array Specifications

Parameter	DUO+ 180	DUO+ 240	DUOFLEX+ 120	DUOFLEX+ 180
Model	LS-B 2250+	LS-B 3000+	LS-B 3270	LS-B 4890
Array Optical Power (mW)	R: 750 IR: 1500	R: 1000 IR: 2000	R: 1090 IR: 2180	R: 1630 IR: 3260
Effective Surface Area (cm²)	75	100	109	163
Maximum Power Density (mW/cm²)	R: 10 IR: 20			
Number of LEDs	180	240	120	176
Medium	R: AlGaInP IR: AlGaAs			
Wavelength (nm)	R: 660 IR: 840			
Spectral Width (nm)	R: 32 IR: 80			

Symbols Glossary

Symbol	Title and Description	Standard
	Refer to instruction manual/booklet	ISO 7010
	Manufacturer Indicates the medical device manufacturer.	ISO 15223-1

Symbol	Title and Description	Standard
	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
	UK responsible person 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
	CE mark The CE mark is a registered trademark of the European Community.	Regulation (EU) 2017/745
	Warning; Hot surface	ISO 7010
	Waste Electrical and Electronic Equipment This electrical and electronic equipment is subject to separate waste collection.	EN 50419
	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.	-
	Warning; Laser beam To warn of a laser beam	ISO 7010 (W004)
	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

Symbol	Title and Description	Standard
	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
LASER APERTURE	Aperture Indicates the location of the aperture through which laser radiation is emitted.	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 (ME) 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 radio frequency (RF) communications equipment can affect Medical Electrical Equipment.

List of Cables, Transducers, and Accessories			
Cable	**Length**	**Connected From**	**Connected To**
Treatment Head Cable, DW400.022	2.2 ± 0.05 m	Controller Unit	Treatment Head
Power Cord, CT100.171	3.05 m	Power Supply	Power Outlet
MCU III USB Cable, CT402.105	3 m	Controller Unit	External Computer

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® DualPort System and the BIOFLEX® MultiPort System 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® DualPort System and BIOFLEX® MultiPort System are intended for use in the electromagnetic environment specified below. The customer or the user of the BIOFLEX® DualPort System and BIOFLEX® MultiPort System should assure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	These systems use 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.

Example Emission Class and Group Compliance		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals except for near active HF surgical equipment and the RF shielded room of a Medical Equipment System for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services or may disrupt the operation of nearby equipment. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Example Immunity Test Level Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
The BIOFLEX® DualPort System and BIOFLEX® MultiPort System are intended for use in the electromagnetic environment specified below. The customer or the user of the BIOFLEX® DualPort System and BIOFLEX® MultiPort 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	± 2 kV for power supply 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, ± 2 kV line to ground	± 0.5 kV, ± 1 kV line to line ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.

Example Immunity 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% UT (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% UT (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 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® DualPort System or BIOFLEX® MultiPort System

The BIOFLEX® DualPort System and BIOFLEX® MultiPort System are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BIOFLEX® DualPort System and BIOFLEX® MultiPort System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIOFLEX® DualPort System and BIOFLEX® MultiPort 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 the BIOFLEX® DualPort System or BIOFLEX® MultiPort System, including cables specified by Meditech. 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.

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