PHOTOBIOMODULATION THERAPY

BIOFLEX

Arthritis System

User Manual

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Family: BIOFLEX® Arthritis System
Models: CU+A, SLD+ 180A
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Intended Use and Indications for Use

The BIOFLEX® Arthritis System is used by patients as well as 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 arthritic pain.

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.
- **Strangulation Hazard**: Long cords and straps. Do not wrap cords or straps around the neck.
- 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.

System Basics

Each treatment is initiated by the emission of a stream of red light, automatically followed by infrared light. The latter is not visible to the human eye. Once the treatment has been completed this will be confirmed by a sound marking that event.

Planning Your Treatments

Light therapy is most effective when the LED array is placed firmly over the skin and directly over the focal point of the pain and symptoms. You may also treat adjacent areas above and below the symptomatic region as these areas often contribute to the symptoms being experienced.

Stages of Treatment

There are four pre-programmed stages for each of the twelve treatment areas depicted on the controller unit. Each stage presents specific protocols designed to treat that area or condition. Stage 1 should be used initially and Stage 2 may not be required if the treatment is effective. Generally, it is recommended that treatment is applied once daily for the first 4 - 5 days. If after 5 or more treatments improvement is not significant, one may advance to Stage 2 and after a similar or even greater number of treatments, one may advance to Stage 3 and eventually Stage 4.

Variations in Frequency of Application

In some instances, particularly when pain is acute, two treatment sessions may be applied in sequence or treatment can be administered twice daily for four or more days, allowing 8 to 10 hours between sessions. As your symptoms diminish with continuing therapy, the frequency of treatments may be gradually reduced. Often continuing therapy once or twice each week will continue the healing process and avoid recurrence of symptoms. If symptoms have completely resolved maintenance treatments may be beneficial.

Termination of Treatment

Treatments end automatically, unless one presses the Stop button prior to that event. The LED array may be cleaned after each treatment using an alcohol wipe or a soft, damp cloth. A mild disinfectant may also be used. Do not immerse or rinse the LED array in water. The straps may be cleaned in a washing machine using the gentle cycle. Allow straps to air dry after washing.

LED Array Cooling

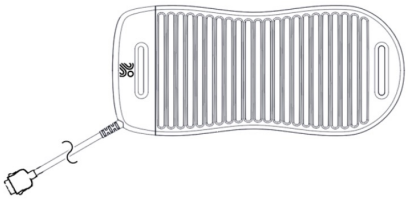
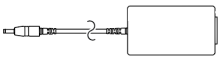
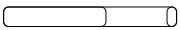
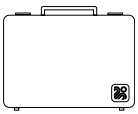
The surface of the LED array may get hot. Caution must be exercised. This is particularly applicable to treatment steps running in infrared light. The higher the power and/or duty cycle, the higher the temperature. Hotter surfaces are also expected if treatments are run consecutively without sufficient time for the LED array to cool down. Do not cover the LED array during treatment.

Essential Performance

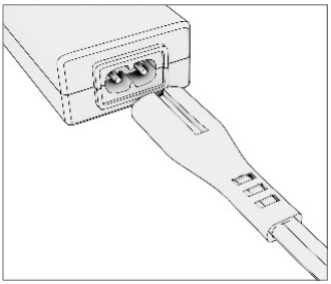
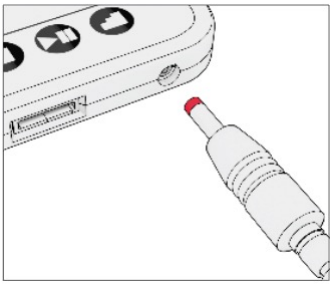
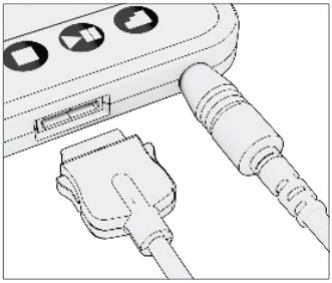
According to IEC 60601-1 Ed. 3.2, essential performance is that of a clinical

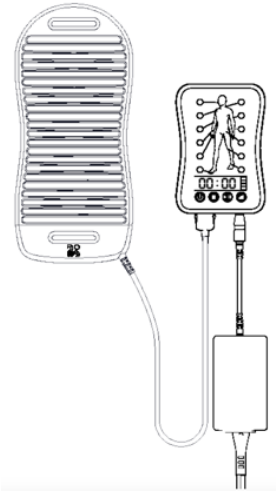
function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. The essential performance of the BIOFLEX® Arthritis System according to IEC 60601-1 Ed. 3.2, is to not radiate harmful levels of light to shine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

System Components

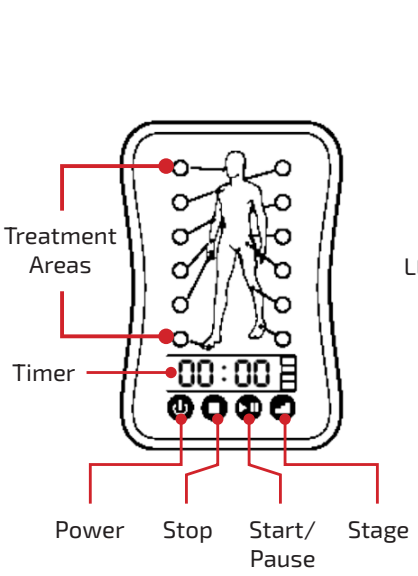
Image	Name and Model
System components are intended to be used with the BIOFLEX® Arthritis System only. Parts may appear visually different than as displayed.	
	Controller Unit CU+A
	LED Array SLD+ 180A
	AC Adapter
	Power Cable
	Retention Strap
	Safety Glasses
	Travel Case

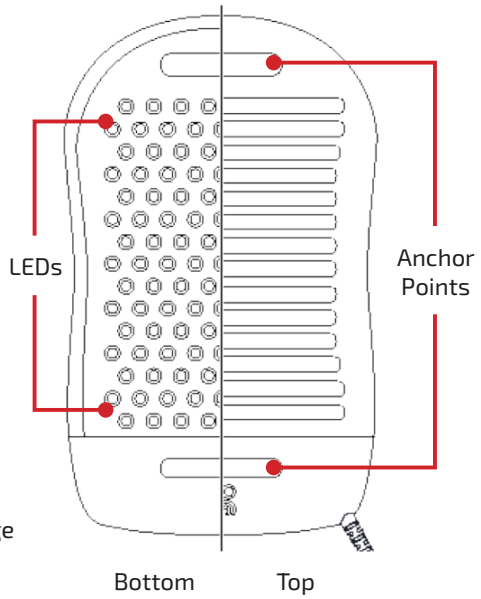
System Setup

Instruction	Image
1. Connect the Power Cable and AC Adapter.	
2. Connect the AC Adapter to the controller Unit. Connect the Power Cable to a wall outlet.	
3. Connect the LED Array to the controller Unit. An audible click will be heard when the connection is secure.	

Instruction	Image
4. The system is now ready for use.	

System Diagram



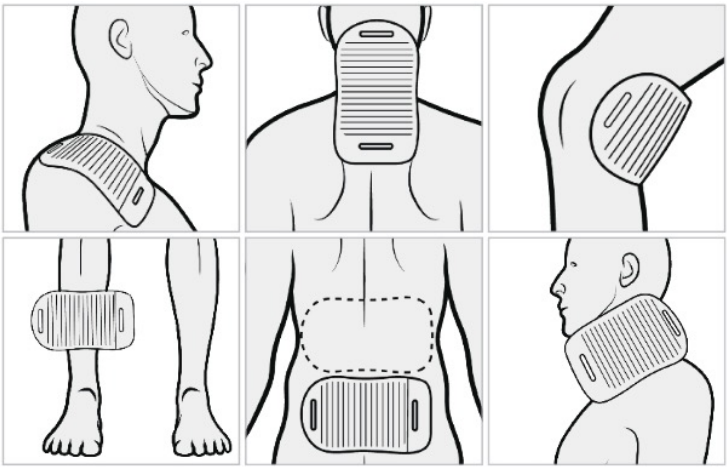


Initiating Treatment

1. Place the LED array directly onto the skin area to be treated to obtain maximum transmission of light into the tissue. The LED array may be held firmly in place either with the provided strap or manually.
2. Press the Power button to turn the system on. The system will sound and the power button will turn blue after it is turned on.
3. Press the circle on the controller unit that corresponds to the area of the body being treated (e.g. face, knee, etc.). When selected, the circle will turn blue.
4. The Treatment Stage automatically selects Stage 1 (recommended for the first five treatments). Press the button again for Stage 1 to 4, as required.
5. Press the Start/Pause button to begin the treatment. The system will sound and the timer will begin to count down. The length of each treatment varies depending on the area selected. For optimal results, run the treatment to completion.
6. Press the Stop button at any time to pause the treatment. Press Stop again to cancel the treatment.

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 below demonstrate typical ways to place the array over a treatment area:



System Troubleshooting

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

Error Code	Problem	Solution
-	One or more parts have been dropped or damaged.	Ensure all cables are properly connected. Press the Power button.
-	One or more parts have been exposed to liquid.	Unplug all cables. Dry using a hair dryer.
-	There is no power.	Ensure all cables are properly connected. Press the Power button.
E01	The LED array is not connected properly.	Unplug and re-plug the LED array. Press the Start/Pause button to resume treatment.
E02	The LED array is hot (> 48°C) due to being covered or running too long.	The LED array will automatically shut off until the temperature has dropped. It needs to be cooled for at least 15 minutes before it is used again.
E03	The LED array cable is disconnected. The temperature sensor has malfunctioned.	Ensure all cables are properly connected.
E04, E05, E06, E07, E08, E09, E10, E11, or E12	The system has malfunctioned.	Record the error code. 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 LED array.)	
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 LED array.)	
Temperature	-25 to +70°C
Relative Humidity	Up to 93% non-condensing
Functional Specifications	
Waveform	Square
Percent of Total Power	1 to 100% (1% steps)
Duration	0 to 3,600 sec (60 min)
Frequency (Modulation Mode)	10 to 10,000 Hz
Duty Cycle	1 to 99% (1% steps)

Classification

The system is classified as a medical device. In accordance with IEC 60601-1:2005+A2:2020 (3.2 Edition):
Class II equipment, according to the type of protection against electric shock;
Type BF applied part, according to the degree of protection against electric shock;
Classified IPX2, 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.

LED Array Specifications

Parameter	Red Light	Infrared Light
LED Maximum Optical Power (mW)	6.6	13.2
Array Optical Power (mW)	1165	2331
Effective Surface Area (cm^2)	163	
Maximum Power Density (mW/cm^2)	7.15	14.3

Parameter	Red Light	Infrared Light
Number of LEDs	176	
Medium	AlGaInP	AlGaAs
Wavelength (nm)	660	840
Spectral Width (nm)	16	40

Symbols Glossary

Symbol	Title and Description	Standard
	Refer to instruction manual/booklet	ISO 7010
	Manufacturer Indicates the medical device manufacturer.	ISO 15223-1
	Medical device Indicates the item is a medical device	ISO 15223-1
	General warning sign	ISO 7010
	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
	TUV SUD mark The TUV SUD mark denotes compliance to listed standards.	-

Safety Standards

This product is classified as medical equipment and has been tested to comply for 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 60601-1-11:2015+A1:2020 (2.1 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 Safety:

- IEC 60601-2-57:2011 (1st 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.

Warning: This system is intended for use by the general public. It is 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 including hospitals except for near active high frequency (HF) surgical equipment and the RF shielded room of an ME system for Magnetic Resonance Imaging (MRI) where the intensity of EM disturbances is high. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.

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® Arthritis 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® Arthritis System 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.		
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	This system is 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 Test Level Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
The BIOFLEX® Arthritis System 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	± 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 line to line	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® Arthritis System

The BIOFLEX® Arthritis System 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 if any serious incident has occurred in relation to the device.

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