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Introduction

The BioFlex 180, for the first time in the history of the application of light therapy, has the capacity to deliver automated, pre-programmed treatment protocols for an extensive number of medical conditions. The system can be easily applied at home, while travelling or otherwise engaged.

The unit is a highly sophisticated derivative product of the BioFlex Series of Professional Laser Therapy Systems that have achieved global acclaim in the mainstream medical community, based on the effective resolution of many challenging pathologies.

Currently BioFlex Systems are utilized in the field of Laser Medicine by health care professionals in over fifty countries. The technology is widely applicable in the treatment of musculoskeletal conditions, arthritis, sports and soft tissue injuries and many other both complex and routine medical problems.

At Meditech International we view this system as a major advance in providing immediate relief of pain and other symptoms. An extensive range of medical problems can be rapidly resolved -- the result of the initiation of a cascade of physiological activities leading to the restoration of normal cell structure and function. The system is also instrumental in providing preventative and maintenance therapy of body tissues.

With the acquisition of this unit, you hold the key to a rapid resolution for many of your medical problems, at your fingertips.

The History of Meditech International Inc.

The design, manufacture and therapeutic application of BioFlex Systems is the primary focus of the company - founded by Fred Kahn, MD, in 1989.

Dr. Kahn is a Fellow of The Royal College of Surgeons of Canada, a Diplomate of the American Board of Surgery and has been elected to The Spinal Hall of Fame for his pioneering efforts in the resolution of back problems.

Prior to initiating research in the field of Laser Technology, he was engaged in a surgical practice specializing in trauma and vascular reconstructive surgery over the course of twenty-five years.
During the past quarter of a century, Dr. Kahn has assembled an innovative team of scientists, clinicians, software and electro-photonic specialists in order to standardize and advance the field of “Laser Medicine”.

During the first ten years of its existence, the company was based at Ryerson University in Toronto, Canada where it developed and verified its initial concepts.

Dr. Kahn has published four texts on the topic of Laser Medicine, along with numerous articles relating to this emerging technology and as a result of this process, has become a recognized leader in this field.

System Basics

The BioFlex 180 is a high performance therapy system that is affordable, cost-effective and easy to use. The ergonomically designed Controller Unit is connected to a flexible Treatment Array in order to deliver a patented sequence of Red and Infrared light therapy to injured or diseased tissue automatically.

Research-based, clinically proven protocols have been developed for 12 anatomical regions, encompassing an extensive number of medical problems. Four protocol stages are available to treat each area.

The Treatment Array’s soft, flexible composition readily adjusts to the configurations of the anatomical area to which it is applied.

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 Treatment Array is placed firmly over the dermis and directly over the focal point of the pain. 60% of the treatment time, both Red and Infrared, should be devoted to that general region. The remaining treatment time may be extended more widely to the adjacent areas and if possible, the region opposite to the focus of the pain. This will make certain that the transmission of all therapy is directed to both the superficial and deeper tissue layers of the area involved.

Stages of Treatment

There are 4 pre-programmed Stages for each of the 12 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 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 subsequently, as clinically indicated, to 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 8-10 hours between sessions. Applying treatment more than twice over a 24-hour period should be avoided.

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. Once symptoms have disappeared completely, occasional maintenance therapy may be beneficial.
Additional Instructions:
Some of these steps have already been described but are repeated for confirmation.

- 60% of the Red and Infrared treatment time prescribed for each condition should be devoted to the area where the pain and other symptoms are most severe. The remaining period of time should be applied more widely to the adjacent areas.

- When treating joint problems particularly, surround the entire joint, devoting 2/3 or even more of the treatment time to the area most severely affected.

- All areas are treated sequentially with the application of the Red, followed by the Infrared Light, automatically.

- Placement of the Treatment Arrays can be performed according to the diagrams demonstrated on pages 10-22. These placements provide guidelines that are more specific.

- As one becomes more familiar with utilization of the system, placements will be largely dictated by the response of the tissues treated. These are characterized by the reduction in pain, swelling, discolouration, etc. and an improving range of motion.

- For most protocols, 40% of each treatment phase utilizes Red light and the other 60% Infrared. 2-3 minutes of each can be devoted to the placement locations depicted in the diagrams included on pages 10-22.

To summarize - there are two methods of application of the treatment that can be followed. One may simply move placement of the Array every 2-5 minutes to cover the area being treated widely.

Conversely, one may follow the more exacting placements depicted on pages 10-22, devoting 2-3 minutes of Red light to each placement and 3-4 minutes of Infrared light.

Either method is acceptable and should achieve satisfactory results. All placements may be manual or maintained with the straps supplied. Whichever course is followed, it is important to move the Arrays periodically to cover the area being treated completely.

Should you require further guidance, please call a Meditech consultant at 1-844-770-0177.
Possible Reactions and Side Effects
The dermis may become discolored, secondary to physiological changes. This condition is of minimal concern and should disappear subsequent to treatment.

One can use the glasses provided for ocular protection, however they are not essential. It is generally good practice to wear them when treating the upper body regions or the facial area.

Termination of Treatment
Treatments end automatically, unless one presses the Stop button prior to that event.

The Treatment 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 Treatment Array in water.

The straps may be cleaned in a washing machine using the gentle cycle. Allow straps to air dry post-washing.

Tips Regarding Use:

Always be patient with regard to improvement. Sometimes relief may be dramatic and at other times it may be slow with only gradual reduction of symptoms after multiple treatments.

If symptoms are acute, rest as much as possible and avoid movements which may aggravate the symptoms.

At all times remember that patience is a virtue, along with persistence. Some conditions and patients respond more rapidly than others but with due care, a positive response is invariably achieved.
Conditions Treated and Placement of Array

Intended Use

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.

More specialized conditions involving each of the areas for which protocols are provided will be described in the appropriate sections. (p.10-21)

The BioFlex Personal is a medical device designed for safe, easy and effective temporary relief of minor muscle and joint pain, arthritis, muscle spasm, stiffness and promoting muscle relaxation in the body.
Face

Common Conditions Treated

TMJ Pain

Placements

A and B direct the location of the Array when facial structures are involved. (Avoid placements close to eyes)
Shoulder

Common Conditions Treated
Joint Pain   Muscle Pain
Arthritis    Tendonitis
Soft Tissue Injuries

Placements
A to C direct the location of the Array when treating the shoulder joint.

Superior
A

Lateral
B

Vertical
C
Elbow

Common Conditions Treated

Joint Pain
Tennis Elbow
Soft Tissue Injuries

Muscle Pain
Arthritis
Tendonitis

Placements

A to D direct the location of the Array when treating the elbow joint.

Either combination of placements are acceptable (i.e. A and B or C and D).
Wrist

Common Conditions Treated
Joint Pain  Tendonitis
Soft Tissue Injuries  Arthritis

Placements
A to D direct the location of the Array when treating the wrist joint.

Placements A and B are preferable however in some instances C and D may be more appropriate.

Dorsal

Ventral (Palmar)

Dorsal Longitudinal

Ventral Longitudinal
Hand/Digits

Common Conditions Treated
Joint Pain  Tendonitis
Soft Tissue injuries  Arthritis

Placements
A and B direct the location of the Array when treating the hands.

The wrist and hand/digits may be treated separately or jointly depending on the dimensions of the area involved.

In some situations C and D may be preferable. Generally cover all the small joints involved.
Foot

Common Conditions Treated

Arthritis
Joint Pain
Soft Tissue Injuries
Tendonitis
Muscle Pain

Placements

A to D direct the location of the Array when treating the foot.

Place according to major area of pain.
Ankle

**Common Conditions Treated**
- Arthritis
- Joint Pain
- Soft Tissue Injuries
- Tendonitis
- Muscle Pain

**Placements**
A to C direct the location of the Array when treating the ankle.
Cervical Spine (Neck)

Common Conditions Treated
- Arthritis
- Joint Pain
- Soft Tissue Injuries
- Tendonitis
- Muscle Pain

Placements
A to D direct the location of the Array when treating the neck.
Thoracic Spine (Upper Back)

**Common Conditions Treated**

- Soft Tissue Injuries
- Muscle Pain
- Muscle Spasm

**Placements**

A and B direct the location of the Array when treating the upper back. Schematic outlines indicate additional placements.

**Vertical 1 or 2 placements**

![Vertical 1 or 2 placements](image)

**Transverse 1 or 2 placements**

![Transverse 1 or 2 placements](image)
Lumbar Spine (Lower Back)
Common Conditions Treated
Soft Tissue Injuries
Muscle Pain
Muscle Spasm

Placements
A to D direct the location of the Array when treating the lower back. Schematic outlines indicate additional placements.
Hip

Common Conditions Treated

- Arthritis
- Joint Pain
- Soft Tissue Injuries
- Tendonitis
- Muscle Pain

Placements

A to F direct the location of the Array when treating the hip joint.

Treatment can be applied using transverse or vertical placements extending from the mid-line anteriorly to the mid-line posteriorly. Vertical approach may require 4 or 5 individual placements.
Knee

Common Conditions Treated

Arthritis  
Joint Pain  
Soft Tissue Injuries  

Arthritis  
Joint Pain  
Soft Tissue Injuries  

Placements

A to F direct the location of the Array when treating the knee.

It is important to treat the entire circumference of the joint, always devoting more time to the primary focus of symptoms.

Transverse Placements

Vertical Placements
What’s In The Box

When you receive your BioFlex Personal System, check to make certain that all of the parts shown below are included and undamaged. If parts are missing or damaged, contact BioFlex at 1-844-770-0177 or customerservice@bioflexpersonal.com

Note: System parts may appear visually different than as displayed.
Connecting The System

This is as easy as 1-2-3:

1. Connect the power cord, AC adapter and Controller as shown

2. Connect the Controller Unit to AC adapter
3. Connect Treatment Array to Controller Unit, squeeze the sides of the Treatment Array connector firmly to insert easily - and squeeze again to remove.

Your fully connected system should appear as demonstrated below.
Initiating Therapy

Controller Unit

- Face
- Shoulder
- Elbow
- Wrist
- Hand
- Foot
- Timer
- Power Button
- Stop
- Start/Pause
- Select Stage

Treatment Array

- Strap Anchor Points
- Treatment LEDs
- Power LED

Top View of Treatment Array
Bottom View of Treatment Array
Application Of Treatment

Step 1
Place Array on the area to be treated. Apply to dermis (skin) to obtain maximum transmission of light into the tissues. The Treatment Array may be held firmly in place either with the straps provided or manually.

Step 2
Press the power button to turn the system on or off. You will hear an audible double beep and the power button will turn blue after it is turned on.

Step 3
Press the circle on the Controller Unit that corresponds to the area of the body to be treated (e.g., face, knee, etc.). When selected, the circle will turn blue.

Step 4
The Treatment Stage of the BioFlex 180 automatically selects Stage 1 (recommended for at least the first five treatments or longer). Press the button again for Stage 1 - 4, as required.

Step 5
Press the Start/Pause button to begin the treatment. There will be an audible beep and the countdown timer will start. The length of each treatment varies depending on the area selected. For optimal results, run the treatment to completion (until the timer signals the termination).

If you need to stop or pause your treatment for any reason, press the Start/Pause button. Pressing the Start/Pause button again will resume your treatment.

Step 6
Press the Stop button at any time to pause the treatment. Press Stop twice to cancel the treatment.
Important Information

It is appropriate to read and understand the User Manual. Failure to follow the instructions noted may result in problems and void the product warranty. If you have any questions, call BioFlex at 1-844-770-0177.

• This device is to be utilized for the conditions listed in this manual.

• The device is to be used in a dry environment only and must be kept dry at all times.

• The system is not waterproof. Do not get it wet or rinse under water. Do not use while bathing.

• 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 exert excessive pressure or twist/bend the system parts. Keep the Treatment Array away from sharp objects as they may puncture it.

• Do not pull, kink or pinch the cables. Never tightly wrap cables around the Treatment Array.

• Do not drop the system.

• Do not attempt to modify or open any part of the system.

• Choking hazard: Do not wrap cords or straps around the neck.

• Do not cover the Treatment Array during treatment.

• Do not use the system to treat over the eyes. It is inappropriate to shine the light emanating from the Treatment Array into the eyes.

• Use the provided glasses if your eyes are sensitive to the bright light coming from the Treatment Array. Do not use the glasses for any purpose other than for treatment with the BioFlex 180 system.

• Do not leave the device unattended when it is running.

• Use carefully. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the BioFlex 180 system by children/infants or incapacitated persons may be dangerous. Keep the system out of the reach of children.
## System Troubleshooting

This section summarizes the most common problems encountered with the Personal System. If you are unable to solve the problem with the information below, contact BioFlex Service at 1-844-770-0177.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part or all of the system becomes damaged and does not work.</td>
<td>System has been dropped or otherwise damaged.</td>
<td>Check all power connections. Make certain all cables are secure and properly connected. Press the Power button on the Controller Unit. If it does not power on, contact BioFlex Service.</td>
</tr>
<tr>
<td>System has become contaminated by liquids.</td>
<td>i.e. water, humidity, etc.</td>
<td>Immediately unplug all system components from the electrical outlet. Dry using hair dryer. Contact BioFlex Service.</td>
</tr>
<tr>
<td>Issue</td>
<td>Possible Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>-------</td>
<td>---------------</td>
<td>---------</td>
</tr>
</tbody>
</table>
| No power or display is blank. | The power supply is not connected.  
Power is not turned on. | Plug the power supply into a wall outlet.  
Ensure the cable is plugged into the Controller Unit. The Unit will beep once the power is connected.  
Press the Power button. |
| System beeps and displays an **E01** error. | The Treatment Array is not connected properly. | Unplug and re-plug the Treatment Array and press the start/pause button on the Controller Unit to continue the treatment.  
If problem persists, contact BioFlex Service. |
| System beeps and displays an **E02** error. | The Treatment Array is hot (temperature exceeds 48°C) due to being covered or running too long. | In the event that the Treatment Array gets too hot, it will shut off until the temperature has dropped.  
The Treatment Array needs to be cooled for at least 15 minutes before it is used again. |
| System beeps and displays an **E03** error. | The Teatment Array cable may have been removed unexpectedly.  
The temperature sensor has malfunctioned. | Make sure the cable is properly connected to the Controller.  
If problem persists, contact BioFlex Service. |
| System beeps and displays an **E04, E05, E06, E07, E08, E09, E10, E11 or E12** error. | The system has malfunctioned. | Record the error code and contact BioFlex Service for further assistance. |
## System Specifications

### Electrical Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated voltage</td>
<td>100-240V</td>
</tr>
<tr>
<td>Rated frequency</td>
<td>50-60 Hz</td>
</tr>
</tbody>
</table>

### Operating Conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>+5°C to +40°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>15% to 93% (non-condensing)</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>700hPa to 1,060hPa</td>
</tr>
</tbody>
</table>

### Storage Conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature / humidity</td>
<td>-25°C without relative humidity control</td>
</tr>
<tr>
<td></td>
<td>+70°C at a relative humidity up to 93%, non-condensing</td>
</tr>
</tbody>
</table>

### Classification

(Sub-clause 6 of IEC 60601-1 and Clause 6 of IEC 60601-1:2005)

- 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;
- NOT CLASSIFIED, 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
### Canadian Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAN/CSA C22.2 No. 60601.1, Third ed.</td>
<td>Medical Electrical Equipment - Part 1: General Requirements for Safety</td>
</tr>
<tr>
<td>CAN/CSA C22.2 No. 601-1.M90</td>
<td>Medical Electrical Equipment – Part 1: General Requirements for Safety</td>
</tr>
<tr>
<td></td>
<td>Canadian and United States of America standards UL 60601-1, First ed.</td>
</tr>
</tbody>
</table>

### International Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSI/AAMI ES60601-1:2005</td>
<td>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</td>
</tr>
</tbody>
</table>
Warning Symbols and Labels

Controller Unit

Consult User Manual
Refer to the User Manual instructions.

TYPE BF APPLIED PART
This product is classified as a Type BF Applied Part, according to the degree of protection against electric shock.

Waste Electrical and Electronic Equipment Directive
This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

Model and Serial Number Label
This label shows the models and serial numbers (S/N) of your system’s components.

Serial Number System

05 10 524D-9420-1

Region
S/N
MFG Code
Year
Month

S/N: 9420
JOB: 0510524D
MODEL: SLD00

S/N: 05 10 524D 94200 C
MODEL: CU+
## Treatment Array

<table>
<thead>
<tr>
<th>Heat Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is normal for the Treatment Array surface to get warm after extended use.</td>
</tr>
<tr>
<td>In the event that the Treatment Array gets hot, the system will pause until the temperature has dropped. The Treatment Array needs to be cooled for at least 15 minutes before it is used again.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class I LED</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product uses LEDs that under normal use do not pose a danger to the eyes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Warning Symbol</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>UL Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>The UL mark is a registered trademark of the Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards.</td>
</tr>
</tbody>
</table>
Electromagnetic Compatibility (EMC)

This equipment complies with the European rules for EMC according to the safety standard IEC 60601-1-2. The device complies with EMC rules under test conditions that include use of system cables and connectors between system components.

This equipment requires special precaution with regard to the EMC and must be installed and placed into service according to the information provided in this manual.

The use of accessories and cables other than those specified and sold by the manufacturer 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. Replace cables and connectors between components only with BioFlex approved cables and connectors.

This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take appropriate measures, such as reorienting or relocating the equipment or shielding the location.
# BioFlex Personal Parts List

<table>
<thead>
<tr>
<th>Components</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Unit</td>
<td>DW100.785</td>
</tr>
<tr>
<td>Personal 180 Treatment Array</td>
<td>DW400.004</td>
</tr>
<tr>
<td>Carrying Case</td>
<td>CT402.009</td>
</tr>
<tr>
<td>User Manual - Canada</td>
<td>MN100.794</td>
</tr>
<tr>
<td>User Manual - USA</td>
<td>MN421.000</td>
</tr>
<tr>
<td>Power Supply</td>
<td>CT402.006</td>
</tr>
<tr>
<td>Power Cord</td>
<td>CT100.171</td>
</tr>
<tr>
<td>Safety Glasses</td>
<td>CT402.016</td>
</tr>
</tbody>
</table>