APPLICATION FOR VARIANCE

21 CFR 1040.10 (f) (3)

Meditech International Inc.
65 Harbour Square, Suite 1908
Toronto, Ontario, Canada
M5J 2L4

August 24,1998

FDA Accession Number 9810192

Application for Variance

(i) The Bioflex professional system manufactured by Meditech International Inc. is a Low Intensity Laser Therapy system designed for use by medical practitioners for the treatment of musculosceletal disorders. The system is intended to supply laser light or photon energy directly to the human body. The system is composed of a computer, main controller and a variety of treatment heads. There are a total of six treatment heads available with the system, two of which contain a single laser diode and four of which contain an array of super luminous diodes. All treatment heads are classed as IIIb. The red laser diode treatment head (LD-R25) is rated at 25mW @ 680nm and the infra-red laser diode treatment head (LD-I75) is rated at 75mW @ 830nm. The laser diode treatment heads include a proximity switch, called a "body switch", which is located directly at the laser aperture and activates the laser when the head is enabled and is in direct contact with the skin. Further, it prevents emission when the probe is removed from the skin.

(ii) Class IIIb laser products are required to incorporate a remote interlock connector as per 21 CFR 1040.10 (f) (3). The intent of the interlock is to prevent unintentional exposure to stray laser beams. The "body switch", utilized with the laser diode treatment heads provides an equivalent degree of safety as the beam will only be active when the aperture is in direct contact with the target tissue, thus preventing stray beams.

(iii) In lieu of the remote interlock connector, all laser diode based treatment heads will incorporate the body switch feature.

(iv) The advantage of the body switch system is the elimination of stray beams when the laser is activated, greatly reducing the potential for direct ocular exposure. From an installation standpoint, additional wiring and switches are not required.

(v) For a detailed description of the body switch design and operation please refer to attachment 7.5

(vi) Meditech International Inc. requests that the variance be in effect as long as the laser diode treatment heads are manufactured with the body switch.

(vii) N/A

(viii) N/A

(ix) N/A

(x) N/A

(xi) N/A

APPLICATION FOR VARIANCE

21 CFR 1040.10 (f) (5) (ii)

Meditech International Inc.
65 Harbour Square, Suite 1908
Toronto, Ontario, Canada
M5J 2L4

August 24,1998

FDA Accession Number 9810192

Application for Variance

(i) The Bioflex professional system manufactured by Meditech International Inc. is a Low Intensity Laser Therapy system designed for use by medical practitioners for the treatment of musculosceletal disorders. The system is intended to supply laser light or photon energy directly to the human body. The system is composed of a computer, main controller and a variety of treatment heads. There are a total of six treatment heads available with the system, two of which contain a single laser diode and four of which contain an array of super luminous diodes. All treatment heads are classed as IIIb. The red laser diode treatment head (LD-R25) is rated at 25mW @ 680nm and the infra-red laser diode treatment head (LD-I75) is rated at 75mW @ 830nm. The laser diode treatment heads include a proximity switch, called a "body switch", which is located directly at the laser aperture and activates the laser when the head is enabled and is in direct contact with the skin. Further, it prevents emission when the probe is removed from the skin.

(ii) Class IIIb laser products are required to incorporate an emission delay prior to emission as required per 21 CFR 1040.10 (f) (5) (ii). The intent of the emission delay is to allow time for appropriate action to avoid exposure to the laser radiation. The "body switch", utilized with the laser diode treatment heads provides an equivalent degree of safety as the beam will only be active when the aperture is in direct contact with the target tissue. The treatment head must be enabled in order for the body switch to become active. Adding an emission delay would be restrictive to practitioners as the treatment time per point is generally in the order of seconds, thus the total time required to treat a patient would be increased. As well, applying the treatment would become more tedious and the practitioner would be more susceptible to fatigue while targeting the treatment head to specific locations on a continuous basis.

(iii) In lieu of the remote interlock connector, all laser diode based treatment heads will incorporate the body switch feature.

(iv) The advantage of the body switch system is that the laser will only be active when the treatment head is in direct contact with the target tissue.

(v) For a detailed description of the body switch design and operation please refer to attachment 7.5

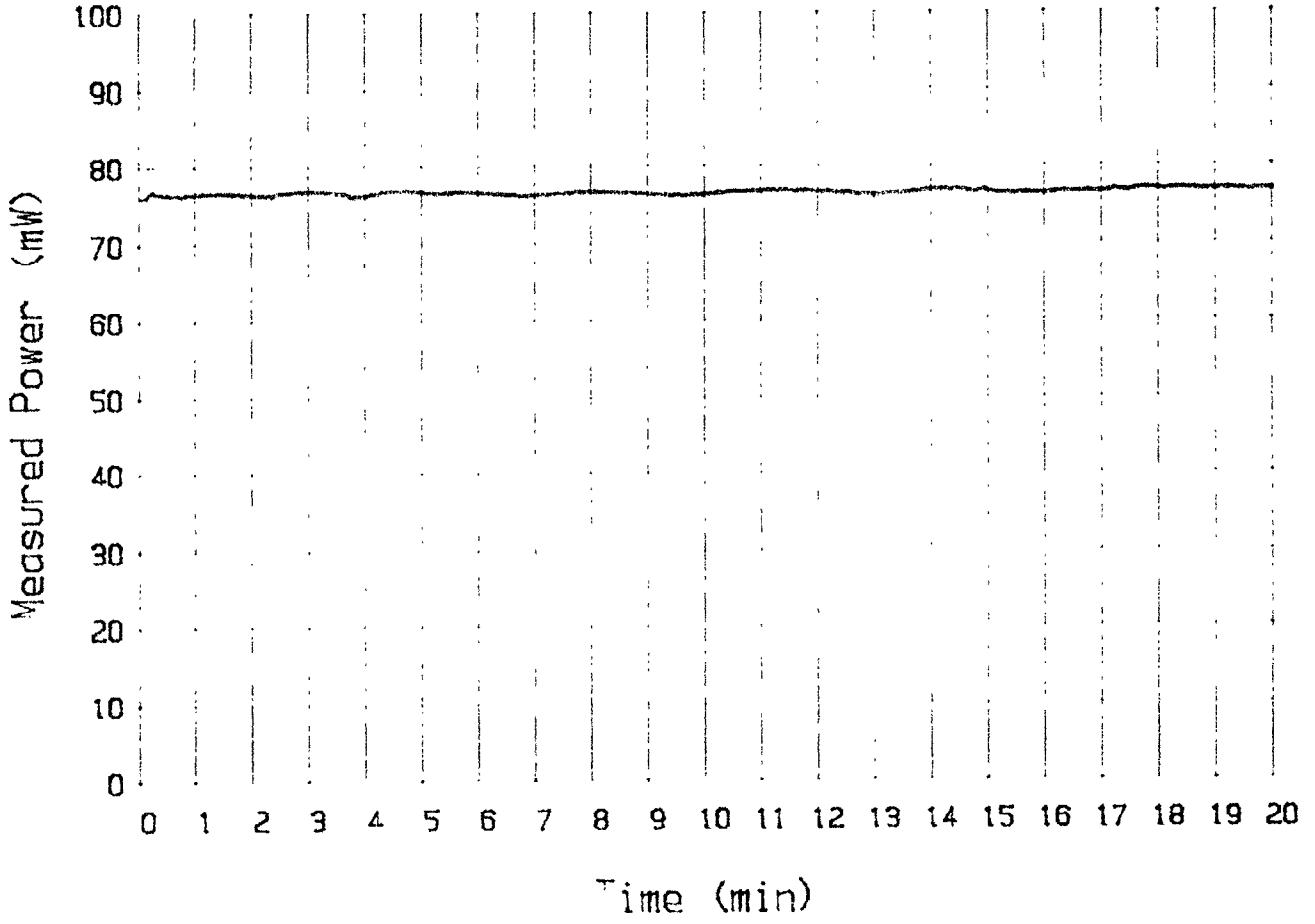
(vi) Meditech International Inc. requests that the variance be in effect as long as the laser diode treatment heads are manufactured with the body switch.

vii) N/A
(viii) N/A
(ix) N/A
(x) N/A
(xi) N/A

BioFlex Output Power Stability

LS-I75 S/N: 0008
Wavelength: 830 nm
Optical Power Meter: ANDO AQ-1135E

Ave. Power: 76.64 mW
Power Deviation: 1.32 %



Date: 24 AUG 98 Time: 14:11:25

Ryerson Polytechnic University

Attachment 7.5

Please note:

The following provides a detailed description of the design and operation of the "body switch" incorporated in the LD series treatment heads.

With this design, laser radiation will only be emitted when the probe is in direct contact with the human body, preventing direct ocular exposure, thus the need for a remote interlock is superfluous.

As with the flexible head described earlier, safety features have been incorporated in the point source head to prevent ocular hazards, particularly with the use of laser diodes. Two indicator light-emitting diodes 714 and 715 respectively are provided on either side of the head 700. The position of the indicator diodes 714 and 715 provides a high degree of visibility from all angles. The light-emitting diodes utilized in this embodiment are of the bi-colour type and provide a green output when the head is enabled and a red output when the head is active. To provide a start control for the operation of the head, a proximity sensor device 716 is mounted on either side of the laser diode 702 and projects to the surface of the tip 710. The proximity sensor 716 includes a pair of contact electrodes 718,720 which when placed in contact with a suitable medium such as the skin provides a conduction path between the electrodes 718,720. Preferably the electrodes 718,720 are integrally molded from a conductive epoxy with the balance of the tip 710 molded from a non-conductive epoxy material. The electrodes are then covered with a think protective layer, i.e. paint, to reduce the effects of moisture. The electrodes 718,720 are attached to conductors passing through the housing 703, a driver circuit which is composed of an oscillator whose frequency varies with the capacity of the electrode and then converts the output frequency to DC signal of varying voltage. The μp 915 monitors this voltage and when the head is in contact with the skin, a voltage of predetermined value is obtained which allows the head to be activated. Similarly, removal of the head from the skin terminates operation of the head. Thus, the proximity sensor also serves as a local start/stop switch, namely activating the head when the head is enabled and in contact with the skin and stopped when the head is enabled but removed from contact with the skin. An automatic delay may be incorporated within the head control circuitry to delay activation of the laser diode, in response to a signal from the proximity sensor, in order to avoid unintentional spurious luminous output. The proximity sensor provides an advantage to a practitioner since it allows a sequence of points to be illuminated for short durations without having to consciously or physically having to keep activating the laser diode. The laser diode used in the present embodiment has a power output that may range from 10's milliwatts to several hundred milliwatts which is calculated to produce an irradiance in the order of 1,000 milliwatts per square centimeter.

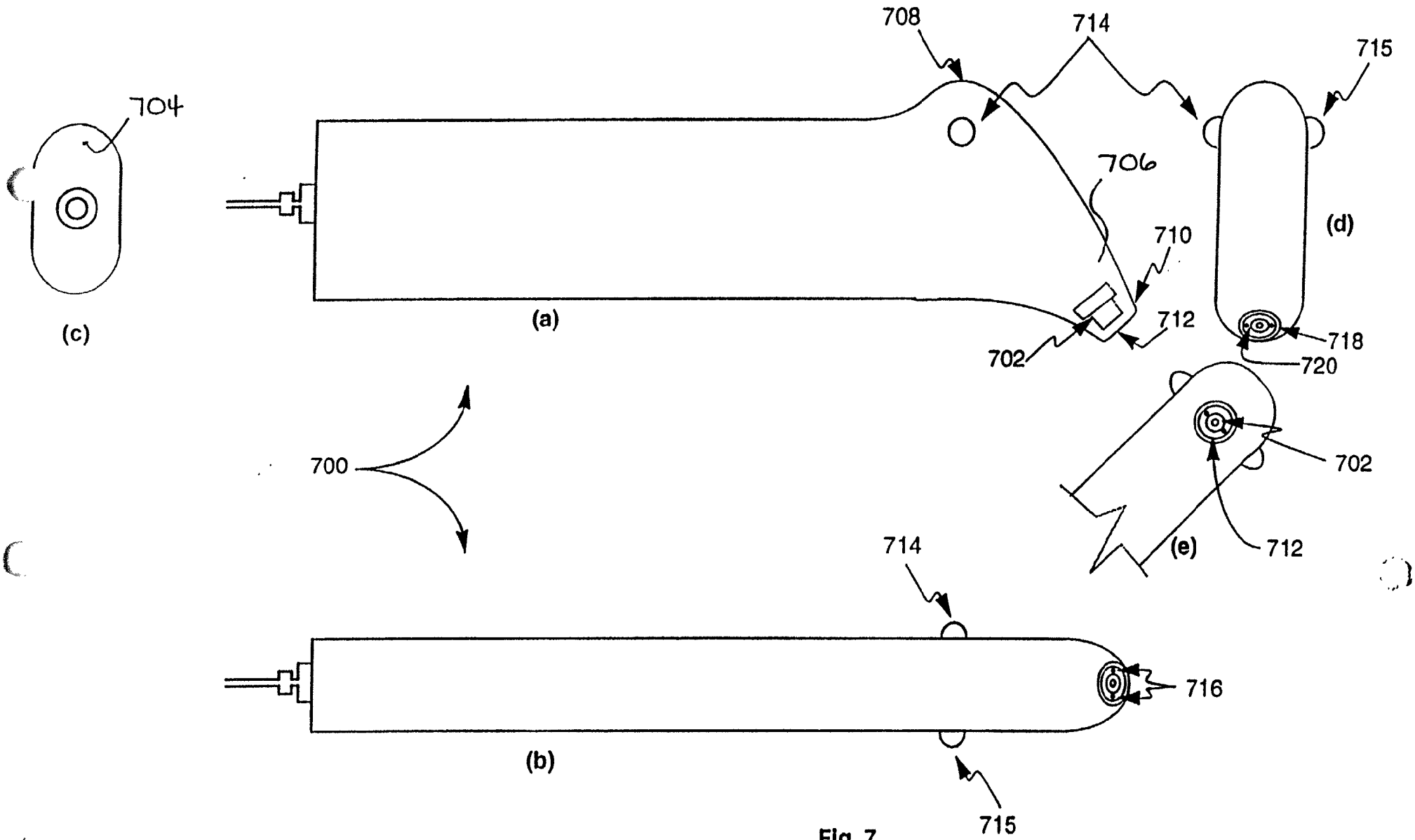

704
(c)
708
714
715
706
710
712
718
720
702
(a)
(d)
700
714
716
(b)
715
702
712
(e)

Fig. 7

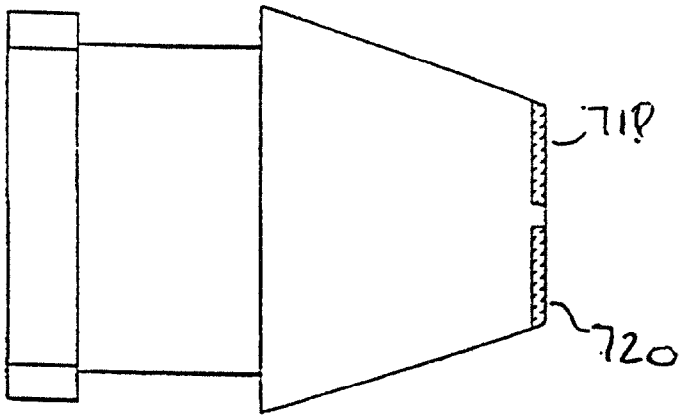


Fig. 7g

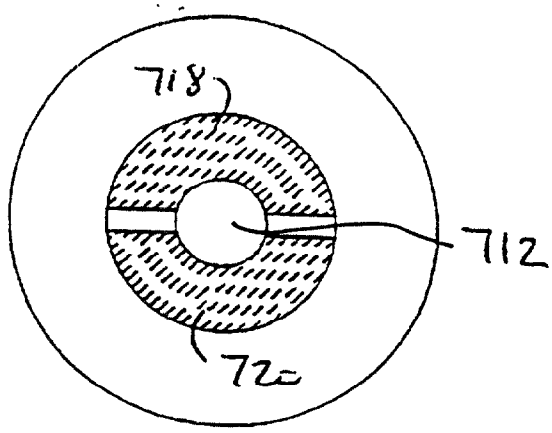


Fig. 7h

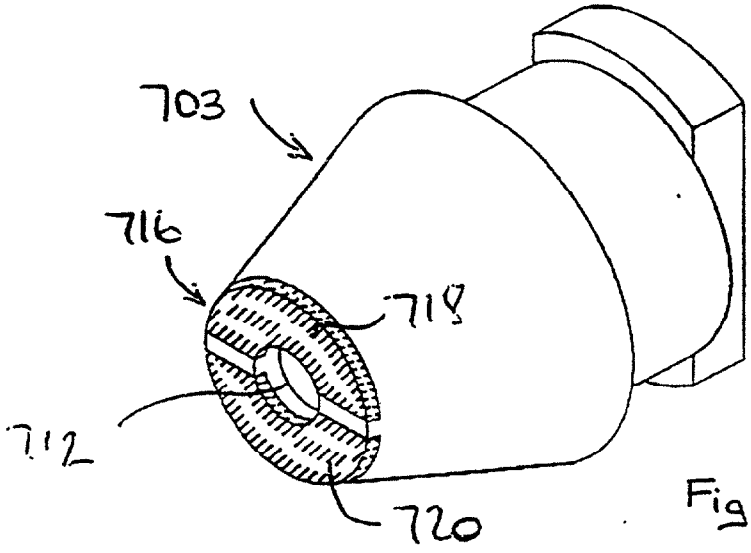


Fig. 7f

Attachment 7.5

Please note:

The following provides a detailed description of the design and operation of the "body switch" incorporated in the LD series treatment heads.

With this design, laser radiation will only be emitted when the probe is in direct contact with the human body, preventing direct ocular exposure. thus the need for a remote interlock is superfluous.

As with the flexible head described earlier, safety features have been incorporated in the point source head to prevent ocular hazards, particularly with the use of laser diodes. Two indicator light-emitting diodes 714 and 715 respectively are provided on either side of the head 700. The position of the indicator diodes 714 and 715 provides a high degree of visibility from all angles. The light-emitting diodes utilized in this embodiment are of the bi-colour type and provide a green output when the head is enabled and a red output when the head is active. To provide a start control for the operation of the head, a proximity sensor device 716 is mounted on either side of the laser diode 702 and projects to the surface of the tip 710. The proximity sensor 716 includes a pair of contact electrodes 718,720 which when placed in contact with a suitable medium such as the skin provides a conduction path between the electrodes 718,720. Preferably the electrodes 718,720 are integrally molded from a conductive epoxy with the balance of the tip 710 molded from a non-conductive epoxy material. The electrodes are then covered with a think protective layer, i.e. paint, to reduce the effects of moisture. The electrodes 718,720 are attached to conductors passing through the housing 703, a driver circuit which is composed of an oscillator whose frequency varies with the capacity of the electrode and then converts the output frequency to DC signal of varying voltage. The μp 915 monitors this voltage and when the head is in contact with the skin, a voltage of predetermined value is obtained which allows the head to be activated. Similarly, removal of the head from the skin terminates operation of the head. Thus, the proximity sensor also serves as a local start/stop switch, namely activating the head when the head is enabled and in contact with the skin and stopped when the head is enabled but removed from contact with the skin. An automatic delay may be incorporated within the head control circuitry to delay activation of the laser diode, in response to a signal from the proximity sensor, in order to avoid unintentional spurious luminous output. The proximity sensor provides an advantage to a practitioner since it allows a sequence of points to be illuminated for short durations without having to consciously or physically having to keep activating the laser diode. The laser diode used in the present embodiment has a power output that may range from 10's milliwatts to several hundred milliwatts which is calculated to produce an irradiance in the order of 1,000 milliwatts per square centimeter.

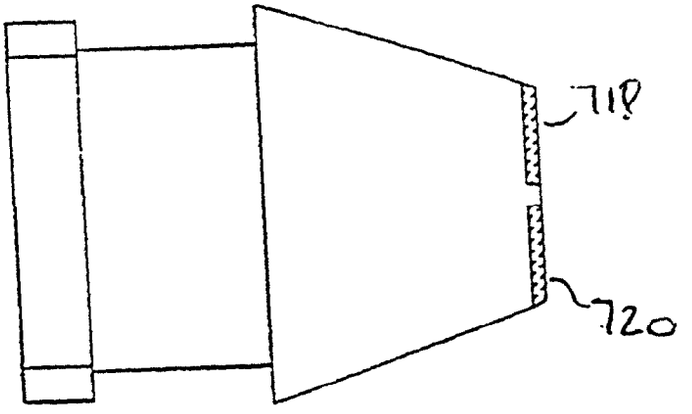


Fig. 7g

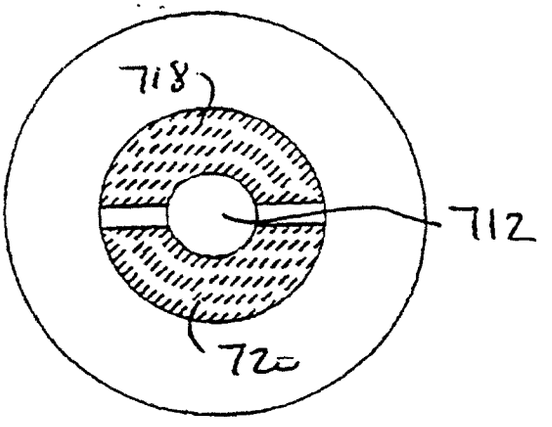


Fig. 7h

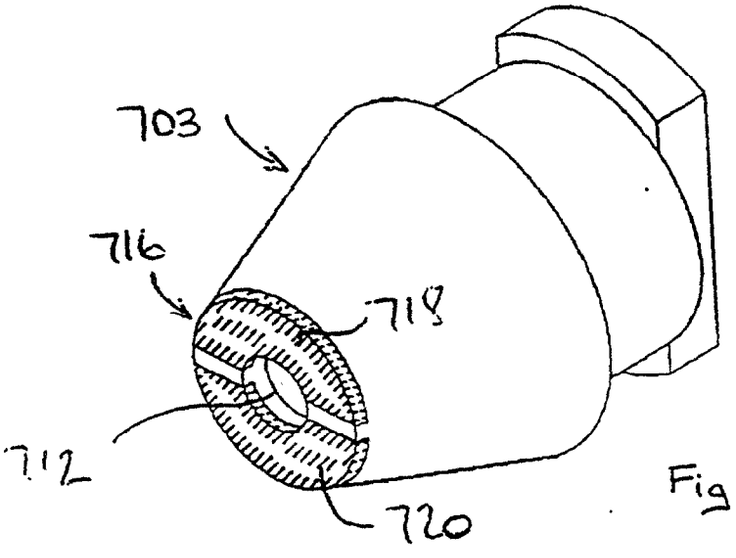


Fig. 7f

Attachment 7.14

As stated earlier, a plurality of pockets may be connected together in parallel. In order to ensure that a predictable and consistent luminous signal is provided by the treatment heads 200, a feedback loop was implemented. This is achieved in principle by monitoring the luminous output from one of the diodes in the string. The assumption is that by constructing or ensuring that the remaining strings of diodes in the other pockets behave in a similar manner to the pocket used in the feedback loop, a more consistent luminous output can be achieved.

As shown in Figure 8, the feedback diode 814 is optically coupled to a pin diode 820, which is responsive to the photon energy generated by the diode 814. The output from the pin diode is fed via an amplifier 822 to an analog to digital input 824 of a microprocessor 815. The microprocessor 815 performs a comparison with this input and with the input from the control signal which is received on the analog to digital input 824. The output from the pin diode 820 and the input from the control signal 818 are compared in a summer 826 to provide the output control signal 812 for the device drivers 810. As may be seen then, the feedback loop around the pin diode 820 and the summer 826 provides a real-time loop with high bandwidth (1 MHz) and thus provides stable and

absolute luminous output power that is not dependent upon the type of modulation or the underlying limitations of the diodes. The benefits of this feedback are invaluable in that, for example, if a treatment head is composed of a number of SLD devices - for example 60 - but one of the 60 is used to provide feedback as a representative sample, then based on the assumption that the remaining 59 devices will behave in a similar fashion, the effects due to diverse linearity, heating and aging effects are all but eliminated. A further significance of monitoring the luminous output directly in this type of feedback arrangement is that it achieves a direct control of the luminous output rather than the drive current. A pin diode is preferably used as a photo receptor as it provides a linear response while being relatively temperature-insensitive, extremely fast and accepts a wide range of power and spectral intensities.

A further advantage of this feedback arrangement is that the feedback loop integrity may be ensured by utilizing the microprocessor 815 to constantly measure or compare the desired output signal with the measured output signal. These signal lines are indicated as numerals 824 and 822 respectively. Should the signals be dissimilar, the software contained within the microprocessor would inform the main control unit via the RS232 line.

The total current through the diodes 210 is monitored by a current monitor indicated by block 828, which provides a signal on an analogue-to-digital input line of the microprocessor 815. The microprocessor utilized in this embodiment is a PIC 16C71 chip which includes 4 analogue-to-digital input lines. Thus, by monitoring the total current through the diodes 210, a failure of one or more diodes will be noted by a change in total current and once again the microprocessor will communicate this via the RS232 line to the main controller unit. Also, as devices age, more current will be required to maintain a desired intensity; thus a current monitor may inform the user when the useful lifetime of a head has been realized. Thus, the net effect of the feedback loop combined with the built-in diagnostics in the microprocessor 815 ensures a stable, absolute and reliable luminous output.

A photo diode 830 located within a pocket 802 is connected via a current-to-voltage converter to an analogue-to-digital input 832 of the microprocessor in order to provide a signal indicative of the ambient light. The microprocessor 815 receives this ambient light monitor signal 832, relays the information to the MCU over

In Figure 9, an electrical circuit diagram showing the major functional blocks for control of the point source treatment head is shown generally by block 900. As may be seen, the control circuitry for the diode 702 is similar to that of the control circuitry for the flexible head as shown in Figure 8. However, an optical feedback is provided by a PIN diode 904 which is incorporated with the module containing laser diode 702. The remaining components will not be discussed further as they are similar to that of the control circuitry described with reference to Figure 8 but for clarity are identified by like reference numerals with 9 and the m.s.d. rather than 8.

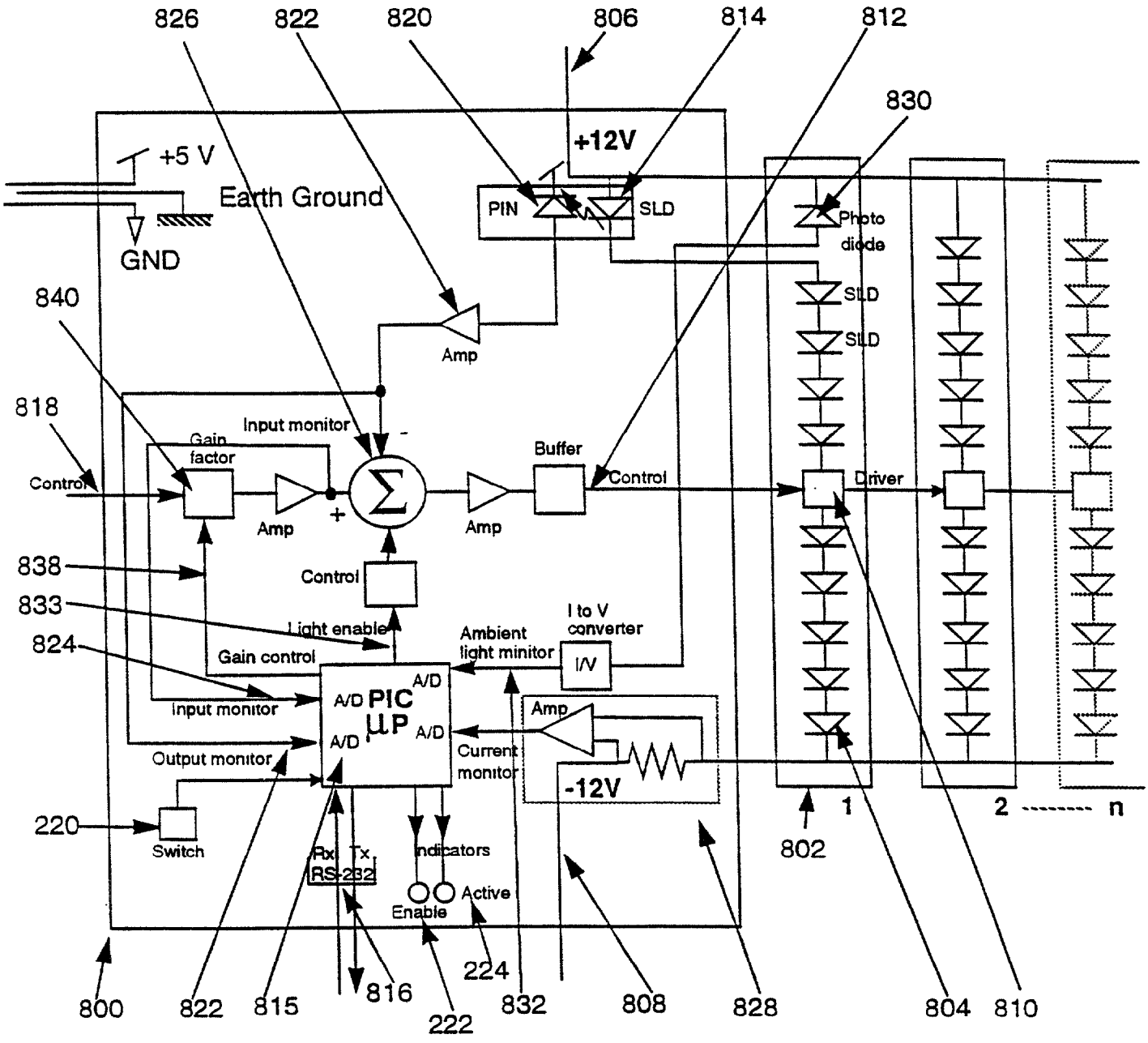

826
822
820
806
814
812
830
+5 V
Earth Ground
GND
+12V
PIN
SLD
Photo diode
SLD
SLD
840
Amp
818
Input monitor
Gain factor
Control
Amp
+
Amp
Buffer
Control
Driver
838
Control
833
Light enable
824
Gain control
Ambient light minitor
I to V converter
I/V
Input monitor
A/D
PIC µP
A/D
A/D
A/D
Amp
Output monitor
Current monitor
-12V
220
Switch
Rx Tx RS-232
Indicators
Active
Enable
802
1
2
n
800
822
815
816
222
224
832
808
828
804
810

Fig. 8

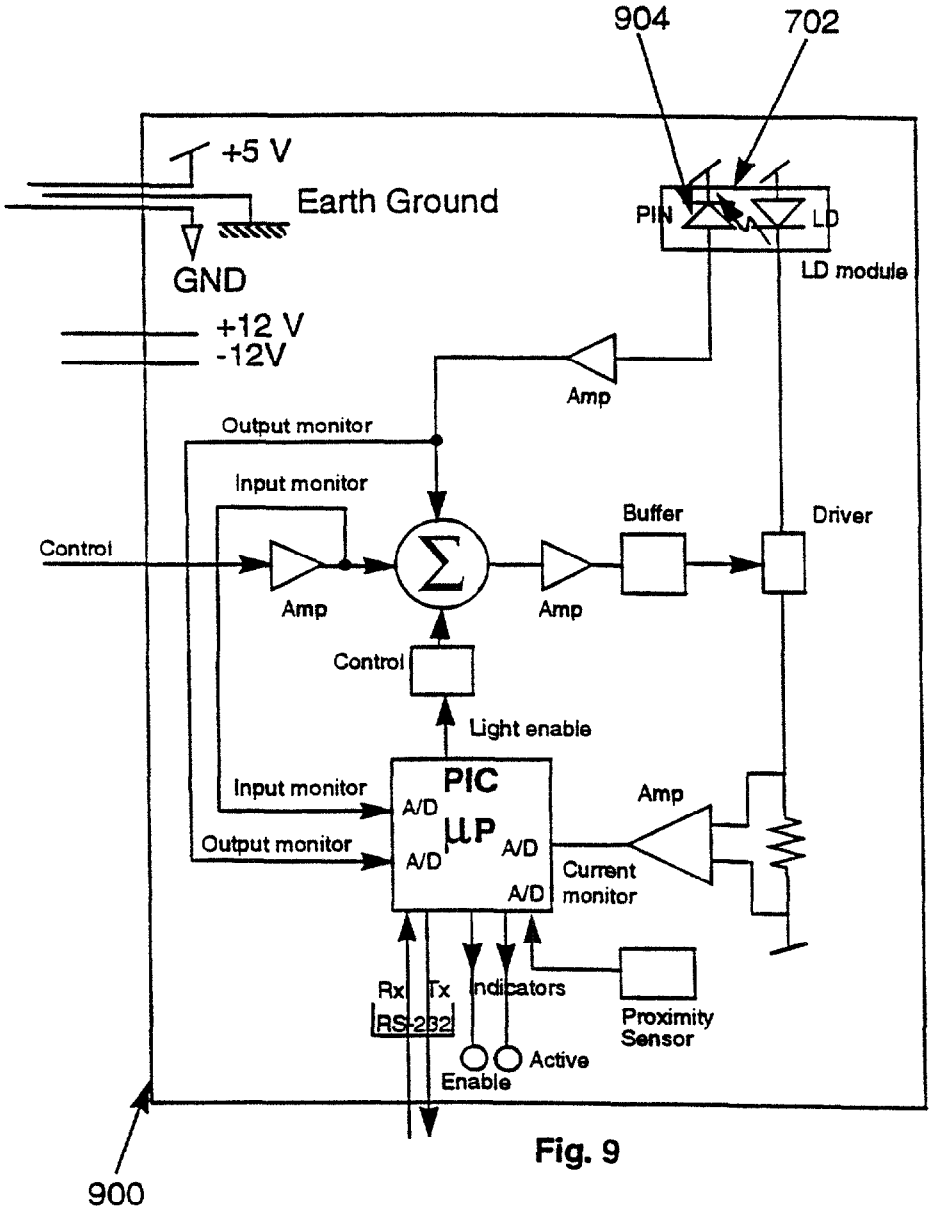

904
702
+5 V
Earth Ground
GND
+12 V
-12V
PIN
LD
LD module
Amp
Output monitor
Input monitor
Buffer
Driver
Control
Amp
Amp
Control
Light enable
PIC
Input monitor
A/D
μP
Amp
Output monitor
A/D
A/D
A/D
Current
monitor
Rx
Tx
Indicators
RS-232
Proximity
Sensor
Active
Enable
900

Fig. 9

Complies with 21 CFR 1040.10 and 1040.11

CLASS IIIB LASER PRODUCT GaAlAs 830nm + 20nm 75mW

Complies with 21 CFR 1040.10 and 1040.11

CLASS IIIB LASER PRODUCT AlGaInP 685nm + 10nm 25mW

MEDITECH INTERNATIONAL INC., TORONTO,ONTARIO, CANADA M5J 2L4

BIOFLEX LD - R 25

MODEL LD-R25 S/N _____ MANUFACTURED _____

MEDITECH INTERNATIONAL INC., TORONTO,ONTARIO, CANADA M5J 2L4

BIOFLEX LD - I 75

MODEL LD-I75 S/N _____ MANUFACTURED _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 1998

Ref: FDA Docket No. 98V-0816
98V-0817
Accession Number 9810192

Dr. Fred Kahn
President
Meditech International
65 Harbour Square, Suite 1908
Toronto, Ontario
Canada, M5J 2L4

Dear Dr. Kahn:

This is in response to your August 25, 1998, correspondence hand-delivered on August 31, 1998, concerning labeling revisions and variance applications for the BioFlex Professional Laser Therapy System for pain treatment. The product was found to be noncompliant with the Federal laser product performance standard in that it lacked a remote interlock connector, emission delay, calibration procedures and schedule, accurate labels, and quality control information. The August 25th 1998 correspondence addressed these items and thus has been controlled as a supplement to your report on file, Accession Number 9810192-01.

I am approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Meditech International, dated August 25, 1998, for a variance from the requirements of 21 CFR 1040.10(f)(3) and 1040.10(f)(5)(ii) of the Federal performance standard for laser products to incorporate a remote interlock connector and an emission delay. This variance will allow the introduction into commerce of the BioFlex Professional Laser Therapy System manufactured by Meditech International as identified in paragraph D below under the conditions stated in paragraph F.

A. Variance Number

98V0816/7

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated 5 years from the date of this letter.

D. Laser Product for Which Variance is Granted

This variance is granted for the BioFlex Professional Laser Therapy System.

E. Provisions From Which Variance is Granted

The variance is granted from provisions of 21 CFR 1040.10(f)(3) and 1040.10(f)(5)(ii) of the performance standard for laser products requiring that each Class IIIb laser product have a remote interlock connector and have a visible or audible emission indication sufficiently prior to emission to allow appropriate action to avoid exposure to laser radiation.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions Under Which Variance is Granted

In lieu of the requirements referred to in item E above, the following conditions shall apply to the BioFlex Professional Laser Therapy System manufactured under this variance:

1. The laser handpiece's proximity sensor shall prevent laser emission unless placed in direct contact with the desired target.

2. If the handpiece is moved away from the target the beam emission shall cease, not reemitting until placed in direct contact with a target by the operator.

G. Basis for Approval of Variance

CDRH has determined, in accordance with 21 CFR 1010.4(a)(1), that the laser product, the BioFlex Professional Laser Therapy System, incorporates alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard.

As an alternate for a remote interlock connector and an emission delay the product incorporates a proximity sensor that prevents emission until the handpiece is in direct contact with a target. Since the beam cannot emit unless the target is in contact and the Start

button is depressed, the proximity sensor is believed to constitute an equivalent degree of safety as a remote interlock connector and an emission delay.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

> "This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 98V0816/7 effective ."

This variance action is available for public disclosure in the Dockets Management Branch, FDA, and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,

for/ Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

MARK SLONCHKA
MEDITECH INTERNATIONAL INC.
Phone: 416-251-1055
411 HORNER AVE
UNIT: 1
ETOBICOKE
ON M8W4W3
CANADA

LTR 1 OF 1
SHP#: F887 09MN KY9
SHP WT: LTR
DATE: 17 SEP 2003

MD 207 9-04

SHIP TO:
DIRECTOR OF DOCKETS MANAGEMENT
DOCKETS MANAGEMENT BRANCH
301-827-6860
5630 FISHERS LANE
ROOM 1061 (HFA-305)
ROCKVILLE
MD 20852
UNITED STATES

UPS EXPRESS
TRACKING #: 1Z F88 709 66 6670 0442
1

BILLING: P/P
DESC: DOCUMENTS ONLY

Fold Here

CCX 5.0.1.0 WindowsPr 16.0A 01/2002

EDI-DOC