DIOMED **15**PLUS	DIOMED **30**PLUS

DIODE LASER

Operator Manual Addendum
(Automatic Laser Configuration)

Version 1.0 US   September 2003   MAN / 17 / 0065 US

[Not all products in this manual are available in all countries.]

Manufactured in the United Kingdom by DIOMED Limited

CONTENTS

1   INTRODUCTION

This document is an addendum to the "DIOMED 15*PLUS* & DIOMED 30*PLUS* Diode Laser Operator Manual" and must be read in conjunction with that manual.

The DIOMED Automatic Laser Configuration (ALC) system provides a means of identifying the fiber that is connected to a **DIOMED 15/30***PLUS*. A small identification device is located inside the grip at the SMA end of the fiber and this is read by the **DIOMED 15/30***PLUS* whenever it is switched on and a fiber connected to it. The identification device is read by means of a low power communication system called Radio Frequency Identification, or RFID. It holds the following information:

The type of fiber	This tells the system what type of fiber or accessory has been connected to it.[1]
The date when the sterility of the fiber expires	If the sterility expiration date is earlier than the current date in the internal clock of the **DIOMED 15/30***PLUS* then the fiber is invalid and cannot be used.
How many times the fiber may be safely used	The number of "uses" [2] is decreased each time the system is used with the connected fiber. When the figure reaches zero, the fiber becomes invalid and cannot be used again.

The ALC system therefore provides the following benefits:

- Single-use fibers cannot be re-used, minimizing the risk of patient infection or fiber failure
- Fibers that have passed their sterility expiration date cannot be used, minimizing the risk of patient infection.
- The number of available "uses", subject to satisfactory calibration, for Multiple-use and Spot Handpiece fibers is displayed on the screen, giving a clear indication of when a fiber is due for replacement.
- Operation of the **DIOMED 15/30***PLUS* is simplified, because the ALC system is able to automatically recognize devices independently of the user – for example, the type of Spot Handpiece.

In order to obtain full advantage of the DIOMED ALC system you should always use fibers supplied by DIOMED or fibersdirect.com. A list of the currently available fibers that are compatible with the ALC system is provided in section 7 below.

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[1] The system will read the fiber's data if the power is on and an ALC system fiber is connected or if the **DIOMED 15/30***PLUS* is powered up with an ALC system fiber already connected.

[2] The number of available "uses" is only decreased once per procedure and only after the **DIOMED 15/30***PLUS* has been fired. Subsequent firing of the **DIOMED 15/30***PLUS* during a continuous procedure will not result in the number of available "uses" being further decreased.

2   TECHNICAL SPECIFICATIONS

The following technical specifications are in addition to those listed in the "DIOMED 15*PLUS* & DIOMED 30*PLUS* Diode Laser Operator Manual".

ALC System Operating Frequency	125 kHz $\pm$ 5 kHz
ALC System Operating Range	Maximum of 40 mm from the laser output port
Standards	FCC 47 Part 15c Canadian RSS-210 EN 300 330-1, EN 300 330-2, EN 301 489-1, EN 301 489-3

This product complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.
Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at their expense.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.
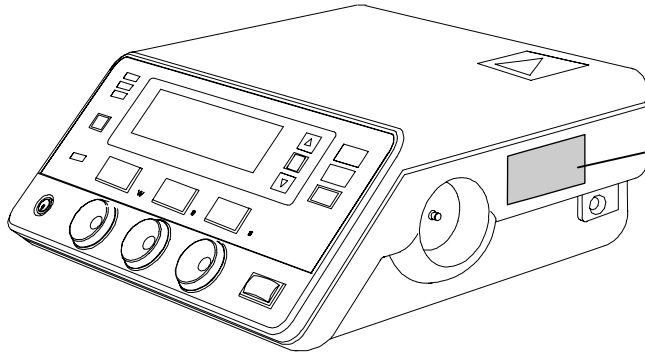
DIOMED follows a policy of continual improvement and reserves the right to alter the design or specification without notice.

The specification may vary for different countries.

2.1   Labelling

The following labels are in addition to those listed in the "DIOMED 15*PLUS* & DIOMED 30*PLUS* Diode Laser Operator Manual".
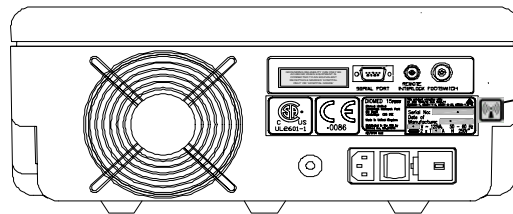
FCC Declaration Label

This device contains an intentional radiator part number **AS/597**

FCC ID: RBQAS597
This product complies with part 15 of the FCC Rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received,
including interference that may cause undesired operation.

Canada IC: 4690A-AS597
This device complies with Canadian RSS-210
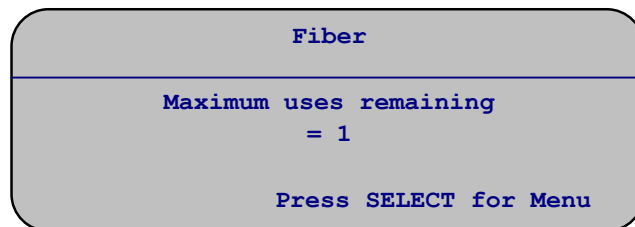
Intentional Radiator Label

3   USING THE ALC SYSTEM

When a fiber equipped with the ALC system is connected to a **DIOMED15/30***PLUS*, the system will detect the presence of the fiber and set up a communication link with it. This link is used to determine what type of fiber is connected, how many more times it may be used and whether it has passed its sterility expiration date.
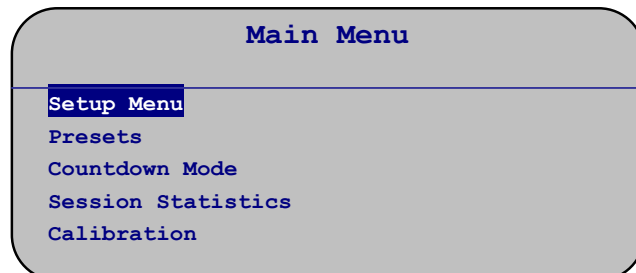
The ALC system works with Single-use, Multiple-Use and Spot Handpiece fibers. It automatically detects the fiber type and, after checking that it is valid, goes straight to the main menu.

3.1   Single-use Fiber

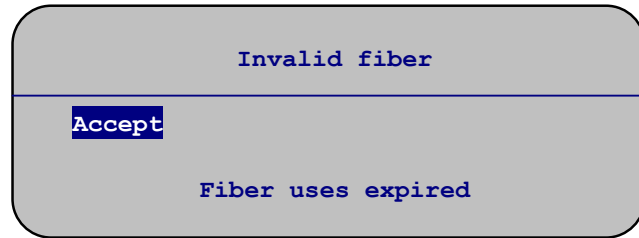A typical single-use ALC system fiber will cause the following screen to be displayed.

```
                    Fiber
        _____

             Maximum uses remaining
                     = 1

                   Press SELECT for Menu
```

Press **SELECT** and the main menu will be displayed as shown below.

```
                  Main Menu
        _____

        Setup Menu
        Presets
        Countdown Mode
        Session Statistics
        Calibration
```
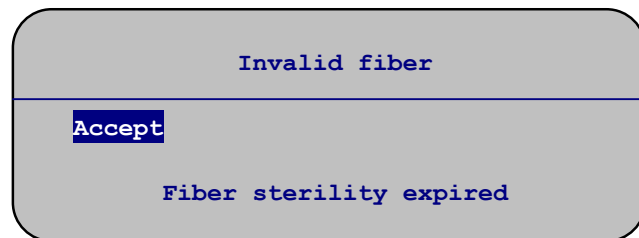
You may now continue to operate the **DIOMED15/30***PLUS* as described in the main Operator Manual.

If a previously used single-use fiber is connected to the **DIOMED 15/30***PLUS***, then the following screen will be displayed.

```
                       Invalid fiber
 ───────────────────────────────────────────────────
  Accept

                    Fiber uses expired
```

Similarly, if the sterility expiry date of the attached fiber has been passed, then the following screen will be displayed.

```
                       Invalid fiber
 ───────────────────────────────────────────────────
   Accept

                  Fiber sterility expired
```
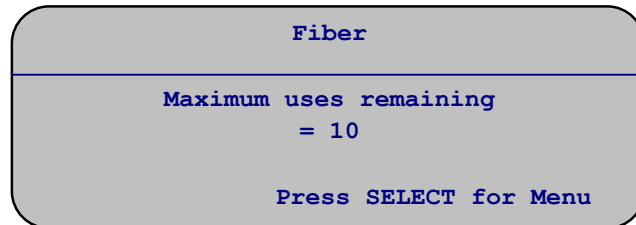
If an invalid fiber is detected by the ALC system then further operation of the **DIOMED15/30***PLUS*** will not be allowed.
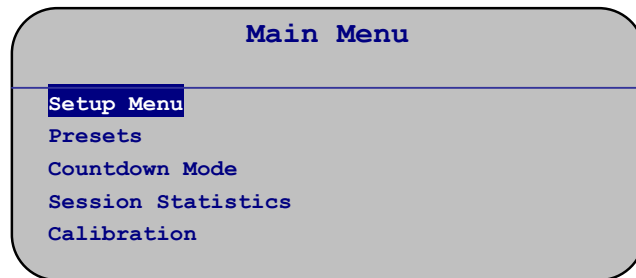
3.2 <u>**Multiple-use Fiber**</u>

When a multiple-use ALC system fiber is connected to a **DIOMED15/30***PLUS*, the ALC system will check that the fiber has valid uses remaining and that it has not passed its sterility expiration date.

A typical multiple-use ALC system fiber with 10 uses remaining will cause the following screen to be displayed.

```
              Fiber
  ─────────────────────────────
       Maximum uses remaining
              = 10

          Press SELECT for Menu
```

Press **SELECT** and the main menu will be displayed as shown below.

```
            Main Menu
  ─────────────────────────────
    Setup Menu
    Presets
    Countdown Mode
    Session Statistics
    Calibration
```
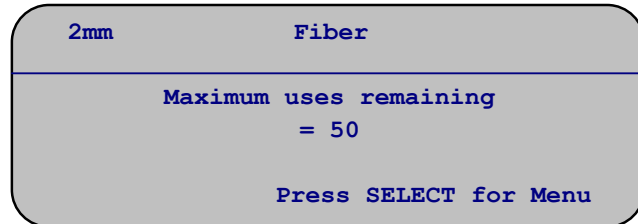
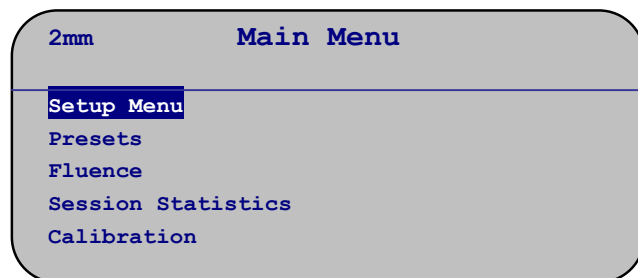You may now continue to operate the **DIOMED15/30***PLUS* as described in the main Operator Manual.

If the fiber is found to have no valid uses remaining or if it has passed its sterility expiration date then the appropriate Invalid Fiber message will be displayed, as shown in section 3.1 above

3.3   Spot Handpiece

When a spot handpiece, equipped with an ALC system fiber, is connected to a **DIOMED15/30***PLUS*, the ALC system will check that the fiber has valid uses remaining.

```
2mm              Fiber

        Maximum uses remaining
               = 50

           Press SELECT for Menu
```
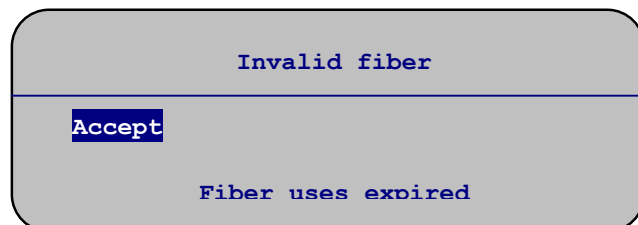
Press **SELECT** and the main menu will be displayed as shown below. The spot size of the handpiece is automatically detected by the ALC system and configures the laser accordingly. The spot size is displayed in the top left corner of the display.

```
2mm           Main Menu

Setup Menu
Presets
Fluence
Session Statistics
Calibration
```

You may now continue to operate the **DIOMED15/30***PLUS* as described in the main Operator Manual.

If the fiber is found to have no valid uses remaining then the following screen will be displayed.

```
              Invalid fiber

Accept

          Fiber uses expired
```
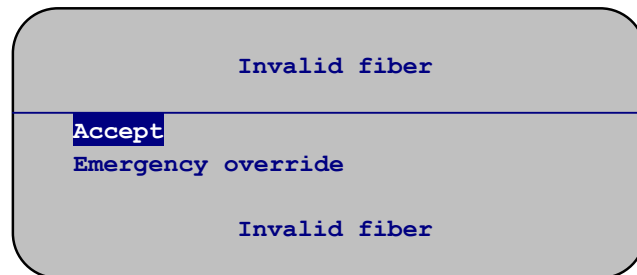
4   EMERGENCY OVERRIDE

An Emergency Override option is included to allow the **DIOMED 15/30***PLUS* to be used **once only**, in the following circumstances:

- The attached fiber is not equipped with the ALC system

- The ALC system fiber is faulty and cannot be identified by the laser

- A session fault has occurred, preventing the completion of treatment – see section 4.1 below for a more detailed explanation of this.

Once the Emergency Override option has been activated, the **DIOMED 15/30***PLUS* cannot be used in any of the situations listed above until the option is reset with a special reset device[3]. See section 4.2 below for details of the reset operation.
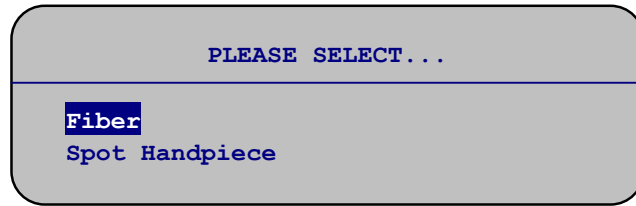
The Emergency Override option cannot be used if the fiber's sterility expiry date has been passed or if the fiber is invalid because the number of "uses" have all been consumed.

When one of the three conditions above is true, the Emergency Override option will be displayed as shown on the following screen.

```
                    Invalid fiber

    Accept
    Emergency override

                    Invalid fiber
```
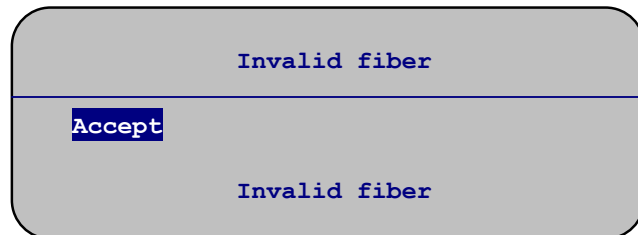
Use the ▲ or ▼ keys to select 'Emergency Override' and press **SELECT**. The **DIOMED 15/30***PLUS* will now show the fiber selection screen and allow you to proceed with treatment.

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[3] The unit will continue to operate correctly with ALC system fibers, even if the Emergency Override option has been activated.

```
                PLEASE SELECT...
    ──────────────────────────────────────
    Fiber
    Spot Handpiece
```

The next time that an invalid fiber is attached to the **DIOMED 15/30***PLUS* the Emergency Override will not be available and the following screen will be displayed.

```
                      Invalid fiber
    ──────────────────────────────────────
    Accept

                      Invalid fiber
```

The Emergency Override can only be used again if it is reset by means of a special reset device. See section 4.2 below for full details.

4.1   Session Fault Override

In extreme circumstances, such as a power cut or a technical problem, the **DIOMED 15/30***PLUS* needs to be re-started and will log a Session Fault. If this occurs during a treatment then the fiber in use may become invalid.[4]

In these circumstances, the Emergency Override may be activated to allow treatment to continue. This option is only available immediately after the Session Fault has been cleared and will not work if an attempt is made to use an expired fiber at any other time.

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[4] **WARNING** - to avoid accidental invalidation of a single-use ALC fiber:

a.   Do not disconnect the fiber from the laser during a procedure unless directed to by the Operator Manual or the unit's display.

b.   Do not switch off the unit by the key switch or mains switch part way through a procedure.
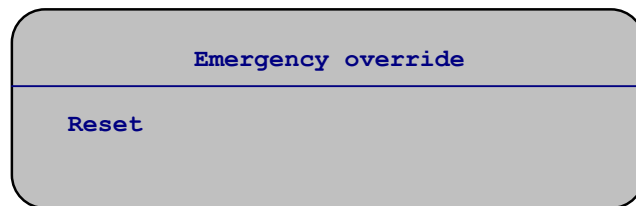
4.2   Resetting the Emergency Override

The Emergency Override can be reset by means of a special reset device. One of these devices (part number AS/598) is supplied with the **DIOMED 15/30***PLUS.*.

Each device can only be used once, after which is it advisable to contact your local DIOMED representative as soon as possible, to obtain a replacement.
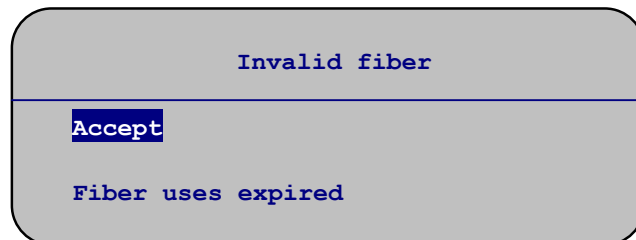
To reset the Emergency Override:

- Switch on the laser

- Attach the device by screwing it on to the laser output port, in the same way as you would attach a fiber

- The unit will detect the device and reset the Emergency Override. The following screen will be displayed.

```
          Emergency override

    Reset

```

Press **SELECT** and the **DIOMED 15/30***PLUS* will reset the Emergency Override option and display a notification on the screen.

If a used Emergency Override reset device is attached to the **DIOMED 15/30***PLUS* then the following screen will be displayed.

```
          Invalid fiber

 Accept

    Fiber uses expired

```

Do not attempt to fire the laser when the Emergency Override reset device is attached.

WARNING

5   ERROR MESSAGES

The following error messages are additional to those listed in the **DIOMED 15/30*PLUS*** Operator Manual. All error messages will be displayed on the lower part of the display screen. To clear the error message, carry out the displayed instructions.

Fiber uses expired

All the available uses of the connected fiber have expired. Replace the fiber with either a new single-use fiber or a multiple-use fiber that has uses remaining.

Fiber sterility expired

DIOMED fibers are programmed at manufacture with a sterility expiry date. This message is displayed when the expiry date is before the date in the laser's internal clock. Replace the fiber with one having a valid sterility expiry date.

If the error message is still present, check that the clock of the **DIOMED 15/30*PLUS*** is set correctly.

Invalid Fiber

The fiber attached to the **DIOMED 15/30*PLUS*** is not equipped with the ALC system. Either replace with an appropriate fiber or use the Emergency Override option.

6   TROUBLE-SHOOTING

The DIOMED ALC system has been extensively tested. In the unlikely event of a problem being experienced please perform the following checks before contacting your local DIOMED representative for further advice.

"Invalid Fiber" is displayed even with a new unused ALC system fiber

(1) Disconnect and then reconnect the fiber to the **DIOMED 15/30*PLUS***. This will cause the unit to try and read the tag again.

(2) Ensure that the **DIOMED 15/30*PLUS*** is at least 2 meters away from any other electrical or electronic equipment that might interfere with the ALC system, such as computers or other electronic or medical equipment.

I need to use a non-ALC system fiber

Select the Emergency Override option to allow single use of a non-ALC system fiber

The Emergency Override option is not available

After it has been used once, the Emergency Override option must be reset before it can be used again, as described in section 4.2 above. Contact your local DIOMED representative to obtain a spare reset device.

The fiber is still within its sterility date but the laser shows it as expired

Check that the date of the internal clock in the **DIOMED 15/30*PLUS*** is set correctly.

The procedure for setting the clock is described in the main Operator Manual.

The DIOMED 15/30*PLUS* does not recognize ALC system fibers

Please make sure that you are using a **DIOMED 15/30*PLUS*** that is equipped with the ALC system. Consult your local DIOMED representative if you require further advice.

7   ORDERING INFORMATION

The following order codes should be quoted when ordering replacement procedure kits and fibers for your **DIOMED 15/30*PLUS***.

Description	DIOMED or fibersdirect.com part number
EVLT Procedure Kit	EVLT/PK-20
2mm Spot Handpiece fiber	AS/0601
4mm Spot Handpiece fiber	AS/0602

This list was correct at the time of publication but new procedure kits, fibers and accessories may be added at any time. Please check with your local DIOMED representative for the latest information.