VariLase®

1470nm Laser Console

User's Manual

Vascular SOLUTIONS

VariLase®
Endovenous Laser Console

1470nm Laser User's Manual

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Caution

1. Read the operating instructions thoroughly before connecting the laser unit to mains power and prior to use. The laser unit must be set, regulated and used in accordance with these instructions. Failure to observe usual safety precautions may present a risk of hazardous exposure to laser radiation.
2. The Vari-Lase laser console is a Class 4 laser, which emits invisible laser radiation.
3. Avoid exposure to direct or scattered radiation.
4. Suitable protective eyewear must be worn by patient, operator and all persons in contact with the laser. Protective eye wear must meet IEC 60825 and EN 207 standards.
5. The fiber systems for the Vari-Lase laser console must be used only with a suitable hand piece or as a delivery system in connection with endovenous treatments.
6. When the laser unit is not in use, ensure it is rendered inaccessible to unauthorized personnel, by removing the key to disable the laser unit.

Warning labels on laser unit

Restrictions on use of Class 4 laser equipment

The Vari-Lase laser system is intended solely for physicians trained in the use of these instruments. The safety precautions for Class 4 laser equipment must be followed. The physician is responsible for evaluating each patient's suitability to undergo laser surgery and furthermore to inform the patient about any risks involved, the actual treatment, pre- and postoperative care and any other relevant information.

All use of the equipment is based on the doctors' knowledge and experience. The doctor is responsible for correct diagnosis and for all treatment results.

MedArt undertakes no liability whatsoever for any damage or injury as a result of an application of a product which is not in strict accordance with intended use and the instructions provided with the product. This waiver also includes liability for any damage and injury arising as a result of the product user's lack of qualification to evaluate the treatment applied in the actual individual circumstances, or as a result of errors or mistakes committed by such user who would otherwise be considered as having the necessary professional skills to apply such treatment.

Handling Precautions

Do not bend the fiber excessively. Minimum bending diameter 120mm. Avoid touching the fiber ends.

Introduction

We congratulate you on your purchase of the Vari-Lase laser system; among the most advanced and user-friendly diode lasers on the market. It constitutes a fruition of years of experience in the field of manufacture and development of high-end technology, medical laser equipment.

The Vari-Lase unit is fed by a diode laser module that can provide a continuous or pulsed wave laser beam. It boasts a highly intelligent and compact user friendly interface.

Rigorous control & testing techniques are employed to ensure the highest level of quality and reliability.

The laser system incorporates various fail-safe systems and conforms to international standards for medical electrical equipment, IEC 60601-1 and those specifically for laser equipment, IEC 60601-2-22 and IEC 60825.

The Vari-Lase laser unit conforms to the EU Medical Device Directive 93/42/EEC.

This product is marked with a unique serial number (SN) that identifies the product. The SN is placed on the rear panel of the MedArt® 715 laser unit. The product type number is located on the rear panel of the product.

The Vari-Lase laser console is marked with

CE 0459

MedArt A/S

Intended Use & Indications for Use

The Vari-Lase laser console is indicated for endovascular medical therapy of vascular conditions. It transmits through an optical fiber and the power density reaches 12kW/cm^2 [1] enabling the laser to coagulate, evaporate and carbonize tissue.

The Vari-Lase laser console operates with a wavelength of 1470nm. The 1470nm wavelength is absorbed in melanin, hemoglobin, dark tissue and in water. This enables a fast heat increase in the irradiated area, leading to effective heating of tissue at low output power.

Indications for the Vari-Lase laser console
The Vari-Lase laser console is indicated for the medical treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein.

Contraindications for the Vari-Lase laser console
The Vari-Lase laser console procedure is contraindicated in patients with an aneurismal section in the vein segment to be treated.

The Vari-Lase laser console procedure is contraindicated in patients with severe peripheral vascular disease, as evidenced by an ankle-brachial index of < 0.5.

The Vari-Lase laser console procedure is contraindicated in patients with thrombus in the vein segment to be treated.

The Vari-Lase laser console is contraindicated in patients with a history of deep vein thrombosis.

Warning

Caution should be used in advancing the sheath in case of extremely tortuous anatomy of the great saphenous vein to minimize damage to the vessel.

Warning

Improper endovenous laser treatment can pose a major risk to the patient's health. Endovenous laser treatment shall only be carried out by appropriately trained physicians.

Caution

Caution should be exercised with patients who have a history of peripheral vascular disease to ensure that this is accounted for during treatment.

Caution

Caution should be used when localizing the fiber tip during the procedure. The aiming light can be used as a guide, but an ultrasonic Doppler is required in order to ensure correct and precise fiber tip positioning.

[1] Max. Power density in a 600µm fiber

Endovenous Procedure Kit

Warning

The endovenous procedure kit is single use and must never be reused.

Endovenous procedure kits are supplied sterile and are only sterile when the seal is intact. If the seal is broken or the packaging is damaged the entire kit must not be used and must be disposed of.

Never autoclave, sterilize or use any other method to clean any part of the endovenous procedure kit.

If the endovenous procedure kit's due date is exceeded the entire kit must be disposed of.

Vascular Solutions carries no responsibility and cannot be held liable for any injury or transfer of diseases caused by reuse or misuse of any part of the single use endovenous procedure kit.

Installation and User Obligations

The Vari-Lase laser console is designed to operate within normal humidity and temperature conditions. (15-27°C/59-81°F).

The unit must be allowed to acclimatise before use, following exposure to extreme temperature or humidity.

Do not install the unit close to radiators or other sources of heat convection.

The Vari-Lase laser console may overheat due to excessive room temperature in combination with operation at high output power. In case of overheating the laser unit will automatically shut down for a short cooling period. Hereafter the laser unit will be ready for continued treatment.

We advise against the use of lasers at a distance of less than 2.5m from short-wave or microwave equipment, since unstable laser irradiation may occur.

No attempt should be made by unauthorized persons to open the Vari-Lase laser console with a view to repair. Failure to observe this caution may present a serious safety hazard and will void warranty.

MedArt cannot be held liable for any events resulting from negligence, abuse or incorrect operation of the unit. Please acquaint yourself thoroughly with the instructions for use, and in the event of any doubt contact your Vari-Lase dealer.

The Vari-Lase laser console is designed and tested for maximum safety for both the user and patient. It is however, ultimately the operator's responsibility to introduce safe practices, which ensure the safety of personnel and equipment.

WARNING

The Vari-Lase laser console contains no user serviceable parts and only appropriately trained MedArt personnel should attempt to inspect and/or repair the Vari-Lase laser console.

Do not open the Vari-Lase laser console. This is dangerous and will void the manufacturer's warranty.

Electrical safety

The system must be grounded.

Optical safety

Avoid exposure to laser radiation during installation and operation of the Vari-Lase laser console in excess of allowable limits in CFR Title 21 parts 1040.10 and 1040.11

WARNING

Injury to the eyes and the epidermis can result from either direct or scattered radiation. The power density of the light emitted from lasers can be high enough to cause severe burns to the skin when directly exposed to the beam. All personnel in the operating room must be protected from stray and scattered radiation by wearing the appropriate protective eye wear to guard against ocular injury. Never look directly into any laser beam.

WARNING

Use surgical instruments with a dull and dark anodised finish whenever possible. Shiny surfaces can reflect laser beams. Take extreme care if shiny surgical instruments are used.

Fire and explosion precautions

Avoid exposure to combustible materials as they can ignite when exposed to certain wavelengths of laser radiation.

WARNING

Do not operate the laser in the presence of explosive gases and liquids as well as highly concentrated oxygen.

The following precautions can minimise the risk of fire:

a. Surround the surgical field with wet gauze or towels
b. If possible, eliminate flammable materials from the surgical field

c. Have a fire extinguisher nearby

Always place the laser unit in **STANDBY** when not it in use to prevent accidental firing of the laser.

Precautions against transfer of diseases

The cleansing and sterilization instructions provided by this manual shall always be followed to avoid transfer of diseases through patient contact with operation components.

WARNING

Insufficient cleansing or sterilization of surgical components that come into contact with the patient may cause the transfer of diseases.

Precautions against toxic effects

When undertaking endovenous treatments, it is of utmost importance that all materials introduced into the veins of the patient, are fully bio-compatible.

WARNING

Material that is not properly certified bio-compatible, must never be used for endovenous laser treatment to prevent toxic effects

Precautions against embolic hazard

Warning

The Vari-Lase Procedure Kit is designed for single use only. Reuse of the fiber may result in hot spots causing combustion, fragmented fibers and embolization.

Precautions against hazardous radiation exposure

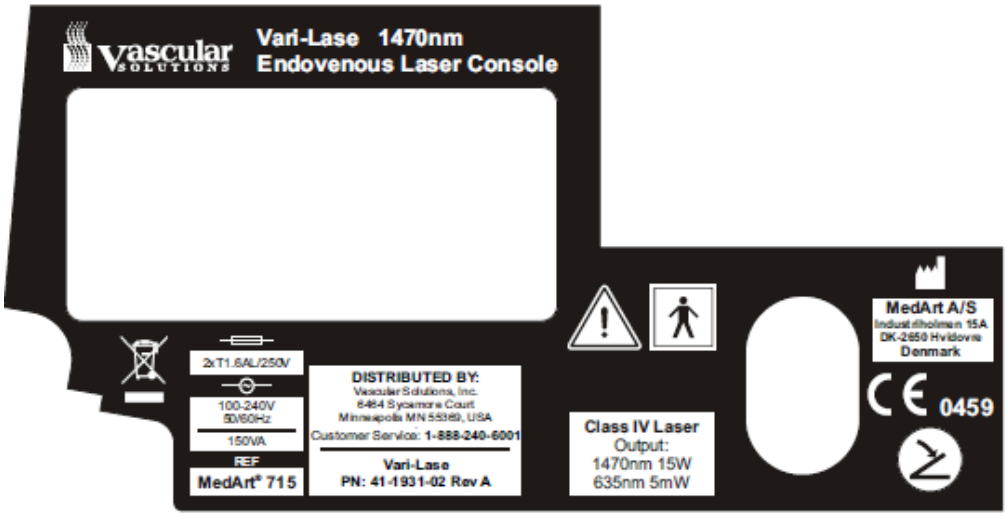
To ensure a safe and efficient treatment, the user must always follow the procedures in this manual.

Warning

Use of controls or adjustments to performance of procedures other than those specified herein may result in hazardous radiation exposure.

Labels and Symbols

Label on rear of laser system.



Specifies the name and address of the manufacturer of the equipment.

Specifies the main power supply rating

Specifies the fuse rating

Specifies type BF applied part (Body Floating)

European Directive 2002/96/EC requires that equipment bearing this symbol must not be disposed of with unsorted municipal waste. For further details, please see appropriate section in this manual.

Indicates the foot switch inlet

"DISTRIBUTED BY"

Specifies the name and address of the corporation, which distributes the equipment within Europe. Please notice; this corporation is not the same as the manufacturer.

Serial number label is situated at the rear panel of the laser.

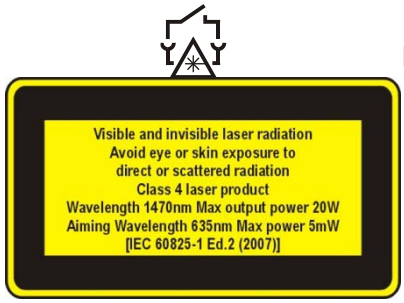
Interlock label under front panel of the laser system

A

Service connector A. **Service use only.**
Display programming.

B

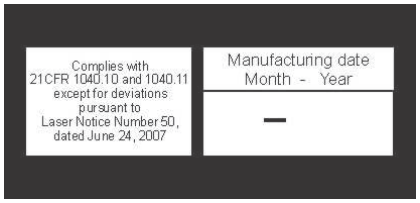
Service connector B. **Service use only.**
Main CPU programming.



Interlocking socket. See paragraph “Remote Interlocking” on page 18. *ComMonitor.*

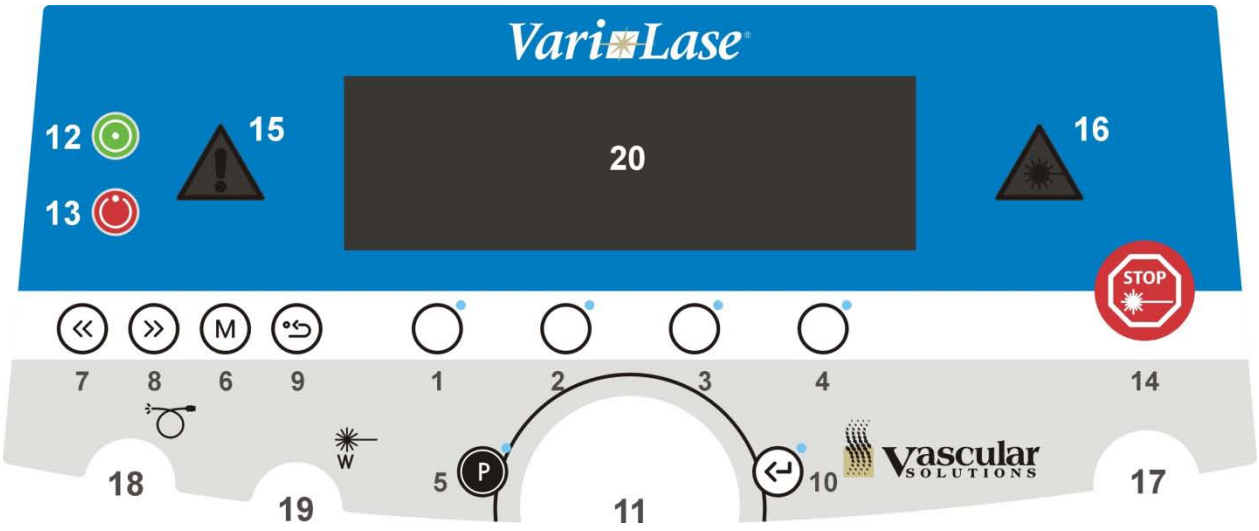
Explanatory label is affixed visibly on the left side of the system.

Laser Warning label is affixed visibly on the left side of the system.



Label showing date of manufacture on rear of system

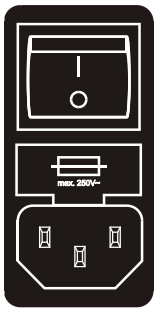
Description of Operating Console



Vari-Lase laser console

1-4	Selector	Parameter selection - accompanying LED lit when active
5	Program	Provides the possibility of choosing any pre-programmed set of treatment parameters - accompanying LED lit when active
6	Menu	Provides access to the various menus features by the Vari-Lase laser console
7	Left	Used for menu browsing and operation
8	Right	Used for menu browsing and operation
9	Back	Used for stepping upwards in the menu hierarchy and leaving the selected menu item without saving changed parameters
10	Enter	Confirms/saves the parameters currently displayed - accompanying LED lit when active
11	Jog wheel	
12	Ready	When activated the Vari-Lase laser console is set into **Ready Mode**. See paragraph “Operation” on page 14 for more details
13	Standby	When activated, the Vari-Lase laser console is set into **Standby Mode**. Parameters can be modified, but no laser output can be generated
14	Emergency Stop	See paragraph “Operation” on page 14

15	Laser ready indicator	Lit whenever the Vari-Lase laser console is emitting aiming light
16	Laser emission indicator	Flashing when laser emission occurs
17	Key switch	The laser unit is disabled when the key is in off-position or when the key is removed. Text “TURN KEY“ and a key symbol is displayed when the key is turned in off-position
18	Fiber connector	Laser pulses are delivered via a fiber assembly
19	Laser beam input port	Laser input port for verification purpose. See paragraph “Output Power Verification” on page 16
20	Display	Display used for displaying visual information to the user
21	Foot switch inlet	Air foot switch inlet and release button, situated on rear panel
22	Remote interlocking	Interlocking socket situated under the front panel. See paragraph “Remote Interlocking” on page 18
23	Service connector	Service connector A. Intended for service use only
24	Service connector	Service connector B. Intended for service use only
25	Mains power switch	
26	Fuse holder	
27	Mains power cable inlet	
28	Follow Instructions for Use	Instructions to follow the information in the Instructions for Use



See “Mains Power Connection and Replacement of Fuses” page 22.

Operation

Preparing for use

1. Carefully insert the fiber in the fiber connector located at the front of the laser unit (18)
2. Plug the foot switch tube into the socket at the rear of the laser unit (21)
3. Insert the mains power cord at the rear of the laser unit (27)
4. Switch on the mains power switch at the rear of the laser unit (25)
5. Connect interlock or insert dummy plug in the connector (22), cf. “Remote Interlocking”
6. Enable the laser unit by inserting and turning the key in the switch (17). The aiming light will be activated and the indicator (15) will be lit.
7. While the Vari-Lase laser console is powering up, laser emissions, all keys and selectors are disabled. Vari-Lase laser console is by default set into **STANDBY** mode
8. Set the treatment parameters
9. Set the Vari-Lase laser console into **READY** mode by pressing the Ready key (12). After a 3 seconds safety-delay the unit will be ready and the text in display will show READY
10. Start treatment by pressing the foot switch to emit laser radiation. When laser radiation is emitted the laser emission indicator (16) will be lit.

Setting treatment parameters

Power, pulse width, and pulse repetition rate can be set to prepare for the required treatment.

Treatment parameter is selected by pressing the associated selector; 1, 2, 3, or 4. Modify the selected parameter by turning the jog wheel.

When all parameters are correct, press Enter (10) to save. Alternatively, press the Ready key to save and bring the unit directly into **READY** mode.

Pressing the Back key (9) terminates the selection without changing the parameter.

Output power
Power can be set in the range 0-15W in 1W increments. The output power level is shown in the display.

Pulse width
Pulse width can be set in the range 10-3000msec. The pulse width is shown in the display.

Pulse repetition frequency
Frequency can be set in the range 0.3-100Hs. Further, output can be set to single pulse and continuous wave (CW). The frequency is shown in the display.

Standby Mode and Ready Mode

Ready 

When the Ready key is pressed, the unit enters **READY** mode and laser radiation will be emitted when the foot switch is pressed. When pulse length is shorter than 50msec, a steady audible tone will be generated twice per second. When pulse length is longer than 50msec, an audible tone will be generated when laser is emitted. Pressing the M, Back, or P key or any selector key will return the system to **STANDBY** mode.

If the system is idle in **READY** mode for 250 seconds, it will automatically return to **STANDBY** mode for operator and patient safety.

Standby 

When the Standby key is pressed, the unit enters **STANDBY** mode and laser radiation cannot be emitted. For safety reasons the laser should always be in **STANDBY** when not in use.

Start and stop of laser radiation

When the laser is active, the yellow Laser emission indicator flashes and an audible tone will be heard.

Caution

When the Laser ready indicator is on, the Vari-Lase laser console emits laser radiation.

READY

When the display shows READY, the Vari-Lase laser console emits laser radiation immediately upon activation of the foot switch.

Foot switch operation

When the foot switch is pressed, the Vari-Lase laser console emits radiation. Releasing the foot switch stops emission.

Emergency STOP key

When the emergency stop key (14) is pressed, the Vari-Lase laser console stops emitting laser radiation and will not function. The mains power switch (25) must be switched OFF for approximately 15 seconds and ON again to restart.

Shut down procedure

The Vari-Lase laser console is shut down by pressing the mains power switch (25) on the rear of the unit and will enter a controlled shut down procedure. The shutdown procedure can be initiated in any mode of operation.

Output Power Verification

The Vari-Lase laser console provides advanced built-in facilities for output power verification purpose.

1. Press the M key (6) to enter the Function Menu
2. Press the Right key (8) to enter the second Function Menu
3. Press “Measure Power” selector (2)
4. Align the output tip of the fiber with the sensor opening (19) and keep it aligned during the entire measuring process
5. Activate the foot switch – and keep the foot switch pressed during the entire measuring process. Any measurement interrupted by the release of the foot switch will be ignored
6. The Vari-Lase laser console automatically tests the laser output by measuring the power level of a number of pulses – wait for this to complete
7. The measured optical output is displayed in watts

Repeated measurements may cause the built-in power meter to heat up. If so, a message will appear urging the user to wait 5 minutes before further measurements are taken.

Caution

All personnel in the operating room must wear protective eye wear during the measurement.

Definition and Retrieval of Treatment Parameter Sets

The Vari-Lase laser console features predefined sets of treatment parameters. These parameter sets can be retrieved for faster unit setup.

Treatment parameter features:

- Storage for 16 parameter sets (programs)
- Stored parameter sets can be quickly retrieved by pressing the button twice
- Each parameter set can have a 16 character definition
- After power off, parameter sets are saved

Power up defaults
When powering up the Vari-Lase laser console the parameters in program 16 are always retrieved. The parameters in program 16 can be changed and stored by the user if different values are preferred.
Note: If you change the preset “DEFAULT” program parameters, the new default settings will be active on next power up

Factory defaults are:

1W, CW (Continuous Wave)
Aiming light level 100%
Aiming light ON in **STANDBY** mode
Laser Energy Emission Every 70J
Laser Energy Emission Mark ON
Laser Energy Beep inc. 30%

Program function modes
The program function has 4 modes that can be selected by pressing the Program key (5).

First press:
Shows simple parameter screen with parameter set names only.
Press one of the 4 Selector keys (1-4) to recall the intended program or press the Left or Right keys (7, 8) to scroll between blocks of 4 parameters.

Second press:
Show detailed information about each program.
Again the Selector keys (1-4) recall a program and the Left or Right keys (7, 8) scroll.

Third press:
Press a Selector key (1-4) to save the current set of parameters.

Fourth press:
Press a Selector key (1-4) to rename the parameter set. Only the name of the parameter set will be changed, the setting will remain unchanged.

Retrieving a preset parameter
1. Make sure the laser unit is in **STANDBY** mode
2. Press the Program key (5) and program names are displayed.
3. Pressing the Program key (5) again the program parameters are displayed and added.
4. Press the Left, Right keys (7, 8) to access the remaining program locations
5. Press the Selector key (1-4) corresponding to the parameter set to be used
6. The previously saved parameter set is recalled and the laser unit is ready to be set into **READY** mode

Changing the name of a program

1. Make sure the laser unit is in **STANDBY** mode
2. Press the Program key (5) 4 times
3. Press the Selector key (1-4) corresponding to the program whose name you wish to change. Use the Left, Right keys (7, 8) to access other program locations
4. Use the Left, Right keys (7, 8) and jog wheel (11) to change the name
5. Press Enter (10) to return to **STANDBY** mode

Note: The name of program 16 is overwritten by system defaults at the next system power up.

Remote Interlocking

The Vari-Lase laser console provides an interlocking feature that can be employed for deactivation of laser emission when doors are opened to the treatment area.

If remote interlocking is not required: The unit is supplied with a special interlocking dummy plug that has to be inserted in the interlocking socket (22).

If remote interlocking is required

If the interlocking feature is required to ensure a safe entry to the treatment area, an appropriate switch may be mounted on the doorframe in a way that ensures contact closure when the door is closed. Multiple doors can be wired in series if needed.

A special cable giving access to the interlocking socket (22) can be supplied at request by Vascular Solutions.

Bare Fiber Connection

Warning

Follow the recommendations below or this could result in damage to the fiber and/or delivery system and consequently harm to the patient or user

Connecting bare fibers

To facilitate endovenous laser treatment, a bare fiber equipped with a standard SMA-905 connector (as specified by International Electro technical Commission IEC document 86B/1903/CDV, connector plug F-SMA I) may be connected to the Vari-Lase laser console using a SMA-to-QSC adapter. Remove the protection cap from the fiber SMA-905 connector. While the QSC adapter is installed in the laser, insert the SMA-905 into the QSC adapter and carefully tighten the nut.

Caution

Keep the fiber cap on when the fiber system is not connected.

Do not touch the fiber connector tip, as this will reduce the lifetime of the fiber.

Connection and Release of Foot Switch

A connector (21) for the foot switch is provided on the rear panel.
For connection simply plug-in the foot switch connector.
Release the foot switch by pressing the adjacent button.

System Setup and Status Display Controls

A number of system features can be setup by the user by following the steps below:

1. Make sure the unit is in **STANDBY** mode
2. Press the M key (6) to enter ***FUNCTION MENU 1***
3. Press Selector key (1) to enter the menu ***USER SETUP 1*** *where four setup options are displayed*
4. Press the Right key (8) or the Menu key (6) to display a further three setup options in ***USER SETUP 2***.

All seven setup options are listed below:

Sound Level
Turn the jog wheel (11) to change the volume of the internal speaker. Press the Enter key (10) to select, when the desired volume is found. For safety reasons the level cannot be set to values lower than 30%.

Display Contrast
Turn the jog wheel (11) to change the display contrast. Press Enter key (10) to select, when the desired display brightness level is reached.

Aiming Beam
Turn the jog wheel (11) to adjust the brightness of the aiming beam. Press the Enter key (10) to select, when the desired brightness is found. The selected aiming beam level will be visible on the fiber output during adjustment.

Energy Mark
Turn the jog wheel (11) to change the energy mark level. Press Enter key (10) to select, when the desired display brightness level is reached.

Status Display 1/Status Display 2
The user can select two status display options for use during operation from the following:

1. None: No status is displayed
2. Pulses: Displays number of pulses generated
3. Active Time: Display time the laser has been active
4. Joules: Displays the joules generated

Use the jog wheel (11) to browse the four options.
Press the Enter key (10) to select, when the desired display is found.
The reading will be displayed when the unit is in either **STANDBY** or **READY** mode.

Choose Language
Turn the jog wheel (11) to browse the languages and select by pressing the Enter key (10) to select, when the desired language is found.

Reset Counters
The user may want to reset the readings; e.g. before a patient treatment is initiated. To do this, please follow the steps below:

1. Make sure the unit is in **STANDBY** mode
2. Press the Menu key (6) to enter ***FUNCTION MENU 1***
3. Press Selector key (2) to reset the status display readings

Service/Adjustment Functions

The Vari-Lase laser console provides the user with various features for setting and reading equipment parameters. These adjustable parameters are organized into six service groups that can be accessed when the unit is in **SERVICE** mode.

Follow the steps below to enter Service mode:

1. Make sure the unit is in **STANDBY** mode
2. Press the Menu key (6) to enter ***FUNCTION MENU 1***
3. Press the Right key (8) to enter ***FUNCTION MENU 2***
4. Press Selector key (1) to enter **SERVICE** mode

The following five groups of service settings are accessible to the user:

USER SETTINGS
Standard user controls like display contrast, sound level, etc.

ACCESS CODES
Access codes can be entered for user service or maintenance purposes only. For safety reasons full service access is only granted to MedArt authorized personnel.

UNIT IDs
Reports various IDs associated with each Vari-Lase laser console.

TIME LOG
This group contains time logging and timing functions.

LASER SETUP/ADJ
Setup of aiming beam and laser energy mark functionality behavior.

SERVICE mode controls

All available User Settings are in English regardless of the language selected.

- Use the jog wheel (11) to browse the service settings
- Use the Left, Right keys (7, 8) to change from one group of service settings to another
- Use selector key (4) 'Change' to modify a parameter. Note: the change feature only exists for a subset of the parameters

There are two types of parameter input modes:

- *Limited range parameters*. Operate the jog wheel (11) to change the parameters. Press the Selector key (4) to save the set value.
- *Large number selection*. Operate the jog wheel (11) to change the value of the current digit. Press the Right, Left keys (7, 8) to select another digit. Press the Selector key (4) to save the set value

Available service settings are described in more detail by the following table.

USER SETTINGS	
100	**Sound Level** This setting changes the volume of the internal speaker. The volume changes instantly; but will not be saved until 'Save' is pressed
101	**Display Brightness** This setting changes the brightness the display. The brightness changes instantly; but will not be saved until 'Save' is pressed
102	**Language** This setting changes the language used for displayed text. The selected language is not saved until 'Save' is pressed
103	**Status Display 1** This setting features the selection of status reading 1 (as described on page 19) to be displayed
104	**Status Display 2** This setting features the selection of status reading 2 (as described on page 19) to be displayed
ACCESS CODES	
200	**Access Code** To be used by authorized service personnel only
UNIT IDs	
300	**Serial Number** The laser unit serial number is displayed
301	**Type Number** The laser unit type number is displayed
304	**SW Version** The laser unit software version is displayed
TIME LOG	
500	**Power On Time** Reports the total power-on time of the laser in minutes
501	**Laser Active Total Time** Reports the total Laser Active time at any power level in minutes
509	**Total Joules** Reports the total number of joules emitted from the laser
LASER SETUP/ADJUST	
709	**Aiming Beam Level** Brightness of the aiming beam. The aiming beam output changes instantly; but will not be saved until 'Save' is pressed
711	**Aiming Beam in STANDBY mode** Defines whether or not the aiming beam is on in **STANDBY** mode. The aiming beam output changes instantly; but will not be saved until 'Save' is pressed
712	**Laser Energy Mark Interval** Defines the amount of energy that must be emitted between each laser emission mark.
713	**Laser Energy Mark Beep inc.** Defines whether or not the laser emission mark is played with an increased sound level compared to the standard laser warning beep. The increased level can never exceed the 100% system maximum.
714	**Laser Emission Mark** Defines whether or not the audible laser emission mark enabled or not If enabled a laser emission mark is heard every time a certain amount of laser energy has been emitted corresponding to the value set in 712.

Cleaning and Maintenance

Maintenance
The Vari-Lase laser console requires periodic calibration of the power meter. No other user maintenance is required.

Do not expose the laser unit and accessories to moisture, or extremes of temperature/humidity. Do not attempt to sterilize any part of the equipment.

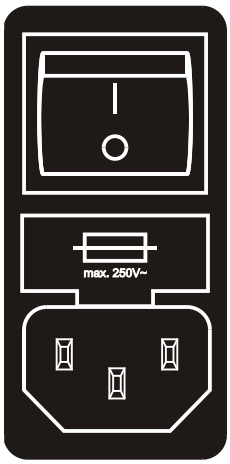
For a routine maintenance schedule, please refer to appendix A.

Power Meter Calibration
Every 24 months the power meter must be calibrated by authorized personnel. Contact your Vari-Lase dealer for information.

Cleaning
Clean the laser unit using a cloth moistened in a mixture of 30% alcohol and 70% water. Pure undiluted alcohol or detergents must not be used.

During cleaning, the laser unit must be switched off and disconnected from the main power supply.

Mains Power Connection and Replacement of Fuses



The laser unit is connected to mains power via the mains power cable inlet (27) on the back panel of the laser unit. The mains power switch (25) is used to switch the laser unit ON or OFF.

The unit is equipped with 2 glass fuses (T1.6AL), which protect the laser unit in case of electrical fault. If the unit cannot be switched ON, try to replace the fuses, before the unit is handed in for repair.

To replace the fuses:

1. Remove the mains power cord
2. Pull out the fuse box (26)
3. Replace the fuses and re-insert the fuses fuse box
4. Close the fuse box

Use only 5x20mm T1.6AL fuses

NOTE: The Vari-Lase laser console must always be grounded.

Troubleshooting

Symptom	Possible Cause	Recommendation
No light in display when switched on	• Defective mains power fuses • Low mains power supply	• Change fuses • Wait min. 5sec for power up
Low output power	• Defective fiber • Defective QSC • Low pulse width combined with low frequency	• Change fiber • Change QSC • Choose higher pulse width
Fluence, pulse duration, or frequency cannot be set as high as it could be previously	Fluence is a physical property closely connected to output power and pulse width. Due to the dependency between the parameters, maximum value of fluence, pulse width and frequency depends on the setting of the other parameters.	• Decrease the value of one or more of the other treatment parameters.
A temperature fault message is displayed and the Vari-Lase laser console stops radiating	• Overheated diode due to combination of high room temperature, high power setting and high duty cycle • Internal laser cooling system ineffective	• Wait a few seconds for the system to cool down. If the problem remains, try to reduce room temperature. Reduce output power. Reduce duty cycle (shorter dwell time, longer breaks). • If this fails, return to MedArt for repair
Aiming beam has faded or diffused	• As the aiming beam passes through the same optical system as the working beam, it provides a good method of checking the unit. If the aiming beam spot is not present at the distal end of the fiber, its intensity is reduced or it looks diffused, the fiber might be damaged.	• Check the unit by undertaking output power verification as described in the paragraph “Output Power Verification” on page 17.

Warnings and Stop Codes

The table below provides a complete overview over the various warnings and stop messages that can be displayed by the Vari-Lase laser console.

If one of the messages appears repeatedly, note the message and call your Vari-Lase laser console dealer.

Error code	Error message	Cause	Recovery
0	**EMERGENCY STOP**	Emergency button has been pressed	Laser shuts down. Cycle mains power switch to recover
1	**I/O SYSTEM STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
3	**OVER CURRENT STOP**	This is an internal laser system situation	All laser circuits are shut down. Cycle key switch to recover/retry. Note: Do not repeatedly provoke an over-current stop; the laser diodes could be damaged. Reduce power and retry
4	**POWER HIGH STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
5	**POWER LOW STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
6	**VDIODE STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
7	**POWER DOWN**	Power supply output voltage low	Saves data internally and shuts down system. Check mains power
8	**DIODE TEMPERATURE STOP**	Laser diode temperature is too high	The laser is shut down. Normal operation will resume when temperature is reduced
12	**CONNECT FIBER**	All laser controls are disabled until a fiber is inserted	Resumes normal operation when the fiber is inserted
13	**CONNECT INTERLOCK**	All laser controls are disabled until an interlock connector/switch is installed. Pin 1 (GND) and 2 (Interlock input) must be shorted on the interlock connector	Resumes normal operation when connected
16	**CONNECT FB SENSOR**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
17	**PARAMETER STOP**	Parameter(s) in the internal code plug or laser is out of range. Pressing the Standby key (13) will initialise the parameters to default values	Laser output is disabled. Resumes normal operation when standby has been pressed
18	**SAFETY PARAMETER STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
22	**LASER TEMPERATURE TOO LOW**	Internal system temperature too low	Switch off the system and let reach room temperature before powering it up

NOHD (Nominal Optical Hazard Distance) and MPE

The Nominal Optical Hazard for the system is calculated.
The basis for this calculation is the wavelength of the system, the max power, and the parameters of the delivery system.
The MPE (Maximum permissible exposure) is also calculated.

	Bare Fiber 600µm-0.37	Bare Fiber 600µm-0.22	Bare Fiber 400µm-0.22
N.A. - Numerical aperture	0.37	0.22	0.22
Divergence ϕ	0.76rad	0.45rad	0.45rad
Optics	0.6mm	0.6mm	0.4mm
NOHD	**0.18m**	**0.30m**	**0.3m**
Spot area in 10cm	43cm^2	15cm^2	15cm^2
E_{10cm} Irradiance in a distance of 10cm, measured in 7mm aperture	3,5kW/m^2	10kW/m^2	10kW/m^2
MPE - E_{mpe}	**995 W/m^2**	**995 W/m^2**	**995 W/m^2**
Required damping Log(E_{10cm}/ E_{mpe})	0.5	1.0	1.0
Min. protective eye wear	L1	L1	L1

Protective Eye Wear

Protective eye wear must be worn at all times when the laser is in operation. Eye-wear must meet the requirements of IEC 60825 and EN 207.

According to these specifications, the protective eye wear must be marked with the following:

Type of laser:	D	continuous wave laser
Wavelength:	1450-1500 nm	or larger wavelength interval
Protective class:	>L1	or higher

Accessories

The list below provides a complete overview over accessories available for the Vari-Lase laser console.

Description	**Vascular Solu-tions Part No.**	**Medart Part No.**
Instruction for use, 1470nm 15W	42-0835-01	98359
Mains power cord, US	10-0431-01	70107
Mains Power cord, Europe	10-0431-02	70101
Mains power cord, UK	10-0431-03	70104
Inter lock dummy plug	10-0691-01	50413
MedArt® Quick Safe Connect (QSC) for 1470nm	10-0690-01	50655
Key for key switch	10-0442	YP1555
Foot switch with protective cover	10-0432	80115
Protective Eyewear for 1470nm	7577	50185
Fuses - 5x20mm T1.6AL	10-0435	FSR20T1,6

Service and disposal

In the event of malfunction or fault, please contact your MedArt dealer.

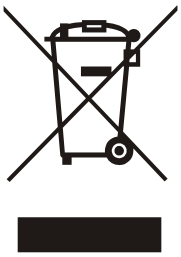
The laser unit contains no user serviceable parts.

Service must be performed only by the Vari-Lase laser console manufacturer or authorized representative, appropriately trained by MedArt A/S.

No attempt should be made by unauthorized personnel to open the Vari-Lase laser console. Failure to observe this caution may present a serious safety hazard and will void all warranties.

The Vari-Lase laser console contains a clearly identified lithium battery:
CR2032PCB, BATTERY, LI-ION
The battery is not changeable by the operator. The battery is expected to have a lifetime that exceeds the life of the system.

The unit must be calibrated and safety-checked by appropriately trained and authorized personnel once every two years.



Separate collection for disposal of waste electrical and electronic equipment.

For information on correct disposal of your MedArt equipment, please contact your Vari-Lase dealer.

Details on the nearest dealer can be obtained from:

MedArt A/S	Phone:	+45 3634 2300
Industriholmen 15A	Fax:	+45 3634 2323
DK-2650 Hvidovre	Mail:	info@medart.dk
Denmark	Web:	www.medart.dk
Vascular Solutions, Inc.	Phone:	+1 763 656 4300
6464 Sycamore Court	Fax:	+1 763 656 4250
Minneapolis, MN 55369	Web:	www.vasc.com
USA		

Product Life Time

The laser system is designed for a lifetime of 10 years. In order to maintain the product performance, the recommended service intervals and activities should be followe throughout the entire service life of the product.

Storing and Transportation

The laser unit must be stored between -10°C and +50°C / 14-122°F. Air humidity must be below 80% and air pressure within the range of 70kPa – 150kPa.

Always transport the Vari-Lase laser console in the original packaging.

Technical Specifications for the Vari-Lase laser console

Type no.:	MedArt® 715
Laser type:	Continuous Wave Diode Laser. Laser Class 4 (IEC 60825)
Output power:	
Range:	1 – 15W in steps of 1W
Maximum:	15W, depending on transmission in connected fiber
Precision:	Better than 10% at maximum output power
Mode of operation:	Continuous wave or pulsed beam
Wavelength:	1470nm ±10nm
Target indicator:	Red indicator light through fiber, 635nm Can be enabled when the laser is in **Standby** mode
Fiber connection:	SMA-905/MedArt® Quick Safe Connect (QSC)
Fiber diameter:	400µm, 600µm & 1000µm
Numerical aperture of fiber:	0.22 or higher
Start/stop functions:	Foot switch
Emergency stop:	Large button on front panel
Warning signal for aiming light radiation	Yellow indicator on the front panel
Warning signals for laser radiation:	Flashing yellow indicator and intermittent sound
Laser Ready warning:	Text READY in display, Yellow indicator on front panel and target indicators
Laser Ready timeout:	250 seconds
Emission:	
Frequency range:	0.3 - 100Hz
Pulse width:	10 - 3000msec
Nominal Ocular Hazard Distance:	0.22NA fiber → NOHD = 0.3 m 0.37NA fiber → NOHD = 0.18 m
Beam divergence:	QSC output 0.45rad
Acoustical mark:	Unique beep sequence after emission of 10 - 500J Volume level increase 0 – 70% Acoustical mark can be enabled or disabled
Output power meter:	
Range:	1W to 150W
Accuracy:	Better than ±20%
Protection against ingress of water:	Class IPX0
Power supply:	Main power connection (100 - 240VAC, 50/60Hs)
Power consumption:	30 - 150VA
Indication of mains power ON:	Display is lit
Fuses:	2 pcs. T1.6AL, Ø5x20mm
Patient leakage current:	Typically 0µA (< 100µA)
Earth leakage current:	Typically 150µA (< 300µA) < 300µA at 110V and at center-tapped 240V
Operating environment:	Room temp. 15 - 27°C/ 59 - 81°F Humidity 10 - 80%, Air pressure 70 kPa – 150 kPa
Safety class:	I type BF
Application in presence of flammable anesthetic mixtures:	Not suited

Sise:	30 x 27 x 17cm
Weight:	Approx. 4.5kg
EMC regulations and testing:	EMC specifications are tested under the following conditions: • Air foot activator was used • Interlock function were connected to 3m twisted pair shielded cable • Connected optical fiber had no influence on the EMC test results

The system is developed and tested in accordance with the following regulations, covering software electrical and laser safety:

EN 60601-1 + A1	Electrical safety
EN 60601-1-1	Medical electrical equipment
EN 60601-1-4, 2nd edition	Medical systems with software
IEC 60601-2-22	Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC 60825-1, Ed 2	Safety of laser products
IEC 62304, 3rd edition	Medical device software

The following regulations and standards has been used to obtain the necessary EMC approvals:

IEC 60601-1-2	EMC standards

Guidance and manufacturer's declaration – EMC topics

Guidance and manufacturer's declaration – electromagnetic emissions		
MedArt® 715 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	MedArt® 715 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	MedArt® 715 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	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
MedArt® 715 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% RH.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of MedArt® 715 requires continued operation during mains power interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power frequency (50/60Hs) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains power voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
MedArt® 715 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MedArt® 715, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3Vrms 150kHs to 80MHs	3Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHs to 2.5GHs	3V/m	$d = 1.2\sqrt{P}$ 80M to 800MHs $d = 2.3\sqrt{P}$ 800M to 2.5GHs 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]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80MHs and 800MHs, 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.			

[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 MedArt® 715 is used exceeds the applicable RF compliance level above, the MedArt® 715 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MedArt® 715 system.

[b] Over the frequency range 150kHs to 80MHs, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the MedArt® 715 laser system

The MedArt® 715 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MedArt® 715 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MedArt® 715 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**		
	150kHs to 80MHs $d = 1.2\sqrt{P}$	**80MHs to 800MHs** $d = 1.2\sqrt{P}$	**800MHs to 2.5GHs** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
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 meters [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 80MHs and 800MHs, 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.

Appendix A

Table A-1
Routine Maintenance Schedule

Service	Frequency	Performed by
Check the exterior of the unit making certain that there are no loose electrical connections or damage	Daily	Clinic or hospital staff
Test fiber	Daily	Clinic or hospital staff
Verify output power (see page 17)	Daily	Clinic or hospital staff
Perform power meter and laser output Calibration. Check that power-meter has an accuracy of 20% or better. Check that laser output has an accuracy of 10% or better. Use an external calibrated power-meter for both checks.	Every 24 months	Vari-Lase laser console manufacturer authorized personnel only

Table A-2
Power Meter Calibration Procedure

Note: This chapter highlights the instructions for the Verification of Calibration of the Vari-Lase laser console. These instructions are provided to comply with Federal Regulations.

These procedures should be performed only by the Vari-Lase laser console manufacturer or a duly authorized representative, trained by the Vari-Lase laser console manufacturer. Calibration verification performed by any other individual will void any manufacturer's warranty, stated or implied.

1. Enter **SERVICE** mode
2. Set the “PowerMeter Gain” setting 800 to: 100%
3. Check that the power meter temperature is close to ambient temperature (±3°C). The power meter temperature can be read from service setting 802. Set the measurement power to 0W and start the power measurement by pressing Ready. The power meter temperature is displayed at the end of the measurement cycle.
4. Set the laser power to 15W using service setting 705 and measure the output power using an external calibrated power meter
5. Point the fiber at the internal power meter and measure the power using service setting 802
6. Set the “PowerMeter Gain” setting 800 to:

$$PowerMeterGain = \frac{External\ Power\ meter\ reading}{Internal\ Power\ meter\ reading} \times 100$$

Note: The “PowerMeter Loss” is set to 0.1 as factory default and should not be changed. This value is based on the material properties of the power meter.

VariLase®

1470nm Laser Console

User's Manual

Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, Minnesota 55369 USA
USA Customer Service: (888) 240-6001

www.vasc.com
www.treatveins.com

Manufacturer:
MedArt A/S
Industriholmen 15A
DK-2650 Hvidovre
Denmark

42-0835-01 Rev. A 04/13