Instruction Manual and Warranty Certificate

VF1000Led

Vein Locator

Fabinject™
TECHNOLOGY

Manufactured by:
Fabinject LLC
7006 Stapoint Ct, Ste I
Winter Park, FL 32792, USA

Customer Service:
Phone: +1 (321) 972-4528
E-mail: contact@fabinject.com
Site: www.fabinject.com

BATCH:

MANUFACTURE DATE:

01 - INTRODUCTION

The purpose of this manual is to help the user operate the described equipment safely and effectively. The instructions should be carefully followed to ensure safety, avoid problems, and enable the effective use of the equipment. The equipment should not be used for purposes other than those described in this manual. Incorrect use or lack of maintenance by the user completely exempts the manufacturer from any responsibility, such as damage, defect, or any other malfunction.

This manual provides essential information for the operation and routine use of the VF1000 LED device and may be altered, without prior notice, whenever FABINJECT makes modifications or improvements to the product.

The VF1000 LED is a medical device that assists in locating shallow veins. By placing the illuminated side on the patient's skin, the healthcare professional can explore the skin's depth in search of veins.

Typical applications of the VF1000 LED include:

• Sclerotherapy, for locating feeder veins – recommended for vascular doctors or aesthetic medicine specialists;
• Botulinum toxin injections, fillers, aimed at locating veins to avoid them – recommended for dermatologists and aesthetic medicine specialists;
• Locating veins for puncturing in children and the elderly, where visual location is difficult – recommended for nursing technicians, emergency doctors, pediatricians, and general practitioners;
• Insulin application or subcutaneous injection, to avoid veins – recommended for diabetics or patients who self-administer medications and need to locate veins to avoid them.

VF1000 LED consists of an ABS plastic case, with an electronic board that contains 20 high-brightness red LEDs. By inserting two AA batteries, respecting their polarity, and pressing the side on/off button, the LEDs will light up.
VF1000 LED should be handheld by the operator. Once the equipment is turned on, the illuminated side should be placed against the patient's skin.

02 - RULES AND REGULATIONS

The VF1000 LED was designed and developed to comply with the following standards:

• NBR IEC 60601-1 General Requirements for Safety.
• NBR IEC 60601-1-2 Electromedical equipment – Part 1-2: Collateral standard: Electromagnetic compatibility.
• NBR IEC 60601-1-6 Electromedical equipment – Part 1-6: Collateral standard: Usability.
• NBR IEC 60601-1-9 Electromedical equipment – Part 1-9: Collateral standard: Requirements for an eco-friendly design.
• EN ISO 10993 Biological evaluation of medical devices.

03 – SYMBOLS USED

To comply with international standards and to enhance the user's understanding of the VF1000 LED device, several symbols are used both in the manual and on the device:

Warning: Whenever you see this notice, read it carefully as it refers to operational safety.

Applied part Type B.

Refer to the manual: It is mandatory to read the VF1000 LED instruction manual before operating the device.

Power Off.

Power On.

Manufacturing Date.

04 - SAFETY PROCEDURES

For the safety of both the patient and the user, the following points must be observed. It is essential that all individuals who will operate the VF1000 LED read and fully understand this manual before using the device. This manual has been prepared to provide all the necessary information for the correct installation, handling, programming, and maintenance of the equipment.

IMPORTANT NOTICES

• The VF1000 LED equipment may pose safety risks to the operator and patient under certain circumstances, particularly in cases of improper installation, use, operation, and maintenance.
• VF1000 LED should not be used in the presence of flammable gases.
• VF1000 LED is not suitable for use in oxygen-rich environments.
• Use only FABINJECT's Technical Support services or agents authorized and accredited by them.
• Never modify the VF1000 LED device. Unauthorized modifications to the VF1000 LED by the user or anyone else may result in safety risks to the patient and operator, including fire, death, or electric shock.
• VF1000 LED should not undergo technical assistance while in use with a patient.
• Do not autoclave, introduce into an oven, or immerse the product in liquids such as water, alcohol, or germicidal solutions.
• VF1000 LED is intended for use by healthcare professionals. This equipment may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the VF1000 LED or shielding the area.
• The emission characteristics of the VF1000 LED make it suitable for use in industrial areas and hospitals (ABNT NBR IEC/CISPR 11 Class A). If used in a residential environment (which typically requires ABNT NBR IEC/CISPR 11 Class B), this equipment may not provide adequate protection against radio frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment.
• VF1000 LED is considered electro-medical equipment and requires special care regarding electromagnetic compatibility. It must be installed and operated according to the electromagnetic compatibility information provided in this manual.
• RF communication devices, portable and mobile, may affect the operation of the VF1000 LED. Avoid using the VF1000 LED in clinics or hospitals near active high-frequency surgical equipment or within a radio-frequency shielded room of an electro-medical system for magnetic resonance imaging, where electromagnetic disturbance intensity is high.
• If the performance of the VF1000 LED does not meet the expected operation, or if any malfunction occurs, it will not cause unacceptable harm to the patient.
• The ambient temperature and relative humidity must meet the conditions specified in Item 7 - Technical Data, for the proper functioning of the equipment.
• Carefully follow the recommendations in Item 08 - LOCATION AND INSTALLATION INSTRUCTIONS.
• Carefully follow the recommendations in Item 09 - HANDLING, CLEANING, PREVENTIVE **MAINTENANCE.**
• Use the equipment only for the recommended indications.
• Remove the batteries from the equipment if it is likely that the VF1000 LED will not be used for some time.

EQUIPMENT SUBJECT TO INTERFERENCE DURING THE OPERATION OF ELECTROSURGICAL EQUIPMENT, ELECTRIC SCALPEL, OR OTHER DEVICES EMITTING INTENSE ELECTROMAGNETIC FIELDS.

05 - CONTENT OF THE PACKAGE / COMPOSITION

The VF1000 LED is an electro-electronic device, so it is important to avoid exposing it to direct sunlight or high temperatures. It is advisable to install this equipment in a cool, dust-free, and well-ventilated room.

The ambient temperature and relative humidity must meet the conditions specified in Item 7 - Technical Data, for the proper functioning of the equipment.

The VF1000 LED was built and packaged to withstand common modes of transportation, air, land, and sea carriers, with multiple handling of the packaging box.

The equipment should not be tipped over, thrown, or exposed to rain.

Visually inspect the box for any possible damage caused during transport. If there is any suspicion of damage, contact the transport company immediately and inform FABINJECT.

Contents: cardboard box containing the VF1000 LED vein locator, two AA batteries, and an instruction manual.

No accessories included.

06 - GETTING TO KNOW THE DEVICE

Fully understanding the device BEFORE initial use is essential for its correct handling.

VF1000 LED - FRONT

VF1000 LED - BACK

07 - TECHNICAL DATA

PRODUCT	Vein locator with red light.
MODEL	VF1000 LED.
DIMENSIONS	Width: 7 cm, Length: 17 cm, Height: 3 cm. Weight without batteries: 0.055 kg. Weight with batteries: 0.100 kg.
POWER SUPPLY	3 VDC - two common, alkaline, or rechargeable AA batteries, installed in series and observing the mounting side as marked on the product. Maximum consumption: 1.0 VA.
CLASSIFICATION	Type of protection against electric shock: Internally powered. Degree of protection against electric shock: TYPE B. Degree of protection against the ingress of liquids and solid particles: IPX0. Not suitable for use in oxygen-rich environments. Internally powered equipment.
OPERATION MODE	Continuous.
ESSENTIAL PERFORMANCE	No essential performance determination is required for the equipment.
ENVIRONMENTAL OPERATING CONDITIONS	Temperature: 15°C to 25°C. Relative Humidity: 10% to 50%. Operational Altitude (max): 2,000 m above sea level.
TRANSPORT AND STORAGE CONDITIONS	Temperature: 5°C to 35°C. Relative Humidity: 10% to 100%. Pressure: 500 hPa to 1060 hPa.
PACKAGING DIMENSIONS	Width: 7 cm, Length: 18 cm, Height: 3.5 cm. Weight: 0.140 kg.

Protection of Radio Services and Other Equipment
The VF1000 LED is classified under IEC/CISPR 11 as Group 1 (electro-medical equipment that uses radiofrequency energy only for internal operation), Class A (VF1000 LED is suitable for use by healthcare professionals and is not intended for general sale. Use in hospitals or medical offices).

ELECTROMAGNETIC IMMUNITY REQUIREMENTS (ABNT NBR IEC 60601-1-2:2017)

Table 4 - Cabinet Interface

Phenomenon	Basic EMC Standard or Testing Method	Immunity Test Levels for Professional Healthcare Environment
Electrostatic Discharge (ESD)	ABNT NBR IEC 61000-4-2	±8kV Contact. ±2kV, ±4kV, ±8kV, ±15kV Air.
Radiated RF EM Fields	ABNT NBR IEC 61000-4-3	3V/m. 80 MHz - 2.7 GHz. 80% AM at 1 kHz.
Fields Near Wireles Communication Equipment by RF	ABNT NBR IEC 61000-4-3	See Table 9 below.
Magnetic Field at Declared Power Frequency	IEC 61000-4-8	30 A/m. 50Hz or 60Hz.

Table 7 - Patient Coupling Interface

Phenomenon	Basic EMC Standard or Testing Method	Immunity Test Levels for Professional Healthcare Environment
Electrostatic Discharge (ESD)	ABNT NBR IEC 61000-4-2	±8kV Contact. ±2kV, ±4kV, ±8kV, ±15kV Air.

Table 8 - Signal Input/Output Interface

Phenomenon	Basic EMC Standard or Testing Method	Immunity Test Levels for Professional Healthcare Environment
Electrostatic Discharge (ESD)	ABNT NBR IEC 61000-4-2	±8kV Contact. ±2kV, ±4kV, ±8kV, ±15kV Air.

Table 9 - Testing Specifications for Immunity of Cabinet Interface to Wireless Communication Equipment by RF

Test Frequency (MHz)	Band (Mhz)	Service	Modulation	Maximum energy (W)	Distance (m)	Test Level Immunity (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM deviation of ±5kHz with 1kHz sine wave	2	0,3	28
710 745 780	704-787	Band LTE 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	Pulse Modulation 18Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; DECT; Band LTE 1, 3, 4, 25; UMTS	Pulse Modulation 217Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, Band LTE 7	Pulse Modulation 217Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0,2	0,3	9

08 - LOCATION AND USAGE INSTRUCTIONS

The VF1000 LED should be used in a medical environment, specifically in a closed, clean room free from dust, and at temperatures not exceeding 25º C.

• Natural ventilation of the product must not be obstructed. The ventilation openings should always remain clear.
• Do not expose the device to direct sunlight.

Battery Installation:

Open the battery compartment. Insert 2 AA batteries, observing the polarity indications. Test the operation of the LEDs. Replace the cover. The device is ready for use. Turn the device on or off using the switch on the side of the unit. ON (I) turns the LEDs on, OFF (O) turns them off.

IT IS RECOMMENDED THAT THE TIME OF LED EXPOSURE TO THE PATIENT'S SKIN DOES NOT EXCEED 10 MINUTES. FOR BETTER RESULTS, ALWAYS DIM THE AMBIENT LIGHTING.

09 - HANDLING, CLEANING, PREVENTIVE MAINTENANCE

Clean the device with a cloth dampened with water and mild soap. Alcohol can be used on the cable and plastic parts. Avoid leaving batteries installed in the VF1000 LED for more than 1 (one) month without use, as batteries may leak and damage the device. Never spill liquids on the device, as this could cause malfunction or loss of functionality. Rechargeable batteries of good quality can be used.

10 - SPECIAL CARE AND USAGE RESTRICTIONS

Avoid pointing the light beam directly at the eyes. Avoid looking directly at the light beam.
Never use the equipment in the presence of flammable gases.
Do not allow children to operate the device.
There are no contraindications.

11 - TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
The unit does not turn on.	Battery is exhausted.	Replace the batteries.
	Battery inserted incorrectly.	Check the correct positioning of the batteries.
The unit does not turn on, even with new batteries installed correctly.	Internal wires are disconnected.	Contact Technical Support.

Fabinject provides, upon request, the circuit diagram, list of components, descriptions, or other information that may assist service personnel in repairing simple issues such as internal wiring. For more complex cases (such as LED or circuit board replacement), the equipment should be sent to the manufacturer.
In case of doubt, contact Fabinject Support.

12 - ENVIRONMENT

The VF1000 LED is made mostly from recyclable materials. Therefore, when disposing of it, maintain the same ecological awareness and do not throw it in regular trash. Avoid discarding batteries in rivers and lakes. Dispose of used batteries in battery collection points that may exist in your city. If desired, send the device to Fabinject for disposal. The device contains some materials that, at the end of its life, can be recycled at recycling centers.

Specifically, the VF1000 LED is made of the following materials:
• ABS plastic structure.

13 - WARRANTY
Fabinject LLC.
WARRANTY CERTIFICATE – CONSUMER

MODEL:		
CLIENT:		
ADDRESS:		
PHONE: ( )	CITY:	STATE:
INVOICE:	DATE OF PURCHASE:	

Warranty:
This product is warranted against manufacturing defects for a period of 1 (one) year from the date of delivery to the buyer or at the address specified by them. Presentation of the Purchase Invoice is required to exercise the warranty, provided that the product has been used in accordance with the Instruction Manual. This warranty covers defects related to material failure or construction failure.

Coverage:
This warranty covers labor and replacement parts only for the product itself. We are not responsible for damage to other equipment/accessories that are not manufactured/distributed by us. Parts requiring replacement will be replaced after analysis by Technical Support and are the property of FABINJECT. The equipment is designed exclusively for use in medical offices. If the equipment is used for purposes other than those specified here, FABINJECT does not guarantee the results and assumes no obligation or responsibility, rendering this warranty void. The warranty covers defects in material and manufacturing that occur during the specified period. This warranty does not cover damage caused by battery leakage or drops that result in breakage.

Cancellation of Warranty:
This warranty will be void if defects are caused by negligence, inexperience, misuse, incorrect installation, mechanical stress, or any other cause not originating from a manufacturing defect. It will also be void if repairs are attempted by unauthorized agents or if the serial number identification label has been tampered with or altered.

1 -	
2 -	
3 -	
4-	
FOR TECHNICAL SUPPORT USE	**STAMP AND SIGNATURE**

Manufactured by:
FABINJECT LLC
7006 Stapoint Court, Suite I, Winter Park,
Florida 32792 – Eastpoint Industrial Park.

Customer Service and Technical Support:
Phone: +1 (321) 972-4528
E-mail: contact@fabinject.com
Site: www.fabinject.com

VF1000Led

Vein Locator

www.fabinject.com