These Instructions for Use are intended to assist in the safe and effective operation of the Vektor Medical, Inc. ("Vektor Medical" or "Vektor") Computational ECG Mapping System ("vMap™" or "vMap").

Before attempting to operate vMap™, please read and act in accordance with these Instructions for Use in their entirety, paying particular attention to all warnings, precautions, instructions, and procedures contained herein.

This Instructions for Use document is intended for the U.S. market only.

Overview

Welcome to vMap™

vMap™ (or the "device") is a non-invasive software-driven tool for beat-by-beat, multi-chamber, two-dimensional ("2D") and three-dimensional ("3D") analysis and mapping of the heart. The device displays ECG signals, 2D cardiac data, and 3D maps.

vMap™ receives electrocardiographic signals acquired non-invasively from the body surface. The ECG signals are used in proprietary algorithms to transform the measured body surface signals into cardiac signals. vMap™ software utilizes this data to provide various 2D cardiac information and interactive 3D color maps, including cardiac electrical features, for analysis by a physician. vMap™ can be used in the clinical environment, such as the electrophysiology ("EP") lab.

The device provides information directly to the physician to help assess patients exhibiting abnormal heart rhythms (arrhythmias). vMap™ provides this information by analyzing electrocardiographic information with reference to an arrhythmia-specific cardiac voltage library.

The vMap™ System consists of three key components:

1. the vMap™ software and its core analysis functionalities,
2. the vMap™ hardware, namely the computer workstation which facilitates the use of the vMap™ software,
3. the vMap™ disposable, which includes a "Mapping Key" that serves as a license mechanism for the software. Commercial off-the-shelf components such as a USB flash drive and a set of FDA-cleared ECG leads are additionally provided within the disposable kit for the physician's ease of use.

Overview

Intended Use/Indications for Use

vMap™ is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.

Contraindications

There are no known contraindications.

Potential Adverse Events and Complications

As with any medical procedure, there are risks involved in treatment of abnormal heart rhythms (arrhythmias). Infrequent vMap™ complications may result in a delay of the procedure that includes reversion to the current standard of care.

While vMap™ is designed to assist in the mapping of potential arrhythmia sources per standard of care, it is not intended to take the place of medical training, clinical experience, and available clinical information (e.g., CT, MRI or other imaging information, patient history, disease characteristics, arrhythmia characteristics, anatomical mapping, voltage mapping), nor should the information provided by vMap™ be construed as definitive activation sources of arrhythmias. Such factors as the signal quality of a collected ECG sample, proximity and strength of sources of electrical interference, and other patient and environmental factors may influence vMap™ functionality and results. If, in the judgment of the clinician, these factors are sufficient to preclude proper use of vMap™, use of vMap™ should be suspended.

Situations where the outputs of vMap™ may be inaccurate include, but are not limited to:

1. Patients with the specified pre-existing condition(s) below.
2. Use with components of other systems, unless otherwise specified.

vMap™ has not been tested for use with patients with a history of unstable coronary artery disease, confirmed intracardiac thrombus in the chamber of interest, active sepsis, complex congenital heart disease, dextrocardia, severe pulmonary hypertension, decompensated heart failure, mechanical heart valve, or myocardial infarction within the preceding one month.

Contact Vektor Medical, Inc.

- phone: 619-736-7821
- email: info@vektormedical.com
- online: https://www.vektormedical.com/contact

Product of Vektor Medical, Inc.

Created in California.

Vektor Medical, Inc.
7875 Sitio Abeto
Carlsbad, CA 92009
USA

Visit us online at https://www.vektormedical.com

Principles of Operation

vMap™ receives electrocardiographic signals acquired non-invasively from the body surface. The ECG signals are used in proprietary algorithms to transform the measured body surface signals into cardiac signals. vMap™ software utilizes this data to provide various 2D cardiac information and interactive 3D color maps, including cardiac electrical features, for analysis by a physician.

Warnings & Precautions

Read these warnings and precautions carefully before using vMap™:

- Read all instructions and understand all warnings and cautions before using vMap™ and accessories. Failure to do so may decrease the effectiveness of vMap™. Refer to the Instructions for Use that accompanies vMap™ devices before use to confirm proper use of the device.
- Do not use vMap™ before adequately considering the risks of the entire procedure for each patient. Any treatment, including cardiac ablation, should be conducted only after careful analysis of the treatment area. Do not conduct treatment until all available data has been considered.
- Do not connect vMap™ to a network.
- Do not use the provided vMap™ ECG patches if the patient has moderate to severe allergy to the components of the electrode patches. Do not place electrode patches on sites of wounds, sores, disease of the thorax area, or other severe skin conditions.
- Do not perform magnetic resonance (MR) imaging with the provided ECG patches on the patient. The ECG patches may cause harm to the patient if used in MR imaging. Remove patches prior to performing MR imaging studies.

Overview

- The provided ECG patches are intended for single use only. Reusing ECG patches may result in poor system performance or transmission of infection.
- The provided ECG patches are meant to be used only during procedures that use compatible and legally marketed ECG recording systems.
- Store optional ECG patches in their sealed protective pouches until use.
- The system cables and accessories are provided non-sterile. Do not sterilize the cables or accessories.
- vMap™ contains no user serviceable parts, and servicing (other than that explicitly defined elsewhere in this manual) must be performed by the manufacturer or its authorized agent.
- No modification of vMap™ equipment is allowed.
- Do not attempt to repair vMap™. Any malfunction which does not respond to remedies identified in this guide can only be address by manufacturer's service. Vektor Medical requires that the device be returned to Vektor Medical only for any such inspection, service, or repair.
- If system data acquisition seems inaccurate or if the software application does not initiate or malfunctions during use and recommended steps to restore the system are not successful, discontinue use of the system.
- Ensure ECG recording system compatibility prior to use with the vMap™ device.
- Inspect all system components and packaging for damage before use. If components are visibly damaged, do not use the system.
- Do not allow liquids to enter the vMap™ computer or monitor, as this may result in damage or malfunction of the vMap™ device.
- Keep area surrounding vMap™ clean of dust, debris, fluids, clutter, sources of excessive heat, and sources of electrostatic discharge.
- Do not expose any vMap™ hardware or disposable kit components to fluids or solvents, except when following cleaning recommendations in this Instructions For Use document.
- Do not use vMap™ in the presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide.
- Avoid contact between any electrical connections and other conductive parts of vMap™, including those connected to protective earth/ground.
- Connection of vMap™ to unapproved equipment may result in patient leakage currents.
- Modification to vMap™ components (e.g. attachment plug, power cord) may result in electrical shock.
- Switch off power to vMap™ before cleaning it.
- Switch off power to vMap™ when it is not in active use.
- Do not exceed the recommended electrical ratings. Exceeding the ratings could damage vMap™.
- Do not modify the attachment plug. This could cause an electrical hazard.
- The vMap™ device contains sensitive electronic components which may be damaged by electrostatic discharge (ESD). Normal precautions should be taken to avoid causing ESD impulses to occur directly on any unoccupied computer port (e.g. 3.5 mm audio jack on the front panel).
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with a protective earth ground.
- The computer power cord must be connected to an electrical mains supply connection that is separate from the monitor's mains supply connection.
- If vMap™ comes into contact with hazardous chemicals or biological materials, take appropriate cautions to minimize personnel interaction with vMap™ until the system can be cleaned.
- Avoid fluid contact with all cable connections.
- Do not stack other equipment on top of or around vMap™. Ensure adequate airflow around computer chassis and display monitor vents.
- Vektor Medical does not recommend or validate any third-party software with Vektor Medical products, Vektor Medical services, or software apps. Vektor Medical has no responsibility or liability arising from the use of such third-party software or equipment such as damage, inaccuracies, or malfunctions to vMap™ products, services or software apps.

Overview

- Use of vMap™ in a manner not specified in this Instructions for Use document voids the terms of the product warranty.

Environment

- vMap™ equipment must be operated within the following conditions:
  - Temperature: 15°C – 30°C.
  - Relative humidity: 10% – 90%
  - Pressure: 70 kPa – 110 kPa
- vMap™ equipment must be transported or stored within the following conditions:
  - Temperature: -35°C – 55°C.
  - Relative humidity: 5% – 95%.
  - Pressure: 238 hPa – 1066 hPa
  - 2G vibration: 10 Hz – 55 Hz
- Verify that the AC power supply line is appropriate for use (100 – 240V AC).
- Do not allow direct contact between vMap™ operator and the patient during use of vMap™. Patient should not be directly connected to the vMap™ computer at any time.
- Place vMap™ system on a level surface with an incline of less than 10°.

Data Collection & Retention

- vMap™ is only intended to collect de-identifiable patient information that is readily available from the patient's medical record.
- vMap™ is not intended to collect any Personally Identifiable Information ("PII") or Protected Health Information ("PHI") from the patient.
- Users of vMap™ are solely responsible and liable for implementing PII and PHI practices as it relates to patient information.
- Users should be aware of any PII or PHI when transferring data to and from vMap™.
- If a user knows or should know that any PII or PHI was transferred to vMap™, the user should immediately remove and clear all such information from vMap™.

Packaging

- Packaging for each component should be intact upon receipt. Devices should be carefully examined for completeness and for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Vektor Medical.
- vMap™ accessories are single-use components supplied non-sterile. Non-sterile, single-use only product should NOT be sterilized. Do not use if package is opened or damaged. Do not use if the product is damaged in any way. Do not use after the expiration date specified on the product label. Discard after use.
- Expected service life of the computer and peripherals (mouse, keyboard, and power cord) is 5 years. Expected service life of the monitor and peripherals (power supply, DisplayPort cable, USB upstream cable) can be referenced in their respective user guides.

Cleaning

The vMap™ main control unit, monitor, keyboard, and mouse are not intended for sterilization. If necessary, they may be cleaned with a soft towel or wipe dampened with a mild detergent and water solution according to standard hospital practices. Contact Vektor Medical for any additional information related to cleaning.

Technical Description

- Electrical
  - NEMA IEC 60529 degrees of protection provided by enclosures – ingress protection rating of IP20
  - Power Input – Computer
    - 100 – 240 VAC
    - 50 – 60 Hz
    - 3/5 A
- Mechanical
  - Computer dimensions:
    - 376 mm × 107 mm × 351 mm (14.8 in × 4.21 in × 13.82 in)
  - Computer mass:
    - 12.25 kg (27 lbs.)

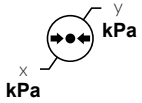
Appendix C: Symbols Glossary

Symbol	Symbol Title	Symbol Description	Standard Reference	Standard Title
	Manufacturer	Indicates the medical device manufacturer.	5.1.1	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Date of Manufacture	Indicates the date when the medical device was manufactured.	5.1.3	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use.	5.4.3	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Caution	Indicates the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
IPX0	Not protected from fluid ingress	Indicates that protection from fluid ingress is not provided.	N/A	IEC 60529:1989 – Degrees of Protection Provided by Enclosures (IP Code)

Appendix C: Symbols Glossary

Symbol	Symbol Title	Symbol Description	Standard Reference	Standard Title
℞ Only	Prescription Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.	N/A	N/A
REF	Catalogue Number	Indicates the manufacturer's Catalogue Number so that the medical device can be identified.	5.1.6	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
LOT	Batch Code	Indicates the manufacturer's Batch Code so that a specific medical device can be identified.	5.1.5	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
SN	Serial Number	Indicates the manufacturer's Serial Number so that a specific medical device can be identified.	5.1.7	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
1 Contents Qty.	Quantity	Indicates the quantity.	N/A	N/A

Appendix C: Symbols Glossary

Symbol	Symbol Title	Symbol Description	Standard Reference	Standard Title
	Do Not Re-Use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Temperature Limit	Indicates the temperature limit to which the medical device can be safely exposed.	5.3.7	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	5.3.9	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Electronic Equipment: Dispose of Properly	Indicates electronic equipment to be disposed of properly.	4.1 b) 2)	EN 50419 -Marking of electrical equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

Appendix C: Symbols Glossary

Symbol	Symbol Title	Symbol Description	Standard Reference	Standard Title
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	5.3.4	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	5.3.2	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Refer to instruction manual/ booklet	Signifies that the instruction manual/booklet must be read.	M002	ISO 7010:2011 Graphical symbols – Safety colors and safety symbols – Registered safety signs