POLYMATECH ELECTRONICS LIMITED · SEMICONDUCTOR & MEDICAL IMAGING

Ravaye™ E2

Vein Finder — Near-Infrared Vein Visualization System

Version: Poly2025

USER MANUAL

UNITED STATES EDITION

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Please read this user manual carefully before operating the Ravaye™ E2 Vein Finder. Retain for future reference.

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NOTE

This is the United States edition of the Ravaye™ E2 Vein Finder user manual (Version Poly2025). For editions applicable to other markets, contact the manufacturer.

SECTION 01

Intended Use

The Ravaye™ E2 Vein Finder is intended to assist qualified healthcare professionals in visualizing certain superficial veins. The device uses near-infrared illumination to enhance the visibility of subcutaneous veins, projecting their position directly onto the skin surface.

It is intended to be used as a supplement to appropriate medical training and experience. It is not a substitute for clinical judgment and should not be used as the sole method for locating veins. The device should be used by a qualified medical professional, either prior to palpation to help identify a vein, or afterwards to confirm a perceived location. When using the device, practitioners should always follow the medical protocols of their facility and exercise sound clinical judgment.

The device may be used wherever determination of superficial vein location is appropriate, such as hospitals and clinics, in connection with procedures such as venipuncture.

IMPORTANT

The device does not replace clinical judgment, standard venipuncture practice, or confirmation of vessel suitability. It is not a diagnostic device and is not intended for treatment of any kind.

SECTION 02

Product Description

The Ravaye™ E2 Vein Finder operates by using near-infrared light to detect veins beneath the skin, then projecting the position of the veins onto the skin surface directly above them. Qualified medical personnel can observe the displayed vasculature to assist in locating a vein of suitable size and position for venipuncture and other procedures requiring the location of superficial veins.

The device displays only superficial vasculature. The maximum depth at which veins are displayed varies by patient. Some patients' veins, or a portion of their veins, may not be displayed well or at all. Factors affecting display quality include, but are not limited to, vein depth, skin conditions (such as eczema or tattoos), scarring, highly contoured skin surfaces, and adipose (fatty) tissue.

When held directly overhead, the device accurately locates the center line of a vein. Increasing displacement from directly overhead results in an offset in the displayed vein position. The displayed width may differ from the actual vein width depending on patient differences. The center line of the vein is accurate when the device is used correctly and should always be used as the target when performing venipuncture.

The Ravaye™ E2 is a portable device. An optional table stand and mobile stand are available.

SECTION 03

Package Contents

On receipt, please verify that the following items are present and undamaged. If any item is missing or damaged, contact your supplier before use.

No.	Item	Quantity
1	Main unit (Ravaye™ E2 Vein Finder)	1
2	Charging cable (USB Type-C)	1
3	Charging adapter	1
4	Aluminum carrying case	1
5	User manual	1
6	Calibration card	1
7	Product certificate	1
8	Warranty card	1

NOTE

An optional table stand and mobile stand are available separately. Contact your supplier or the U.S. representative listed in Section 13 for details.

SECTION 04

Controls & Display Interface

The device is operated using the Power, Sleep, OK, and four arrow keys. The on-screen menu is navigated with the up/down arrows to select a row, and the OK key or left/right arrows to change a setting.

Control Keys

Key	Function
Power	Short press to start up or shut down. The device powers off automatically after 35 minutes of inactivity. Indicator light — Blue: working; Green: fully charged; Red: charging.
Sleep	The device enters sleep mode automatically after 10 minutes of inactivity (default; adjustable via the display menu). A short press enters low-power mode immediately.
OK	Confirms the selected menu row or setting.
Arrow keys	Up / down to move between menu rows; left / right to adjust the selected setting.

On-Screen Menu

The LCD menu provides the following adjustable rows: Color, Size, Inverse, Brightness, Mode, Photograph, and Sleep. Each is described in Section 06.

NOTE

On start-up, the device displays the Ravaye™ boot screen before entering the live projection view.

SECTION 05

Use & Operation

1 Position the device

Hold the device 20 to 26 cm (7.9 to 10.2 in) above the surface of the skin and scan the area of interest.

2 Center over the vein

Once a vein is selected, ensure the projected vein display is centered directly above the vein's center line. Tilting the device to either side will offset the projection from the true location beneath the skin.

3 Optimize the image

Enhance display quality by slightly adjusting height and angle. Moving the device closer or further from the skin can bring additional veins into view, depending on the patient's vasculature, room lighting, and vein depth.

4 Scan, then enhance

Use default mode to scan quickly and narrow down possible locations. After confirming a suitable vein, switch to enhance mode to assist with deeper veins.

5 Confirm before the procedure

After assessing the patient's vasculature, confirm the site by verifying the location and suitability of the vein using standard medical techniques — including visualization, palpation, and sound clinical judgment.

▲ CAUTION

The displayed image is an aid only. Always confirm vein location and suitability using standard clinical methods before performing any procedure.

SECTION 06

Display Settings

Select a row using the up/down arrows, then press OK or use the left/right arrows to adjust.

Setting	Function
Color	Choose the projection color. Twelve options: white, yellow, purple, red, indigo, green, blue, blue & purple, blue & indigo, red & yellow, green & yellow, green & indigo.
Size	Choose the projection size. Three options: L, M, S.
Inverse	Turn inverse mode on or off.
Brightness	Adjust projection brightness. Six levels available.
Mode	Switch display mode. Nine modes: default, enhance, hair removal, guide line, and five mixture colors.
Photograph	Save real-time vein images. Captured images can be accessed via a computer using the USB Type-C cable.
Sleep	Set the idle time before the device enters sleep mode.

TIP

Default mode is best for quickly scanning a region. Switch to enhance mode once a candidate vein is found to improve visibility of deeper vasculature.

SECTION 07

Calibration

A calibration card is supplied with the device. To verify projection accuracy, project the device image onto the calibration card and compare the projected lines against the printed grid and circles. Calibration should be verified before first use and periodically according to facility procedures.

The projected image should align with the card's grid lines and concentric circles without significant deviation.

If the projected image deviates from the card lines, do not continue use. Contact your supplier or the U.S. representative listed in Section 13 for service.

▲ CAUTION

A device that fails calibration may display inaccurate vein positions. Discontinue use and arrange service before returning the device to clinical use.

SECTION 08

Technical Specifications

Parameter	Specification
Detection method	Near-infrared illumination technology
Infrared wavelength	760–940 nm
Infrared detection depth	0–10 mm (0–0.39 in)
Optimal working distance	20–26 cm (7.9–10.2 in)
Vessel position accuracy	±0.3 mm (±0.012 in)
Vessel resolution accuracy	±0.3 mm (±0.012 in)
Projection technology	DLP projection
Working noise	≤ 35 dB
Battery	Rechargeable lithium battery, 4,900 mAh
Battery duration	Approximately 3.5 hours
Battery indication	Capacity display and low-battery prompt
Power supply (charging)	5 V / 4.5 A · Input 100–240 V, 50/60 Hz
Weight	450 g (15.9 oz)
Dimensions (L × W × H)	24 × 6 × 6.5 cm (9.4 × 2.4 × 2.6 in)

NOTE

Specifications are subject to change in the interest of product improvement. Refer to the device labeling for the configuration of your specific unit.

SECTION 09

Symbols Glossary

Symbol	Meaning
i	Refer to instruction manual / consult instructions for use
CE	CE Marked (Low Voltage Directive 2014/35/EU)
SN	Product serial number
REF	Catalog / model reference number
⌂	Manufacturer
☷	Date of manufacture
☂	Keep dry
⚐	Fragile — handle with care
♻	Waste Electrical and Electronic Equipment (WEEE) — dispose of separately in accordance with local regulations.

NOTE

Symbol artwork on the device label follows ISO 15223-1. The descriptions above are provided for reference.

SECTION 10

Warnings & Cautions

▲ WARNING

Always confirm vein location and suitability using standard clinical methods. The projected image is an aid and does not guarantee successful venipuncture.

- Use only as a supplement to assist qualified professionals in locating veins. It is not a diagnostic device and is not for treatment of any kind.
- Performance depends on patient factors. Veins may not display on patients with deep veins, certain skin conditions, hair, scarring, highly contoured skin, or adipose tissue.
- The device displays only superficial veins, to limited depths, and does not indicate vein depth.
- Do not use the device to locate veins in the eyes. Do not shine the display light into the eyes for a prolonged period.
- Projection may not display veins under bright light, such as direct sunlight.
- Keep the instrument dry and clean to prevent fluid ingress.
- The device must be repaired only by authorized, qualified personnel.
- Do not open, disassemble, or service the battery.
- Do not sterilize the device using heat or pressure.
- Electromagnetic interference can affect device performance.
- The device is fragile. Do not drop.
- Use only official accessories. Unofficial accessories can reduce safety.
- Do not expose the device or battery to fire.

SECTION 11

Care, Maintenance & Storage

- Clean the device approximately once a month.
- Before cleaning, unplug the power cable and ensure the device is switched off.
- Wipe the device with a lint-free cloth lightly dampened with 70% alcohol.
- If the vein-light window becomes scratched, return the device to the manufacturer for service.
- If the device will not be used for more than three months, remove the battery. The battery compartment is independent and easy to access.
- Do not open the device to clean its interior.
- After use, return the device to its aluminum carrying case.
- Store in a cool, dry place.

Battery & Charging

Charge using the supplied adapter and USB Type-C cable. The indicator shows red while charging and green when fully charged. The display provides a battery-capacity indication and a low-battery prompt.

NOTE

For continued operation during mains interruptions, the device may be powered from its internal battery or an uninterruptible power supply.

SECTION 12

Electromagnetic Compatibility

The Ravaye™ E2 Vein Finder is intended for use in the electromagnetic environment specified below (IEC 60601-1-2).

Guidance — Electromagnetic Emissions

Emissions test	Compliance	Environment guidance
RF emissions (CISPR 11)	Group 1	Uses RF energy only for its internal function; RF emissions are very low and unlikely to cause interference in nearby equipment.
RF emissions (CISPR 11)	Class B	Suitable for use in all establishments, including domestic and those connected to the public low-voltage supply.
Harmonic emissions (IEC 61000-3-2)	Class A	—
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	—

Guidance — Electromagnetic Immunity

Immunity test	Test / compliance level	Environment guidance
ESD (IEC 61000-4-2)	±6 kV contact, ±8 kV air	Floors should be wood, concrete, or ceramic tile. If synthetic, relative humidity should be at least 30%.
Electrical fast transient / burst (IEC 61000-4-4)	±2 kV mains, ±1 kV I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1 kV diff., ±2 kV common	Mains power quality should be that of a typical commercial or hospital environment.
Power-frequency field (IEC 61000-4-8)	3 A/m	Characteristic of a typical commercial or hospital environment.
Conducted RF (IEC 61000-4-6)	3 Vrms, 150 kHz–80 MHz	Portable/mobile RF equipment should be kept at the recommended separation distance.
Radiated RF (IEC 61000-4-3)	3 V/m, 80 MHz–2.5 GHz	$d = 1.2\sqrt{P}$ (80–800 MHz); $d = 2.3\sqrt{P}$ (800 MHz–2.5 GHz), where P is max. output in watts.

Recommended Separation Distances

Between portable and mobile RF communications equipment and the Ravaye™ E2 Vein Finder. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance as recommended below, according to the maximum output power of the communications equipment.

Rated max. output (W)	150 kHz–80 MHz (m)	80–800 MHz (m)	800 MHz–2.5 GHz (m)
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

NOTE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

SECTION 13

Regulatory, Manufacturer & U.S. Contact Information

Item	Detail
Classification	Class I Medical Device
USA	U.S. FDA Registered Establishment & Device Listed (Registration No. 3027571036 · Listing No. D588842) · Product Code KZA · 510(k)-Exempt
India	CDSCO Class A Medical Device Registration No. POLYMA-Kanch-TN/M/IVD/021765
Certifications	ISO 13485:2016 Medical Device Quality Management System ISO 9001:2015 Quality Management System ISO 14001:2015 Environmental Management System CE Marked (Low Voltage Directive 2014/35/EU)

MANUFACTURER

Polymatech Electronics Limited

SIPCOT Hi-Tech SEZ, Plot No. OZ 13, Oragadam, Kancheepuram District,
Greater Chennai, Tamil Nadu 602105, India

U.S. AGENT (FDA) · SERVICE & SUPPORT — UNITED STATES

Nisene Technology Group

417A Salinas Rd, Royal Oaks, CA 95076, USA · www.nisene.com

Contact: Jason, Executive Vice President · jason@polymatech.in · +1 (262) 395-0174

DISCLAIMER

The Ravaye™ E2 Vein Finder is intended to assist qualified healthcare professionals in visualizing superficial veins. It does not replace clinical judgment, standard venipuncture practice, or confirmation of vessel suitability.

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POLYMATECH ELECTRONICS LIMITED

RAVAYE™

Named for the Sanskrit Ravi — the Sun, the source of light and life.

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