

SmartImaging™ End User License Agreement (EULA)

CONTROLLED

I. Purpose:

This document pertains to the SmartImaging™ software end-user license agreement (EULA). The purpose is to ensure consistent communication of software licensing terms to all users and to meet regulatory and legal disclosure requirements. By the end-user providing their name, institution, and email address on the website, they consent to the collection of this information for purpose of:

- Verify their acceptance of this End User License Agreement (EULA)
- Authorizing the installation and activation of the software

II. Background

SmartImaging™ software utilizes a proprietary algorithm for intravascular ultrasound image analysis. The EULA outlines the terms of use, user responsibilities, and limitations of liability. Posting the EULA on the corporate website will ensure public accessibility and alignment with industry best practices.

III. Content Summary

The EULA governs the use of SmartImaging™ software with the Makoto Intravascular Imaging System. It grants licensed healthcare providers the right to use the software on approved devices for assisting in IVUS image analysis, while prohibiting reverse-engineering, and use outside cleared regulatory indications.

The software automates lumen and vessel border detection using an AI algorithm, but does not replace physician interpretation. All AI-generated contours, measurements, and calculations must be reviewed, verified, and, if necessary, adjusted by a qualified clinician before clinical diagnosis. The EULA emphasizes user responsibility for clinical appropriateness, acknowledges potential sources of error, and limits the licensor's liability for misinterpretation or misuse.

The agreement outlines compliance requirements for patient privacy laws, adherence to hospital IT security protocols, and completion of the licensor-provided training. It specifies that off-label use is at the user's own risk and outside the licensor's liability. Updates, support provisions, and termination conditions are also included.

IV. Appendices

Appendix A: End-User License Agreement (EULA)

Appendix A: SmartImaging™ End-User License Agreement (EULA)

1. IMPORTANT NOTICE

This End-User License Agreement (“Agreement”) is a legal contract between you (“User” or “Licensee”) and Infraredx® (“Licensor”) governing your use of the SmartImaging™ (“Software”). By installing, accessing, or using the Software, you agree to be bound by the terms of this Agreement. If you do not agree, you must not use the Software.

2. DEFINITIONS

- “Software” means the SmartImaging™ application, including executable programs, algorithms, databases, and related documentation.
- “Authorized Device” means the Makoto Intravascular Imaging System or compatible workstation approved by the Licensor.
- “Output Data” means the contours, measurements, annotations, and reports generated by the Software.
- “User” means the healthcare professional operating the Software in accordance with applicable clinical and regulatory standards.

3. LICENSE GRANT

Subject to the terms of this Agreement, Licensor grants you a non-exclusive, non-transferable, revocable license to:

- Run the Software on Authorized Devices for the purpose of assisting in intravascular ultrasound imaging analysis.
- The Software processes patient images in compliance with applicable privacy laws (e.g., HIPAA, GDPR).
- Users are responsible for ensuring that all hospital IT security protocols are followed.
- Use of Software’s AI-generated lumen and vessel border contours to aid in diagnostic decision-making by qualified healthcare professionals only.

4. LICENSE RESTRICTIONS

You agree not to:

- Reverse-engineer, decompile, or otherwise attempt to derive the Software’s source code.
- Use the Software for purposes other than intended, including non-medical research without Licensor’s prior written approval.
- Integrate the Software with unapproved hardware or third-party software
- Rely solely on the Software’s output without independent clinical judgement by a qualified physician
- Distribute, sublicense, lease, or make the Software available to any unauthorized third party.

5. CLINICAL USE DISCLAIMER

- The Software is an assistive tool designed to automate lumen and vessel border detection in IVUS images using an AI algorithm.
- It does not replace physician interpretation. All AI-generated contours and measurements must be reviewed, verified, and approved by a qualified healthcare provider prior to clinical use.
- The Software does not provide diagnostic conclusions; it supports, but does not replace, standard-of-care clinical decision-making.
- The User is solely responsible for ensuring that the Software's output is clinically appropriate for each patient use.

6. DATA PRIVACY AND SECURITY

- The Software processes patient images in compliance with applicable privacy laws (e.g., HIPAA, GDPR).
- Users are responsible for ensuring all hospital IT security protocols are followed.

7. UPDATES AND SUPPORT

- Licensors may provide periodic updates, bug fixes, and improvements at its discretion.
- Continued use of the Software after an update constitutes acceptance of the updated terms.
- Customer Support is available to authorized Users via email at customerservice@infraredx.com

8. WARRANTY AND LIMITATION OF LIABILITY

- No Warranty: The Software is provided "AS IS without warranties of any kind, express or implied, including fitness for a particular purpose or accuracy of AI-generated contours.
- Limitations of Liability: Licensors shall not be liable for any indirect, incidental, special, or consequential damages, or for any clinical misinterpretation arising from reliance on the Software's output.

9. TERMINATION

- This Agreement terminates immediately if you fail to comply with its terms. Upon termination, you must cease all use of the Software.

10. GOVERNING LAW

This Agreement shall be governed by and construed under the laws of the State of Massachusetts, without regard to conflict-of-law principles.

**SmartImaging™ End User License Agreement
(EULA)**

CONTROLLED

By providing your name, institution name, and email, you:

- Confirm you have read, understood, and agree to be bound by the terms and conditions of this End User Agreement (EULA).
- Consent to the collection of your name, email address, and institutional affiliation solely for the purposes of:
 - Verifying your acceptance of this EULA
 - Authorizing installation and activation of the software
- Acknowledge that your information
 - Will not be used for marketing or added to any mailing list
 - Will not be disclosed to third parties except as required by law or regulatory authorities
 - Will be retained only as necessary to meet the above purposes and legal obligations, and will then be securely deleted or anonymized
- Understand that all processing, storage, and deletion of your information will be conducted in compliance with applicable data protection and medical device regulations, including GDPR, CCPA, PIPL, HIPAA (when applicable), ISO 13485, IEC 82304-1, and any other relevant local, state, national, or international requirements.

Name: _____

Institution: _____

Email: _____

Date: _____