

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.
- To make you aware that the Software processes patient images in compliance with applicable privacy laws (e.g., HIPAA, GDPR).
- To make you aware that users are responsible for ensuring that all hospital IT security protocols are followed.
- To make you aware that the use of Software’s AI-generated lumen and vessel border contours to aid in diagnostic decision-making is to be done 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

- Lessor 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: Lessor 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.

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: _____