

## SOFTWARE TOS INCLUDING SOFTWARE DESCRIPTION

### TERMS AND CONDITIONS FOR THE USE OF MYRIAN MEDICAL IMAGING SOFTWARE®

#### 1. PRESENTATION OF THE MYRIAN MEDICAL IMAGING SOFTWARE

**1.1** The company INTRASENSE ("INTRASENSE"), SA with a capital of 2.613.100,75 euros, registered in the Trade and Companies Register of MONTPELLIER under the number 452 479 504, having its head office at 1231, avenue du Mondial 98, 34000 MONTPELLIER, designs, publishes and markets a medical imaging software in English version called Myrian®.

Intra-Community VAT number:  
FR 57 452 479 504.

INTRASENSE can be contacted at the following address:

- By mail, to:  
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The director of publication is: Mr Nicolas REYMOND.

INTRASENSE designs, publishes and markets a French version of a medical imaging software called Myrian®, as well as all its optional modules, files, data and associated materials (the "Software").

The Software is an *"on premise"*

accessible software, its hosting being taken care of by the purchaser (the "User") on a dedicated server (the "Server") that the latter already owns within his information system, or that he wishes to acquire from INTRASENSE.

The Software may, depending on the User's needs, be sold alone or with the following elements and services:

- Remote connection software (DaaS type);
- Third party software distributed by the Seller, and technically linked to the Software, so as to provide additional functionality;
- Specific integrated features (artificial intelligence, etc.);
- Server;
- Installation and setup;
- Training of the User and/or his staff.

**1.2** Use of the Software is governed by these general terms and conditions of use (hereinafter referred to as the "TOS").

**1.3** Any additional service or option related to the use of the Software, made available to the User, will be subject to separate special conditions of use which will be fully applicable to it.

**1.4** Thus, the TOS and, if applicable, the separate special conditions of use, written in English, determine the contractual framework of the

relationship between INTRASENSE and its Users for the use of the Software and, if applicable, any additional services or options related thereto.

## **2. ACCEPTANCE OF THE TOS**

**2.1** The provision of the Software is intended exclusively for professional customers, i.e. natural and legal persons acting in the course of their professional activity. This includes private companies, public institutions, associations, liberal professions, self-employed persons, acting exclusively for their professional needs, excluding consumers and non-professionals within the meaning of Order No. 2016-301 of 14 March 2016.

The User also acknowledges that he/she has the necessary skills and material resources to use the Software. The User undertakes to comply with the terms of these TOS.

**2.2** Any use, installation or transmission of the Software not in accordance with the TOS is prohibited.

**2.3** Subscription and access to the Software are strictly subject to prior acceptance, without restriction or reservation, of these TOS.

## **3. TECHNICAL PREREQUISITES**

The technical requirements for using the Software are detailed in Appendix 1.

## **4. SESSION AND USER PROFILE**

The Software can be installed (i) on a computer terminal (hereinafter the "Terminal"), in "standalone" or (ii) on a Server, with remote access via a Terminal, and the use of a "Citrix" license (or equivalent).

**4.1** In standalone mode, and by default, the Software does not require a password, and can be launched directly, once the User has opened the Windows session that is specific to him (with the login/password combination that is specific to him).

The software then retrieves the identifier of the person concerned via the "Active Directory" service.

There can therefore be several User accounts on the same Terminal, with identification either via the Windows session (and therefore via the Active Directory service), or with login/password management provided directly by the Software. In both cases, there is a profile for each User among the three following levels: observer; operator; administrator.

**4.2** In the case of a Server installation, for which the number of simultaneous Users is defined in the license, identification is systematically carried out via the Active Directory.

**4.3** The process of accessing a user session and creating a User profile is detailed in the user documentation provided with the delivery of the Software, in accordance with its general terms and conditions of sale (the "GTC").

## **5. LIMITATIONS ON THE USE OF THE SOFTWARE**

**5.1** The Software is a medical device. It is not intended to substitute for the skill and judgment of a qualified medical practitioner. Therefore, the Software should only be used by personnel properly trained in the functions, capabilities and limitations of the Software.

**5.2** The Software is CE certified and complies with the requirements issued by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

**5.3** In addition to its certification in EU member countries, the Software meets, as of the date hereof, the regulatory requirements (certification or registration) of the United States, China, Japan, Malaysia, Russia, Serbia, Brazil and Taiwan, authorizing its use as an aid to medical diagnosis in these areas.

For any other country where the use of medical devices is regulated, the User agrees not to use the Software for diagnostic purposes.

**5.4** In general, the use of the Software must not violate national and international laws and regulations.

**5.5** The User undertakes to scrupulously respect the rights of INTRASENSE on the Software.

**5.6 IMPORTANT WARNINGS:**

The Software may not be used for medical diagnostic assistance by Users who have not followed the ordering process set out in the GTC and, where applicable, accepted and signed the GTC.

The non-respect of these stipulations, absolutely essential to preserve the rights of INTRASENSE on the provision of the Software, will authorize INTRASENSE to immediately suspend the provision of the Software to the benefit of the offender, without refund or compensation.

**5.7** The User is aware of the limitations in the accuracy and validity of the data, displayed, printed or exported from the Software. The quality of the data processed by the Software is directly dependent on the quality of the input data, the User's interaction with that data, the quality, characteristics, and settings of the display or printing device, and the need to interpolate the data for display.

Even though the Software has been intensively examined and tested by INTRASENSE, Users are aware that it is by nature impossible to fully test a Software, and that faults may remain or occur due to its use under particular conditions of use. These defects could therefore result in measurement, display or patient identification errors.

The Software stores images from medical examinations combined with patient identification information in its local database and for export. Although encrypted or protected, it is important to protect this data from access by unauthorized persons.

**5.8** Users should be aware that certain display technologies employed in the Software make use of interpolated data. This data is created by the Software based on the original data.

**5.9** Interpolated data may give the appearance of healthy tissue in situations where the pathology is close to or smaller than the resolution used in the acquisition by a specialized medical device.

Occasionally, interpolated data may also include artefacts that should not be interpreted as true pathology.

The image album function is intended to store images with their annotations, and thus provide a qualitative view of the data: these images should never be used for primary diagnosis.

**5.10** Myrian® software is not suitable for use in mammography in the USA and China. Lossy compressed mammography images and digitized films should not be used as the first line of interpretation. In the USA, mammography images may only be interpreted using an FDA-approved monitor that has a resolution of at least 5 megapixels and meets other FDA-approved technical specifications.

**5.11** INTRASENSE grants its User a private, non-transferable, non-collective and non-exclusive right to use the Software. Consequently, the User is forbidden to reproduce, modify, alter, transform or arrange,

disseminate, publish, distribute, concede, transfer or otherwise make available to a third party all or part of the Software on any medium and by any means, except with the express authorization of INTRASENSE or the holders of the rights on the element in question.

**5.12** The User undertakes in particular not to:

- reverse engineer, derive, disassemble or decompile the Software and generally reconstitute, reproduce or transpose its functionality.
- misappropriate or make commercial use of the Software, unless he/she has obtained prior written consent from INTRASENSE.
- interfere with the operation of the software.
- use the Software in an abusive, excessive or otherwise inappropriate or harmful manner.
- engage in or encourage any behavior that would harm or reflect negatively on INTRASENSE or the Software.

If the User does not comply with these rules, he/she may be held civilly and criminally liable, in particular on the basis of counterfeiting.

## **6. DESCRIPTION OF HOW THE SOFTWARE WORKS**

The software's functionality can be marketed as individual modules.

The User has at least the basic functions of a viewer, and depending on his

needs, the User may have access to advanced features for dedicated use.

The features are made available to the user through the activation process.

The range of accessible features consists of the following commercial references listed in Appendix 2.

## **7. AVAILABILITY AND MODIFICATION OF THE SOFTWARE - LIABILITY**

**7.1** INTRASENSE will do its utmost to ensure the proper functioning of the Software 24 hours a day, 7 days a week. In this respect, INTRASENSE is only bound by an obligation of means.

However, INTRASENSE reserves the right to make any changes and improvements to the Software that it deems necessary due to technical developments.

**7.2** Thus, for reasons of maintenance, security, testing, repair or any other nature, related to the improvement and functioning of the Software, its use may be temporarily interrupted by INTRASENSE, without prior notification. INTRASENSE will decide whether or not to grant compensation to the User in case of interruption of the Software.

The User, informed of these limits, releases INTRASENSE from any responsibility in this respect, and waives any claim and/or procedure against it as a result.

**7.3** INTRASENSE cannot be held responsible in the case of force majeure as provided for by law, or in the event of non-execution or poor execution of the Software that would not be directly caused by INTRASENSE, but would be caused by the User or a third party.

**7.4** INTRASENSE does its best to ensure the compatibility, the improvement and the stability of its Software. In this respect, INTRASENSE is only bound by an obligation of means.

In general, the User acknowledges and agrees that:

- The Software is provided "as is";
- Use of the Software is at the sole responsibility and risk of the User;
- INTRASENSE is not responsible for any use of the Software that does not comply with these TOS;
- INTRASENSE cannot be held responsible for the consequences of any kind of damage, direct or indirect, loss of data or profits, which may occur due to the use or non-use of the Software, negligence or any other reason related to the Software.

**7.5** INTRASENSE can in no way be held responsible for the malfunctioning of the Software. Indeed, the User acknowledges that the Software is not intended to replace the competence and judgement of a qualified medical practitioner, and should only be used by personnel who have been properly

trained in its use, and informed of its capabilities, and its limitations.

**7.6** In general, INTRASENSE cannot be held responsible if the User is unable to access all or part of the Software due to any technical defect or problem, including but not limited to:

- Network congestion,
- A failure of Internet service providers,
- Incompatibility with certain equipment and/or functionalities of its computer hardware,
- Human or electrical error,
- Any malicious intervention,
- Failure and/or congestion of telephone connections.

**7.7** The User guarantees INTRASENSE against any demand, claim and/or condemnation to damages that it could be threatened with or be the object of, and/or that could be pronounced against it, if these would have as cause, basis or origin, the violation by the User of the present TOS, of the legislative and regulatory provisions in force, would result directly or indirectly from the actions of the User, or would emanate from the users/partners of the User.

**7.8** The User acknowledges and accepts that the malfunctioning of the Software, or the impossibility to use it for reasons other than repair or maintenance operations, only allows him to request compensation from INTRASENSE after an interruption of more than 5 working days.

In any case, in the event that INTRASENSE is held liable for the provision of the Software, the liability

of INTRASENSE, for any reason whatsoever, shall not exceed the purchase value.

## **8. PRIVACY POLICY**

In the course of using the Software, the User may be required to collect and process personal data within the meaning of the General Data Protection Regulation (the "GDPR") and Law n°78-17 of 6 January 1978 on Data Processing, Data Files and Individual Liberties, as amended (the "French Data Protection Act") (the "Personal Data").

The User undertakes to collect and process Personal Data in accordance with the regulations in force, and in particular the GDPR and the French Data Protection Act.

## **9. INTELLECTUAL PROPERTY**

**9.1** The Software is protected by French and international laws on copyright and intellectual property, and belongs to INTRASENSE. The User must therefore strictly respect the limitations and prohibitions provided in article 5 above.

**9.2** The User is informed that INTRASENSE reserves the right to block access to the Software, in case of any breach of the rules of use of the Software by the User, or any infringement of the rights on the Software.

## **10. REVIEW**

INTRASENSE reserves the right to

modify, add and/or delete certain rules provided for in the TOS. The User will then be informed by any means. Nevertheless, the applicable TOS will be the ones that have been accepted at the time of the purchase of the Software.

However, any legislative or regulatory provisions, which would make it necessary to modify all or part of these TOS, will be applicable from the date they come into force.

## **11. SANCTIONS / TERMINATION**

**11.1** In case of violation by the User of one or more of the provisions hereof, INTRASENSE reserves the right to terminate or restrict, without any prior warning and at its sole discretion, the use and access to the Software, without any compensation.

**11.2** INTRASENSE and/or its assignees may take the necessary sanctions, including civil and criminal proceedings against the offender.

**11.3** INTRASENSE may thus terminate the license to use the Software, with or without prior warning, and with or without prior notification, and initiate all legal proceedings, in case of non-compliance by the User with the rules provided for in the TOS and, in particular in case of:

- Non-compliance with the conditions of access and use of the Software;
- Failure to pay in accordance with the provisions of the GTC;

- Fraudulent payment;
- Non-performance by the User of any of the obligations defined for the purposes hereof;
- Infringement or suspected infringement of intellectual property rights in the Software;
- Fraud or suspected fraud in the use of the Software.

## **12. MISCELLANEOUS PROVISIONS**

**12.1** If any term or condition of the TOS is held to be unlawful, invalid or unenforceable under any national law, that term or condition shall be severed without prejudice to the enforceability of the remaining provisions.

**12.2** No act, delay in taking action or other conduct, whether passive or active, on the part of either Party, shall be deemed to constitute a waiver by that Party of any of its rights and claims under the TOS unless such waiver is evidenced in writing signed by a duly authorized representative.

**12.3** In the event of a contradiction between the title of a clause and the content of the same clause, the content of the clause shall prevail.

## **13. APPLICABLE LAW - DISPUTES**

**13.1** The TOS shall be governed by and construed in accordance with the laws and regulations of France.

**13.2** Only the French language version of the contractual documents shall be enforceable against the Parties and shall be binding in the event of a

dispute. The translated versions are provided for information purposes only.

**13.3** In the event of a dispute relating to the formation, validity, performance or interpretation of the TOS, the

Parties shall attempt to resolve their dispute amicably.

**13.4** If the Parties fail to resolve their dispute amicably within two (2) months, jurisdiction is given to the Commercial Court of Montpellier.

"Appendix 1: see TOS on the Intrasense website ([www.intrasense.fr](http://www.intrasense.fr))

"Appendix 2": see below.

## DESCRIPTION OF THE SOFTWARE FEATURES

(Annex 2 of the TOS)

Myrian® is a medical software suite. Functionalities can be packaged, licensed, and marketed as individual modules. At a minimum, the user uses Myrian® platform, which provides all the basic functions of a viewer, and depending on his needs, the user can have access to advanced features for dedicated use. Features are made available to the user through the activation process.

Myrian® software suite range is composed of the following commercial references:

Device commercial reference	Description
Myrian® Platform	Tools and applications dedicated to the reading of multimodalities images
Myrian® XM-CT	Tools and application dedicated to visualization and analysis of CT images.
Myrian® XM-NM	Tools and application dedicated to the reading of PET/CT and NM/CT images
Myrian® XM-MR	Tools and application dedicated to visualization and analysis of MR images.
Myrian® XM-MG	Tools and application dedicated to the visualization and analysis of mammography and tomosynthesis images
Myrian® XP-Liver	Tools and application dedicated to visualization and analysis of CT images.
Myrian® XP-Cardiac CT	Module for coronary vessel and calcification visualization and analysis.
Myrian® XP-Lung	Module for lung analysis and volume quantification.
Myrian® XP-Lung Nodule	Module for lung nodule volumetric measurement and follow-up.
Myrian® XP-Colon	Module for virtual colonoscopy.
Myrian® XP-Breast	Module for reading and interpreting breast MRI studies with BI-RADS report.
Myrian® XP-Prostate	Module for reading and interpreting prostate MRI studies with PI- RADS report
Myrian® XP-FemalePelvis	Module for reading and interpreting female pelvis MRI studies.
Myrian® XP-AbdoFat	Module for the quantification of abdominal fat.
Myrian® XP-Vessel	Module for vessel CT visualization and analysis.
Myrian® XP-Oncology	Module for oncology follow-up
Myrian® XP-BrainPerfusionCT	Module for visualization, and analysis of parametric maps allowing the study of the hemodynamic parameters of the cerebral parenchyma
Myrian® XP-Dental	Module for the visualization and analysis of medical image derived from ConeBeam CT and CT scans of the jaw

Myrian® 2.12 is CE marked under the European Regulation 745/2017.