Instructions for Use

Relook MSK

Software as a medical device, Class I, Version 1.0

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Table of Contents

1.0 Preface

1.1 Description of the user

This document of for costumers and end users of Relook MSK software.

1.2 Internet

This document is available on the internet under the following URL:

http://www.imera.ai/support/relook/v1.0/IFU

1.3 Ordering documentation

A hard copy of this document can be requested via the following email:

support@imera.ai

1.4 Language

Version 1.0 of Relook MSK is only available in English language.

1.5 Documentation feedback

Documentation feedback is welcomed. Please contact us using the following email:

feedback@imera.ai

1.6 Name and address of the manufacture

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2.0 Description of the product

2.1 Intended Medical Indication

Relook MSK is a software programme that analyses musculoskeletal radiographs ('X-rays') and produces an output as a rectangular box around certain areas of the radiograph. These bounding boxes are suggestions to the clinician to carefully re-look for certain abnormalities. The various types of musculoskeletal radiographs that are intended for use with this software are radiograohs showing the pelvis, lower limbs, shoulder, and upper limbs (see Appendix-A for a complete list of accepted body parts and radiographic views). Relook MSK uses machine learning techniques to identify the areas in the radiographs where clinically significant abnormalities are likely to be present. The abnormalities that may be highlighted are listed in Appendix B. The software is not intended for direct diagnosis. This is a tool to encourage the clinicians to have a second look at certain areas during their usual reading process.

2.2 Characterization of User Profile

The intended users of Relook MSK are clinicians such as doctors, nurse practitioners, radiologists and reporting radiographers who routinely interpret the radiographs in their normal clinical practice. This is applicable in different settings including emergency care, urgent care, specialty care (e.g. Trauma and Orthopaedics), outpatient care, and inpatient care. Relook MSK-annotated radiographs will be available along with the original radiographs for the users when they access the patient radiographs on the picture archiving and communication system (PACS), such that they can read the original and annotated radiographs concomitantly. Relook MSK is a tool prompting for a second look and is not intended to replace a clinician's review of radiograph or his or her clinical judgment. Clinicians must not use Relook MSK-generated outputs as a suggestion for the diagnosis.

2.3 Characterization of Patient Population

Most musculoskeletal radiographs can be processed by Relook MSK software. This includes radiographs from the emergency department, as well as radiographs from the outpatient and inpatient setting. It also processes paediatric radiographs, although the outputs have lower accuracy in the version 1.0. Accepted anatomical areas include the shoulder girdle, upper and lower arm, wrist, hand and fingers, as well as the pelvis, hips, upper legs, lower legs, ankle, foot and toes (please see Appendix A for a full list of DICOM tags).

2.4 Characterization of Use Environment

Relook MSK is a software as a medical device (SaMD). This software is deployed to cloud servers and connects to the existing picture archiving and communication system (PACS) of the clients. It receives radiographs for processing and annotation. Annotated radiographs are sent back to and stored on the client's PACS as an additional radiograph within the respective study (same accession number). The end-user (the clinician) uses its regular PACS client to view the original radiograph alongside its annotated copy. This can be used in different healthcare settings such as emergency care, urgent care, specialty care (e.g. Trauma and Orthopaedics), outpatient care, diagnostic care and inpatient care.

2.5 Minimum system requirements

The imaging hardware and acquisition standards must fulfill general recommendations for medical imaging: The digital receptor should have a minimum matrix size of 1024 x 1024 with a minimum resolution of three-line pairs per millimeter. The greyscale of the images can range from 8 to 16 bits. Relook MSK software can accept cropped images. The digital radiographic images must follow the DICOM standards for medical imaging. Relook MSK software is deployed on a cloud server and is connected to the existing client's PACS and Radiology Information System (RIS) using third-party interfaces.

3.0 Using MSK Relook

3.1 Understanding the user interface

Images outputted by Relook MSK are stored on PACS as part of the same study as the original images. The images are viewed in the same way as any other radiographic view within a study. Retrieving the images for viewing depends on the user's own PACS system. The end-user can not interact with the annotation on the radiographs, they are part of the bitmap data of the DICOM file.

Relook MSK-annotated images have an additional text area at the bottom of the radiograph, containing general information about the software, instructions on how to read the annotations, a disclaimer, and the URL to the Instruction For Use document (see Figure 1).

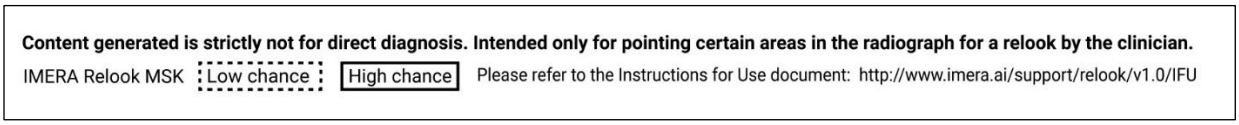

Figure 1. General information and disclaimer displayed at the bottom of the images.

Areas determined by the software for a relook are marked with rectangular bounding boxes. A text along the top border of the bounding box indicates the type of abnormality to look for. The bounding boxes appear either with solid or dotted outlines. A solid outline indicates high confidence of the algorithm that an abnormality will be found, and the dotted outline indicates lower confidence (see Figure 2.)

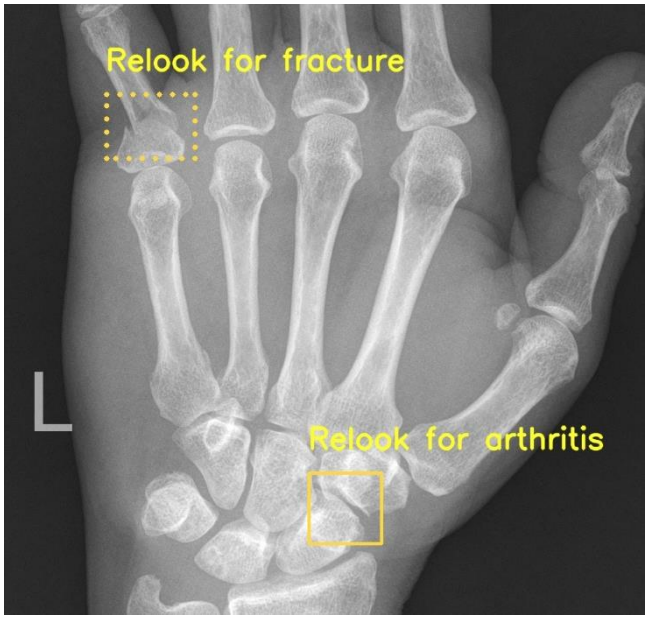

Figure 2. Example of bounding boxes produced by Relook MSK software

In case the software is not able to process the images, an error message appears, overlying the top portion of the images (see Figure 3). A list and explanation of the error codes are found on page 11 of this document.

Figure 3. Example of an error message displayed if IMERA's software can not process the image.

3.2 Recommended use

To maximise the benefits of the MSK Relook software as a support tool in guiding the attention of the user to potential areas of abnormalities on radiographs, and at the same time minimising any potential bias in the reading process, a stepwise approach to the interpretation of the study is recommended in the following order.

1. The user reads the original radiograph in the usual fashion and deducts an initial conclusion.
2. The user reviews the MSK Relook output in the annotated radiographs.
3. The user re-read the original radiograph with a focus on the relook areas as suggested by the software for potential abnormalities, if not already identified in step 1.
4. The user draws own conclusion based on the re-interpretation of the radiographs

3.3 Contraindications

Relook MSK does not provide a direct diagnosis. All results must be checked thoroughly by a qualified clinician. Relook MSK will reject radiographs with incompatible anatomical parts, or radiographs not fulfilling minimum standards (see chapter 2.4). Technically substandard images, such as over or underexposure, or artefacts on the images are accepted for processing but may lead to reduced accuracy of the software.

3.4 Warning and Remaining risks

The user must only use Relook MSK to identify areas requiring a closer relook by the clinicians. The user must use their analysis to interpret the radiographs. There may be abnormalities on the radiographs, which are not labeled by software. Conversely, not all areas that have been labeled by the software may always contain an abnormality. To indicate to the user the degree of confidence the probability of finding an abnormality

within the bounding box, the confidence of the software analysis is indicated by the type of outline produced for the bounding box(see section 0.1). Overall performance of the underlying software is such that it can pick up around 80% of the areas with abnormalities and around 40% of the bounding boxes may not contain any abnormalities. Accuracy of the the software can be lower for paediatric radiographs, radiographs of ankle joint and for highlighting the areas with soft tissue lesions or bony lesions.

3.5 Maintenance

This software and all its interfaces, which may include third-party applications, shall be maintained by a qualified and trained person.

4.0 Error messages

If the output of Relook MSK shows an error message as depicted in the Figure 3, the full explanation of the error message is given in the table below.

Table 1 List of error codes with error message and explanation

Error code	Error message to be displayed on output DICOM annotated image	Interpretation of the error code
001:000	Unsupported image modality: Refer to error code 001:000 in IFU document	Relook MSK software supports the modality descriptors for radiographs: “CR” and “DX”. This error message indicates that input DICOM modality is not “CR” or “DX”.

001:001	Invalid DICOM image (Missing modality attribute): Refer to error code 001:001 in IFU document	This error message indicates that DICOM metadata ['0008|0060'] is missing in the input DICOM image, hence input DICOM image is invalid image. DICOM metadata ['0008|0060'] indicates modality attribute.
002:000	Unsupported image characteristics: Refer to error code 002:000 in IFU document'	Relook MSK software supports PhotometricInterpretation of type "MONOCHROME1" and "MONOCHROME2". This error message indicates that input DICOM modality is not "MONOCHROME1" and "MONOCHROME2"
002:001	Invalid DICOM image (Missing PhotometricInterpretation attribute): Refer to error code 002:001 in IFU document	This error message indicates that DICOM metadata ['0028|0004'] is missing in the input DICOM image, hence input DICOM image is invalid image. DICOM meta data ['0028|0004'] indicates PhotometricInterpretation attribute
003:000	Unsupported image characteristics: Refer to error code 003:000 in IFU	Relook MSK software supports DICOM Image with row size >=500 pixels. This error message indicates that input DICOM

	document	image with row size < 500 pixels
003:001	Invalid DICOM image (DICOM Rows and PNG rows value does not match): Refer to error code 003:002 in IFU document	This error message indicates that DICOM metadata ['0028|0010'] is missing in the input DICOM image. Hence, input DICOM image is an invalid image. DICOM meta data ['0028|0010'] indicates "Row" attribute.
004:000	Unsupported image characteristics: Refer to error code 004:000 in IFU document	Relook MSK software support DICOM Image with column size >=500 pixels. This error message indicates that input DICOM image with column size < 500 pixels.
004:001	Invalid DICOM image (Missing Column attribute): Refer to error code 004:001 in IFU document	This error message indicates that DICOM metadata ['0028|0011'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data ['0028|0010'] indicates "Column" attribute.
005:000	Unsupported image characteristics: Refer to error code 005:000 in IFU	Relook MSK software support SamplesPerPixel of value "1". This error message indicates that input DICOM

	document	SamplesPerPixel is not “1”. DICOM meta data ['0028|0002'] indicates " SamplesPerPixel” attribute.
005:001	Invalid DICOM image(Missing SamplesPerPixel attribute): Refer to error code 005:001 in IFU document	This error message indicates that DICOM metadata ['0028|0002'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data ['0028|0002'] indicates " SamplesPerPixel” attribute.
006:000	Unsupported anatomy: Refer to error code 006:000 in IFU document	Relook MSK software support BodyPartExamined as defined in Appendix A of PR.09.1 Relook MSK Use Specification. This error message indicates that input DICOM BodyPartExamined is not supported. DICOM meta data ['0018|0015'] indicates "BodyPartExamined” attribute.
006:001	Invalid DICOM image (Missing BodyPartExamined attribute): Refer to error code 006:001 in IFU document	This error message indicates that DICOM metadata ['0018|0015'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta

		data ['0018|0015'] indicates "BodyPartExamined" attribute.
007:000	Unsupported x-ray view: Refer to error code 007:000 in IFU document	Relook MSK software support ViewPosition as defined in Appendix A of PR.09.1 Relook MSK Use Specification. This error message indicates that input DICOM ViewPosition is not supported. DICOM meta data ['0018|5101'] indicates " ViewPosition" attribute.
007:001	Invalid DICOM image (Missing ViewPosition attribute): Refer to error code 007:001 in IFU document	This error message indicates that DICOM metadata ['0018|5101'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data ['0018|5101'] indicates " ViewPosition" attribute.
008:000	Unsupported image characteristics: Refer to error code 008:000 in IFU document	Relook MSK software requires minimum 8-bit pixel DICOM image. This error indicates that input DICOM image has less than 8-bit pixel hence DICOM image has low quality. DICOM meta data ['0028|0100'] indicates Number of bits allocated for each pixel

		sample.
008:001	Invalid DICOM image (Missing BitsAllocated attribute): Refer to error code 008:001 in IFU document'	This error message indicates that DICOM metadata ['0028|0100'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data ['0028|0100'] indicates Number of bits allocated for each pixel sample.
009:000	Unsupported image characteristics: Refer to error code 009:000 in IFU document	Relook MSK software requires minimum 8-bit pixel DICOM image. This error indicates that input DICOM image has less than 8-bit pixel hence DICOM image has low quality. DICOM meta data ['0028|0101'] indicates Number of bits stored for each pixel sample.
009:001	Invalid DICOM image (Missing BitsStored attribute): Refer to error code 009:001 in IFU document'	This error message indicates that DICOM metadata ['0028|0101'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data ['0028|0101'] indicates Number of bits stored for each pixel sample.

010:000	Invalid DICOM image (Bits Allocated>=BitsStored): Refer to error code 010:000 in IFU document	This error message indicates that DICOM image pixels can have unintended values since number of bits allocated is more than number of bits stored. This error message requires to check DICOM meta data [‘0028|0100’] and [‘0028|0101’].
011:00	Invalid DICOM image (HighBit < 0): Refer to error code 011:000 in IFU document	This error message indicates that DICOM image pixels can have unintended values since most significant bit for pixel sample data has negative value. This error message requires to check the DICOM meta data [‘0028|0102’] attribute which indicates the most significant bit for pixel sample data.
011:001	Invalid DICOM image: Refer to error code 011:001 in IFU document	This error message indicates that DICOM metadata ['0028|0102'] is missing in the input DICOM image, hence input DICOM image is an invalid image. DICOM meta data [‘0028|0102’] attribute which indicates the most significant bit for pixel sample data.

012:000	Invalid DICOM image: Refer to error code 012:000 in IFU document	This error message indicates that DICOM metadata “patientBirthDate” has garbage values hence input DICOM image is an invalid image. DICOM meta data [‘0010|0030’] attribute which indicates the patientBirthDate.

DICOM Error Code	
001	DICOM meta tag (0008,0060) [Modality]is not present in the image
002	DICOM meta tag (0028,0004) [PhotometricInterpretation]is not present in the image
003	DICOM meta tag (0028,0010) [Rows]is not present in the image
004	DICOM meta tag (0028,0011) [Columns]is not present in the image

005	DICOM meta tag (0028,0002) [SamplesPerPixel]is not present in the image
006	DICOM meta tag (0028,0100) [BitsAllocated]is not present in the image
007	DICOM meta tag (0028,0101) [BitsStored]is not present in the image
008	DICOM meta tag (0028,0101) Invalid values for (0028,0100) [BitsAllocated] and (0028,0101) [BitsStored]; 'BitsAllocated>=BitsStored'
009	DICOM meta tag (0028,0102) [HighBit]is not present in the image
010	DICOM meta tag (0018,0015) [BodyPartExamined]is not present in the image
011	DICOM meta tag (0018,5101) [ViewPosition]is not present in the image

Warning Code	
DICOM Warning Code "001":Refer to 'Instruction For Use' document"	DICOM meta tag (0010,1010) [PatientAge]is not present in the image; It may result in false positives

System Error Code	
System Error Code "001":Refer to 'Instruction For Use' document"	Relook MSK Server encountered system error

5.0 Interoperability requirement

Relook MSK software can be either directly connected to the picture archiving and

communication system (PACS) or Radiology information system (RIS) or through a third-party interconnect. The integration environment must comply with the following.

Interface compatibility to Relook MSK software

The integration environment must provide a compatible interface with Relook MSK input and user interface.

Unique Identity to Relook MSK

Relook MSK software must be given a unique identification on PACS or RIS network.

Correct association with patient study

The integration environment must ensure that input and output DICOM images to Relook MSK software are associated with the correct patient study.

Same Storage for input and output image

The integration environment must ensure that Relook MSK software output annotated DICOM image shall be stored in the same archive as input DICOM data study is stored.

Synchronized communication

The integration environment must ensure that the external client, connecting to the Relook MSK software, request, and response is synchronized with Relook MSK software and that no endless loop exists between the integration environment and Relook MSK software.

Correct association with multiple clients

If multiple clients or customers are accessing the Relook MSK server, the integration environment must ensure that there is the correct association between the Relook MSK input and the Relook MSK output data to multiple clients.

Correctly display the Relook MSK output

The integration environment must ensure that if an end-user requests services from the Relook MSK software, response (output annotated DICOM image) processed from the Relook MSK software should be displayed to the user, along with the original, unannotated radiographs.

Data security during data communication-TLS

For secure communication, the client must support Transport Layer Security (TLS) 1.0 or later (recommended TLS 1.2 or later), for data communication between the client and the Relook MSK software.

Data security during data communication-authentication

Input request and output response must be signed by using an access key ID and a secret access key, associated with the authorized group.

Appendix A

Supported study type and radiographic view for Relook MSK:

Study Type (Anatomic Area of Interest+)	**Radiographic View(s) Supported**
SHOULDER	AP, Lateral
SCAPULA	AP, Lateral
ACJOINT	AP
CLAVICLE	AP
ARM	AP, Lateral
HUMERUS	AP, Lateral
ELBOW	AP, Lateral
FOREARM	AP, Lateral
RADIUS	AP, Lateral

Study Type (Anatomic Area of Interest+)	**Radiographic View(s) Supported**
RADIUSULNA	AP, Lateral
ULNA	AP, Lateral
WRIST	AP, PA, Lateral
HAND	AP, PA, DP, Lateral, Oblique
FINGER	AP, Lateral
THUMB	AP
PELVIS	AP, Lateral,
SSPINE	AP
SIJOINT	AP
ILIUM	AP
Coccyx	AP

Study Type (Anatomic Area of Interest+)	**Radiographic View(s) Supported**
HIP	AP, Lateral
FEMUR	AP, Lateral
KNEE	AP, Lateral
PATELLA	AP, Lateral
TIBIAFIBULA	AP, Lateral
FIBULA	AP, Lateral
ANKLE	AP, Lateral
FOOT	AP, PA, DP, Lateral, Oblique
TOE	AP, Lateral
CALCANEUS	AP, Lateral
Extremity	

Appendix-B

Fractures of the bones

Dislocations or subluxation of the joints

Arthritis of the joints

Lesions in the bone including bony spurs, bony islands and benign and suspicious bone lesions

Soft tissue lesions including significant soft tissue shadows, lesions, calcifications, ectopic bone, calcified vessels.

Radiopaque bodies in the soft tissues such as clips, staples, foreign bodies, external bodies, tubes, drains, catheters.

Internal implants in the bones and joints including various metallic orthopaedic implants and prostheses

Splints such as plaster and external splints

Appendix C

(IFU ID to link IFU content to V&V traceability and Risk control register)

IFU-001: Input DICOM image should have image quality as described in chapter 2.5 of the Use Specification Document (PR.09.1 Relook MSK Use Specification)

IFU-002: MERA Relook MSK requires plain musculoskeletal radiographs in DICOM imaging format, and images are de-identified such that DICOM header with any sensitive information

shall be either removed or masked or replaced with garbage values.

IFU-003: Error message is clearly defined and link to the IFU document is provided at the top of the image, as shown in Figure 3.

IFU-004: Relook MSK software must meet the interoperability requirement as defined in chapter 5.0.

IFU-005: Relook MSK software requires sensitive DICOM metadata to be removed or anonymized, from the input DICOM image.

IFU-006: On request, end-user or audit authority can access the audit data. Audit data shall be stored for 18-months. After 18-months, data shall be deleted. Audit data consists of the following fields but is not limited to:

- Hash-index of DICOM raw pixel data
- Day of processing
- Time of processing
- Bounding boxes produced by the software, if any
- Error messages if any (as listed in Table 1 on page 11)
- Extension field (for future needs if any, otherwise empty)

IFU-007: Output annotated DICOM image provide help on how to interpret the bounding boxes, as shown in Figure 1.