AMRA | Clinical Services

Service User Guide

AMRA® MAsS Scan

Powered by AMRA Profiler 4

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About this Service User Guide

Introduction

This Service User Guide and the *DICOM Conformance Statement* are provided as electronic Instructions for Use at https://amramedical.com/user-guides upon your subscription purchase of AMRA® MAsS Scan service.

This Service User Guide is a standalone document to be used for safe and effective operation of the AMRA® MAsS Scan service powered by AMRA Profiler 4. This document describes how to use AMRA® MAsS Scan, a service that is used to quantify global and regional fat volumes, fat fractions, and lean tissue volumes.

Version History

Version Number	Date of Revision	Updates since last version
1.0	2021-12-07	First version
2.0	2022-05-03	Updates: ● *Data to Export* section ○ Subsection *Input of patient height on the MRI console in case of GE or Philips* added ● *Appendix A* added General: Minor clarifications in text and typo corrections.
3.0	2022-08-22	Updates: ● *5: Fat distribution* and *8: Detailed fat distribution* sections, to cover improved issue notifications in the report: ○ Identified issues are now presented in case fat measurements are not provided ○ A note is presented if Liver images were not received and Liver Fat measurement could not be calculated General: New AMRA logo and graphical profile. Minor clarifications. Images were updated to match updated report.
4.0	2022-11-03	Updates: ● *Patient Data Requirements* section added ● *Manual upload via Ambra Web Portal* section ○ Updated images from the Ambra web portal ● *The Different Elements of the Report* section, image examples and text updated to match changes in report output: ○ Minor layout change of bar plots ○ Liver image is shown, without ROIs, in case Liver Fat value is not provided ○ Issue notes are presented below the Detailed assessment bar plots on page 2 ● *Issue Categories Explained* section ○ Improved issue notifications and explanations

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5.0	2022-12-20	Updates: ● *Data Transfer* section updated to reflect that AMRA can now receive and send back protected health information ● *Patient Data* section updated with Name
6.0	2023-04-12	Updates: ● *Patient Data* section updated with DOB ● *Machine-readable Format* section added
7.0	2023-08-01	Updates: ● *Legal manufacturer information, Intended Purpose, MAsS and corresponding plot, Fat distribution, Detailed fat distribution* and *Performance Specification* sections updated to harmonize the Service User Guide information between different geographical regions ● Minor clarifications
8.0	2024-05-16	Updates: ● Single leg used in case of identified issue in one of the legs and Issue Categories Explained chapters are updated to reflect that measurements affected by a quality issue will now be reported, if they are in compliance with the performance specification ● Updated text in labeling related to incident reporting
9.0	2025-01-17	Updates: ● Data transfer supplier name is changed from Ambra to InteleShare. The 510(k) clearance reference number for InteleShare is updated. ● Minor corrections.
10.0	2026-06-16	Updates: • Added the ‘Colored DICOM images’ section

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About AMRA Profiler 4

Legal Manufacturer Information

Product Name: AMRA Profiler 4 AMRA Profiler 4 is a medical device class I in Canada.	 AMRA Medical Badhusgatan 5 SE-582 22 Linköping SWEDEN www.amramedical.com support@amramedical.com
⚠ **Caution:** Clinical diagnosis should not be based solely on results shown in AMRA Profiler 4 reports. Any serious incident that has occurred in relation to AMRA Profiler 4 should be reported to AMRA at support@amramedical.com and to Health Canada.	

Explanation of symbols used in this guide and the AMRA® MAsS Scan Report

Consult electronic instructions for use

Manufacturer

Caution

Intended Purpose (Canada)

Intended Use

Indicated for use as a Magnetic Resonance (MR) diagnostic device software application for non- invasive fat and muscle evaluation that enables the generation, display and review of 2D MR medical image data.

Designed to utilize DICOM 3.0 compliant MR image datasets, acquired from compatible MR systems, to display the internal structure of the body including the liver. Other physical parameters derived from the images may also be produced.

Provides a number of quantification tools, such as Region of Interest (ROI) placements, to be used for the assessment of regions of an image to quantify liver tissue characteristics, including the determination of fat fraction in the liver, T2* and muscle volume.

These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis.

Medical Indications

- Medical conditions, where the added clinical value of detailed body composition information, as judged by a treating clinician, may assist in diagnosis.

Patient Population

- Adults

Contraindications

General contraindications for MRI apply.

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How to use AMRA® MAsS Scan Service

Requirements for Use

AMRA® MAsS Scan service has the following requirements for use:

- InteleShare platform (DG PACS, 510(k) clearance: K231360), a web-based tool for data transfer, set-up to communicate with AMRA
- PDF-reader installed on the computer in order to read/view the AMRA® MAsS Scan Report

Imaging Requirements

AMRA® MAsS Scan service has the following requirements for the input DICOM data acquired with the magnetic resonance imaging (MRI) scanner:

- MRI scanner from one of the following manufacturers: GE, Siemens or Philips
- MRI images acquired with 1.5 T or 3.0 T main magnetic field strength
- 2-point Dixon data including fat, water, in-phase and opposed-phase images
- Images acquired with inherent transmit/receive body coil unless otherwise specified
- Neck-to-knee coverage in the head-feet direction, and field-of-view that covers subcutaneous tissue of the abdomen and thighs
- A voxel volume of minimum 1.75³ mm³
- A voxel volume of maximum 4.5³ mm³
- An overlap between neighboring slabs of at least 3 cm
- T1-weighted images with a flip angle of 10 degrees and short repetition time
- DICOM files as an archive compliant with the DICOM conformance statement
- Fat, water, in-phase and opposed-phase image separation identifiable by Series Description or Image Type DICOM tags
- For liver fat assessment: Scanner manufacturer's clinical liver application images acquired with factory settings including fat fraction, fat, water and T2*/R2* images, or a multi-echo gradient-echo acquisition of the liver with at least 3 in-phase echo times

Patient Data Requirements

AMRA® MAsS Scan service has the following requirements on the input Patient Data:

- Patient Height shall be measured to the closest cm or half-inch
- Patient Weight shall be measured to the closest kg or lbs
- Patient Sex shall be provided
- Patient Age shall be provided

For detailed information on the required DICOM information, please refer to the *DICOM Conformance Statement* provided at https://amramedical.com/user-guides.

Data to Export

The below list describes which data needs to be exported for transfer to InteleShare.

- Body-slabs: Export fat, water, in-phase and opposite-phase images
- Liver image acquisition for liver fat: Export fat, water, fat fraction and R2* images, as well as in-phase/opposite-phase (GE/Philips) or Original echoes (Siemens)
- Note that compression or enhanced DICOM are not supported
- Transfer complete datasets, including body slabs and liver slabs as one study
- If alternative liver image acquisition for liver fat, T2s (T2*), is used, export all corresponding images (multi-echo series or separate spoiled GRE images with different TEs)

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Exported DICOM files must comply with the *DICOM Conformance Statement* that can be found at https://amramedical.com/user-guides. Note, that information on the patient's sex, height and weight needs to be included in the exported DICOM data. This information is typically typed in at patient registration on the MRI console.

Input of Patient Height on GE or Philips MRI Consoles

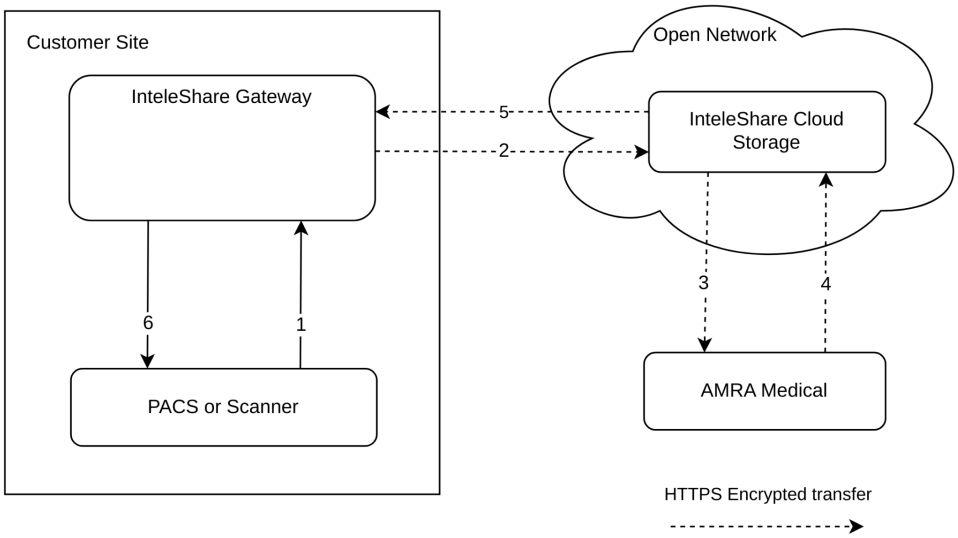
In case of GE or Philips scanners, there is no dedicated field to input patient height on the MRI console. The recommended solution is then to add the height information in the tags Study Comments (Philips) or Additional Patient History (GE) instead. A guide on how to enter the height information in order for the information to be correctly interpreted and used by AMRA can be found as a printable sheet in Appendix A. If manual data upload through InteleShare Web Portal is used, the patient height can be input in the InteleShare Web Portal instead.

Data Transfer

AMRA uses the InteleShare platform for data transfer. AMRA recommends that one of the following three transfer solutions are used to upload the data to the InteleShare Cloud; direct upload from PACS via InteleShare Gateway, transfer between InteleShare accounts via share code, or manual upload to the InteleShare Web Portal. In this chapter, "report" refers to the MAsS Scan Report.

Upload via InteleShare Gateway

This is the flow-chart of the setup when using upload from PACS via InteleShare Gateway.



Automatic data transfer via InteleShare Gateway contains the following steps:

1. *Push of DICOM images, including sex, weight and height of the patient, from PACS or MRI scanner to the InteleShare Gateway*
2. *Automatic upload of images to InteleShare Cloud Storage*
3. *Automatic download of images to AMRA*
4. *A PDF report is returned to InteleShare Cloud Storage*
5. *Automatic download of report to InteleShare Gateway*
6. *Automatic push of the report to the patient exam in PACS*

Set-up

For setup of the InteleShare Gateway solution, contact your PACS or IT administrator.
The following procedures are needed for the setup of InteleShare Gateway.

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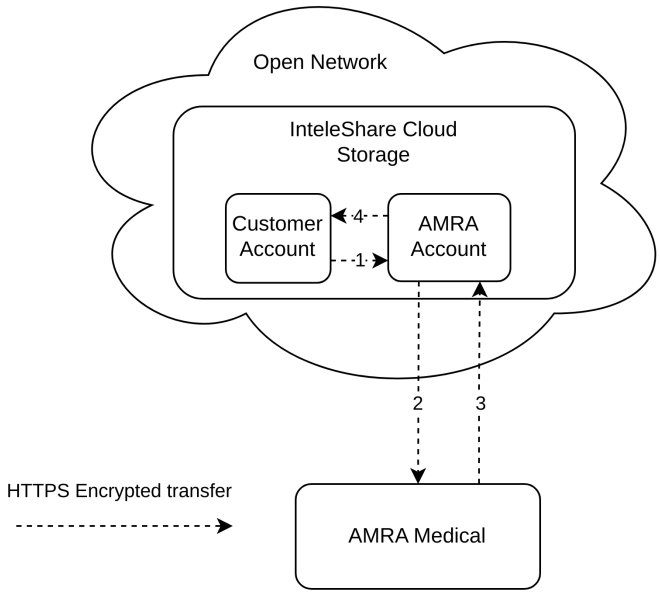
- A physical PC or virtual machine, on which the gateway can be installed, set up as a DICOM node on the same network as the PACS and/or MRI scanner.
- Configuration of a new DICOM route in the PACS or MRI scanner, so that images can be pushed to the gateway.
- The IP address, port and AE Title to be used by the gateway.
- The current IP address, port and AE Title used by the PACS.

Note that it is possible to get a notification if data was not successfully transferred from InteleShare Gateway to the InteleShare cloud. It is recommended that this notification is enabled at all times and that the receiver(s) of this notification is specified and communicated to InteleShare at set-up.

Upload via InteleShare Share Code

This transfer option can be selected if the site is already using InteleShare and have an account. The data transfer can then be done via share code in the InteleShare cloud. This is the flow-chart when using upload via share code.



Automatic data transfer via InteleShare Share Code contains the following steps:

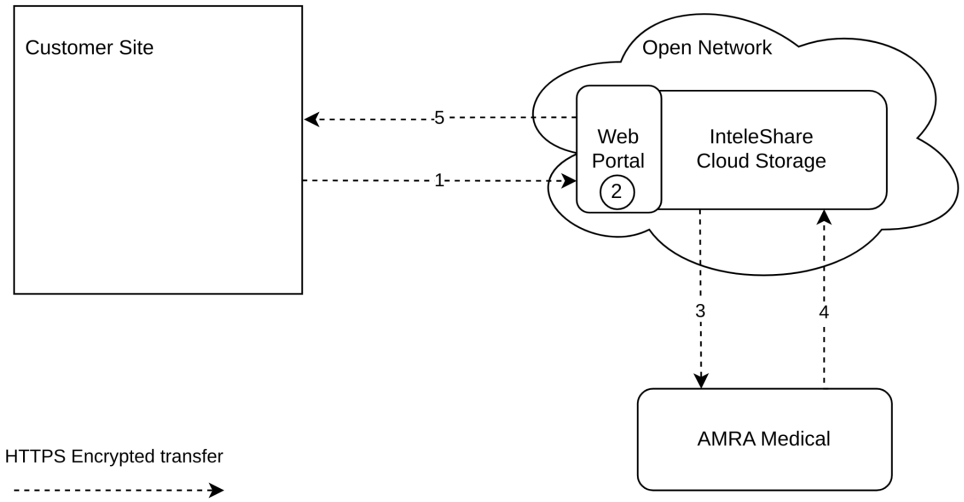
1. *DICOM images, including sex, weight and height of the patient, are shared to AMRA's Account, via share code and the routing rule set up*
2. *Automatic download of DICOM images to AMRA*
3. *Automatic upload of the report to AMRA's Account*
4. *Automatic share of the report to the Customer's Account, via share code and routing rule set up*

Set-up

For set-up of the InteleShare Share Code solution, a share code and routing rule needs to be setup for the Customer Account as well as for the AMRA account in InteleShare cloud. Contact your local PACS or IT administrator.

Manual Upload via InteleShare Web Portal

This is the flow-chart for manual upload to InteleShare Web Portal.



Manual data transfer via InteleShare Web Portal contains the following steps:

1. *DICOM images, including sex, weight and height of the patient, are manually uploaded to the InteleShare Web Portal*
2. *Patient ID, sex, height and weight can be modified in the web portal, if needed*
3. *Automatic download of DICOM images to AMRA*
4. *Automatic upload of the report to InteleShare Cloud Storage*
5. *Manual download of the report from the InteleShare Web Portal*

Set-up

The only requirement to upload images manually to InteleShare is a computer with Internet access. Browser requirements and instructions for the different steps (registration, log in, upload, download and view reports) are described later in this chapter.

Browser Requirements

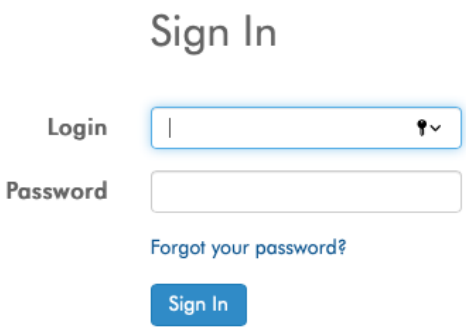
Recommended browser: Google Chrome
Other compatible browsers: Microsoft Internet Explorer 9 or later, Microsoft Edge, Apple Safari and Firefox.

Registration

You will be sent an e-mail invite where you will be asked to register for the InteleShare platform. The invite is sent from support@amramedical.com, please check your spam folder if you haven't received the invite after service subscription startup.

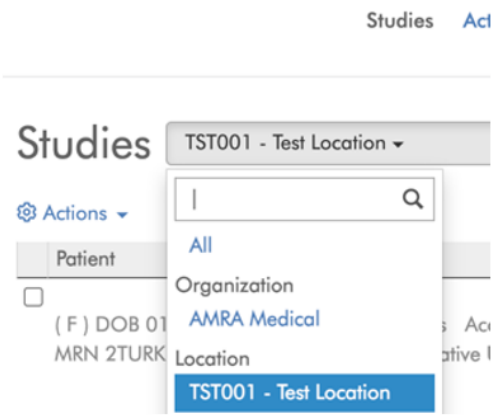
Logging In

To log in, go to: https://amra.ambrahealth.com/
Your email address will be your Login.



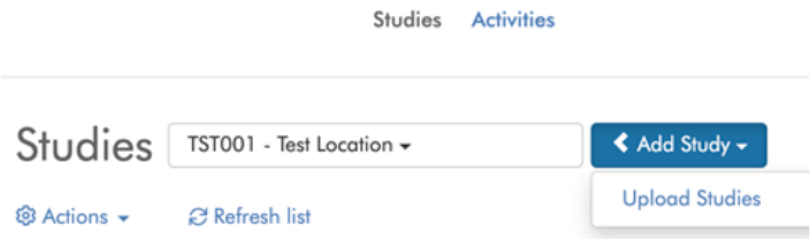
Uploading Studies

1. From the Studies drop-down, select the appropriate location/site.

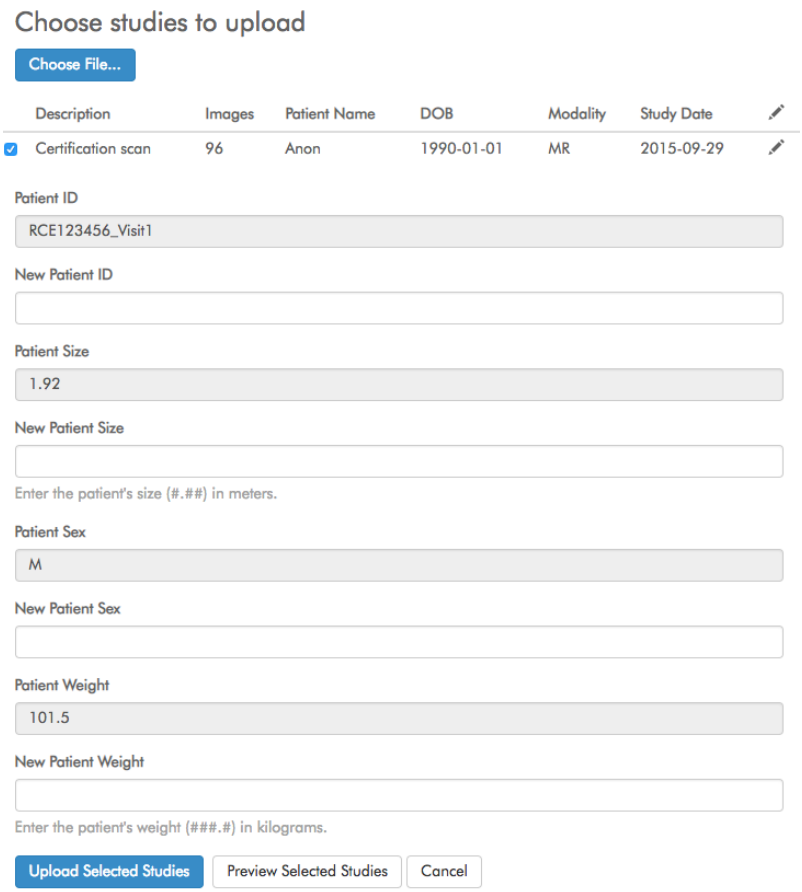


   You will only see the locations that are relevant to your studies. In the startup email, you will receive information about the location name.

2. Click ‘Add Study’ then ‘Upload Studies’.



3. During manual upload you will have the chance to update specific DICOM tags. The resulting MAsS Scan report will be based on the given metadata in these fields, so make sure that they are correct.

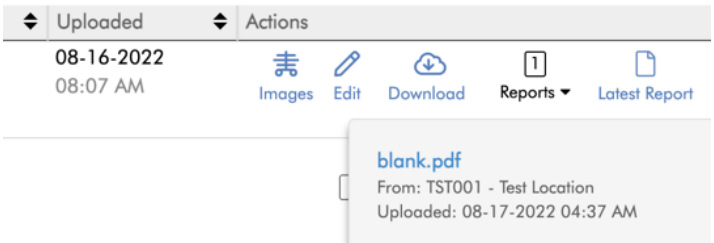


Please note, that any changes done after upload will not automatically be transferred to us. Please email support@amramedical.com alerting us to any changes.

Download and View Reports

When data has been analyzed and results are available, you will receive an e-mail notification. You can then log-in and view/download the report. This is best accomplished with Chrome.

1. From Studies drop-down, select the appropriate site/location.
2. To view, click on the Reports icon from the Actions on the right-hand side of the study in the worklist.



3. Double click the desired report to download.

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De-identification

AMRA is not responsible for de-identification of data. If de-identification is required then the data shall be de-identified before it is shared with AMRA.

The *DICOM Conformance Statement* states which DICOM tags are required in order to generate the MAsS Scan Report output. AMRA will not actively screen for protected health information in the received data.

Cybersecurity

The MAsS Scan report requires an installed PDF-reader on a computer in order to read/view the report. This computer should have an operating system and a viewer kept up to date as well as an updated anti-virus software. Please contact your local system administrator should you have any questions regarding cybersecurity measures or if you suspect any cybersecurity incidents.

Support

If you have any questions, please contact AMRA at support@amramedical.com.

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The AMRA® MAsS Scan Report

This chapter provides the user of the AMRA® MAsS Scan report with more detailed information on the underlying concepts, measurement definitions, how to interpret the different elements of the report, and how issues in input data are handled.

Underlying Concepts

Reference Population

In the AMRA® MAsS Scan, a reference population of more than 30,000 individuals is used. Each individual in this reference population has its own set of data (height, weight, sex) and body composition measurements calculated by AMRA. The reference population is used to calculate informatics measurements (Muscle Fat Index and Muscle Volume Index) for the patient and to put the patient in a relevant context that is helpful when assessing his/her data.

Virtual Control Group

The patient specific virtual control group is extracted from the reference population by finding a group of individuals with the same sex and similar body size (BMI ± 2 kg/m^2) as the patient. With this, each patient that gets a MAsS Scan will get their own individualized reference group. The virtual control group is created based on the Patient Data (height, weight and sex information) that is provided in conjunction with the upload of MRI data to InteleShare.

The patient specific virtual control group is used in two ways; to calculate the Muscle Volume Index and to present an individualized statistical reference group (blue field) in the different visual elements of the report. The blue field in the bar plots and MAsS plot represents the interquartile range (25^{th}-75^{th} percentile) of the virtual control group and is given as a reference to help assess if the patient's measurement is within the statistically expected range, given its sex and body size.

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.

⚠ **Caution:** If comparing reports of a patient scanned at two different points in time, keep in mind that the virtual control group does depend on the patient's sex and weight, which may differ between time points, resulting in a different virtual control group.

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Definitions of Measurements and Anatomical Regions

Anterior Thigh Muscle Group

Includes quadriceps femoris, sartorius and tensor fascia latae.

Posterior Thigh Muscle Group

Includes gluteus muscles, iliacus, adductor muscles and hamstring muscles.

Muscle Fat

Muscle Fat is the fraction of adipose tissue in the muscle, also known as muscle fat infiltration or intramuscular fat. Defined as the average proton density fat fraction within the Muscle Volume. Muscle Fat is measured in percentages (%).

Muscle Volume

The fat-free muscle volume, i.e. the volume of active tissue in the muscle. Defined as the volume of all voxels with fat fraction <50%. Muscle Volume is measured in liters (L).

Muscle Fat Index

Defined as the deviation of the patient's Muscle Fat from the median Muscle Fat within the sex-specific reference population. The Muscle Fat Index is given in percentage points (pp). This is an informatic measurement that relies on provided Patient Data to be calculated.

Muscle Volume Index

Defined as the number of standard deviations the patient's Muscle Volume deviates from the mean Muscle Volume within the patient's virtual control group. The Muscle Volume Index is a z-score, given in number of standard deviations (SD). Muscle Volume Index is Muscle Volume properly adjusted for body size – a known confounding factor for muscle volume assessment unrelated to muscle health. This is an informatic measurement, that relies on provided Patient Data to be calculated.

Muscle Assessment Score (MAsS)

Defined as the combination of Muscle Fat Index and Muscle Volume Index, separated by a "/".

Visceral Fat

Defined as the volume of adipose tissue within the abdominal cavity, excluding adipose tissue outside the abdominal skeletal muscles and adipose tissue and lipids within the cavity and posterior of the spine and back muscles. Visceral Fat is measured in liters (L).

Subcutaneous Fat

Defined as the subcutaneous adipose tissue volume in the abdomen from the top of the femoral heads to the top of the thoracic vertebrae, T9. Subcutaneous Fat is measured in liters (L).

Liver Fat

Defined as the average proton density fat fraction in regions of interest in the liver. Liver Fat is measured in percentages (%).

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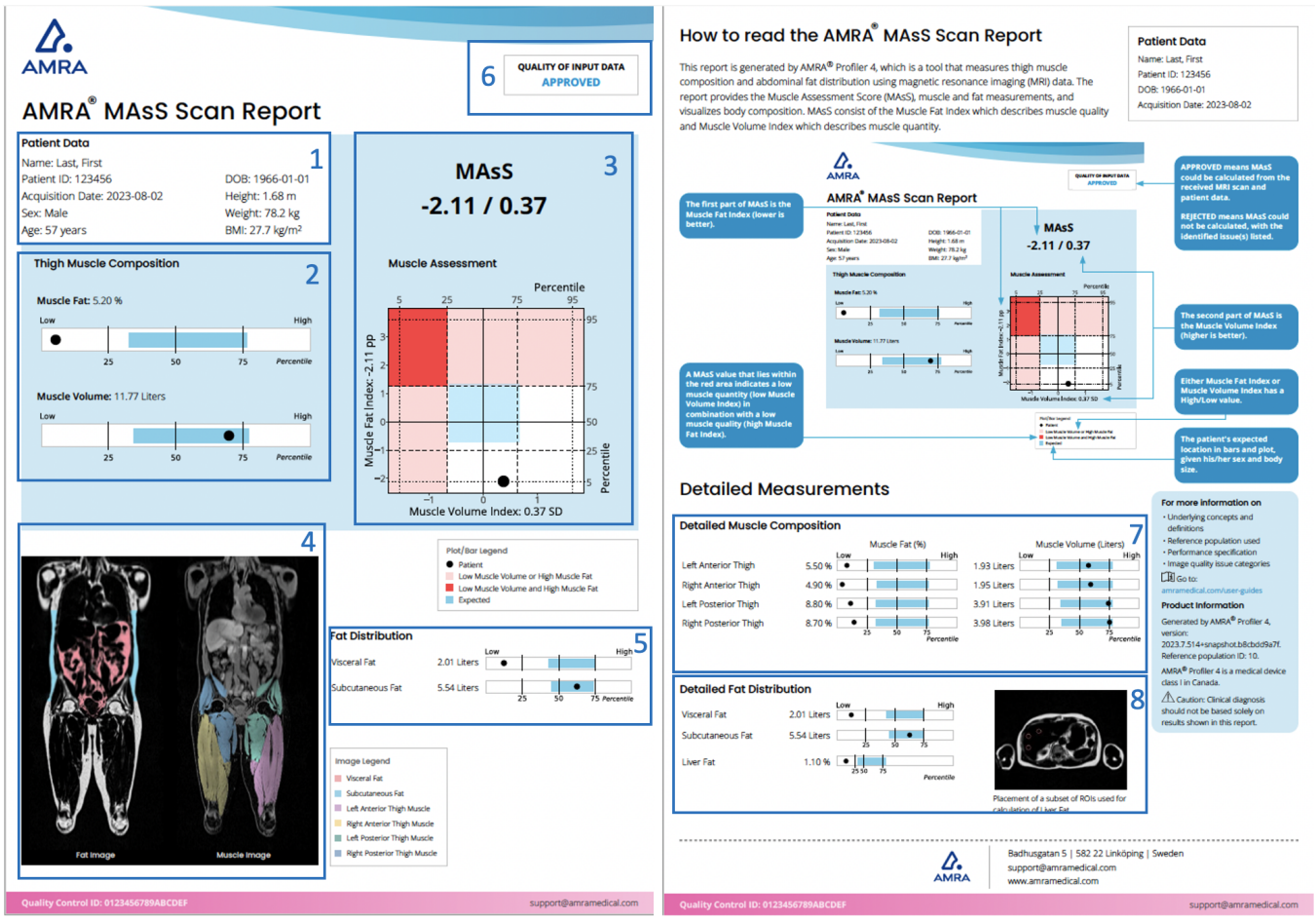
The Different Elements of the Report

The MAsS Scan report contains several different elements, which are described in this section.



The MAsS Scan report, with references to the following descriptions of each element (1-8).

1: Patient Data

The Patient Data element presents the patient specific metadata. This data is used as ground for the results in the report, both in measurements and in the visual elements presented.

Information	Source of information (DICOM tag or other)	Possible to modify in case of manual upload (YES/NO)
Name	(0010, 0010) Patient's Name	YES
DOB	(0010,0030) Patient's Birth Date	YES
Patient ID	(0010,0020) Patient ID	YES
Acquisition Date	(0008,0022) Acquisition Date Attribute	NO
Sex	(0010,0040) Patient's Sex	YES
Age	(0010,1020) Patient's Age	NO
Height	(0010,1020) Patient's Size (m)	YES
Weight	(0010,1030) Patient's Weight (kg)	YES
BMI	Weight / Height^2 (kg/m^2) Calculated by AMRA, given the received Weight and Height numbers.	NO

In case any of the Patient Data was omitted at upload, the value is replaced by a dash "–" in the Patient Data element. Specifically, in case height, weight or sex is omitted, the MAsS Score cannot be calculated and the plots will be presented blank in the MAsS Scan report.

Note that the Name and DOB (Date of Birth) fields can be configured to not be output. This is configured at startup of service.

The Patient ID tag needs to be populated with a string or number, unique for the patient, that is easily accessible for the site. It will be used to identify a specific dataset when AMRA communicates with you. Always refer to the Patient ID if there is a need to contact AMRA support about a specific examination.

2: Thigh Muscle Composition

Measurements

The muscle composition measurements give an objective measure of the thigh muscle fat and muscle volume. The Muscle Fat measurement is calculated as the mean muscle fat infiltration in the anterior thigh muscle groups in both legs. The Muscle Volume measurement is calculated as the thigh fat-free muscle volume of both the anterior and posterior thigh muscle groups.

Bar plots

Each muscle composition measurement is visualized in a bar plot to help put the patient's measurement in a relevant context. The patient's measurement (black dot) is compared to the distribution of measurements within a sex specific reference population (white bar). The 25th, 50th and 75th percentiles of this reference population are presented as solid lines. The

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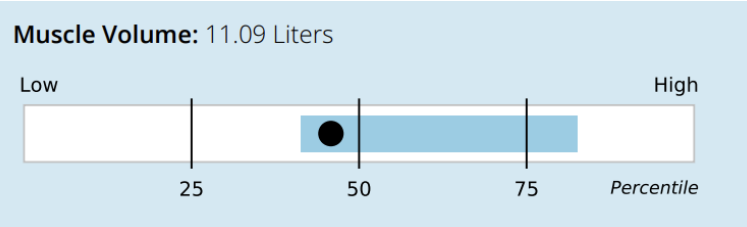
distribution within the patient's virtual control group (blue field) shows the expected range of the muscle measurement, given the provided patient's sex and body size at time of scan.

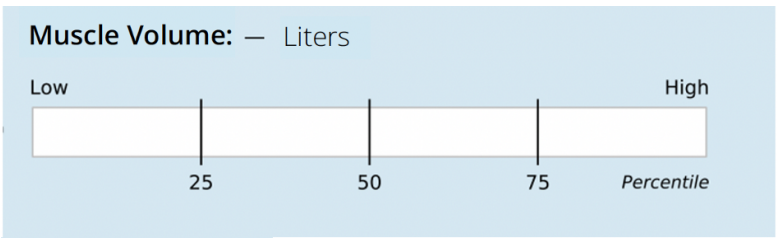


Example: The patient's Muscle Volume is slightly below the median among individuals in the reference population with the same sex (below the 50th percentile). The Muscle Volume is within what could be expected, given the patient's sex and body size (within the blue field), however, often individuals similar to him/her has a higher Muscle Volume (patient is in the left end of the blue field).

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.

Handling of identified input data issues

If issues in the MRI data are identified, the quality of the measurements cannot be guaranteed to be within the stated performance and the affected measurement(s) are therefore not reported. This is indicated by a dash, "–", instead of a value and a blank bar plot will be presented, with no patient marker or expected field visualized.



Example: Issue with the MRI scan resulting in that the Muscle Volume measurement could not be calculated within stated performance. A dash is output instead of a value and a blank bar plot is presented.

If there is an issue identified with the provided Patient Data, values will be presented, but a blank bar plot will be presented, with no patient marker or expected field visualized.

3: MAsS and Corresponding Plot

The Muscle Assessment Score (MAsS) is the combination of Muscle Fat Index (muscle quality) and Muscle Volume Index (muscle quantity) for the patient. The score may assist the clinician in diagnoses by providing objective measurements.

The Muscle Fat Index is a measure of inactive tissue in the muscle. A negative Muscle Fat Index means there is a lower fraction of fat in the muscles compared to the median Muscle Fat within the sex-specific reference population. A positive value means there is a high fraction of fat in the muscles, which indicates a lower muscle quality. A Muscle Fat Index of zero corresponds to the median muscle fat infiltration in the sex specific reference population.

The Muscle Volume Index is a measure of how the patient's Muscle Volume deviates from the mean Muscle Volume within the patient's virtual control group. A positive Muscle Volume Index value means there is a high quantity of fat-free muscle tissue for the patient's body size and sex. A negative value means there is low quantity of fat-free muscle tissue for the patient's body size. A Muscle Volume Index of zero corresponds to the mean within the patient's virtual control group.

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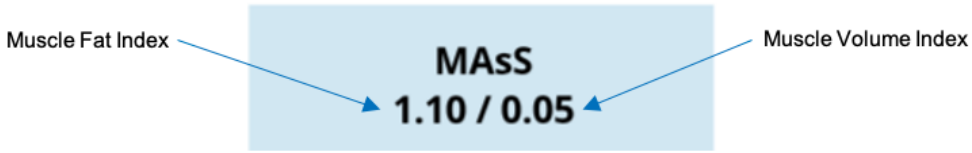


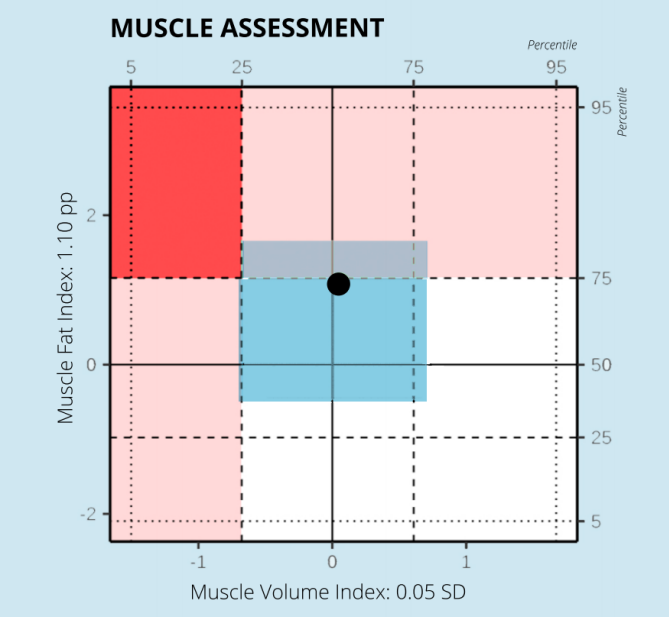
Example: A MAsS of 1.10 / 0.05 means that the patient has elevated muscle fat (1.10 percentage points higher than the median among individuals with the same sex) and an expected level of muscle volume (0.05 standard deviations higher than the mean within his/her virtual control group).

The Muscle Assessment plot visualizes the patient's MAsS. The patient's position in the plot is shown by the black dot. The vertical position (y-axis) shows the patient's Muscle Fat Index and the horizontal position (x-axis) shows its Muscle Volume Index.

The pink areas mark the location where either the Muscle Fat Index is high (above 75th percentile) or Muscle Volume Index is low (below 25th percentile).

The red area marks the combination of high Muscle Fat Index and low Muscle Volume Index. The blue field shows the patient's statistically expected location in the two dimensions (the interquartile range of the patient's virtual control group).

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.



Example: This patient presents with an elevated muscle fat (Muscle Fat Index above 0). It is close to the pink area, which indicates that the elevation is quite high. It is within the expected range, given the patient's sex and body size (within the blue field) even if it is in the higher end. The muscle volume is close to the mean among individuals in the reference population (Muscle Volume Index close to zero), and as expected, given the patient's sex and body size (in the middle of the blue field). The overlapping pink and blue area means that it is common for individuals, with the same sex and similar BMI as the patient, to have a high Muscle Fat Index.

4: Coronal Images

Representative coronal fat and water images of the patient, where the segmented volumes used to calculate the measurements are visualized with different colors. The color of each segmentation is explained in the image legend next to the images. This gives the reader an overview of the muscle and fat status within the patient's body.

In case there is an issue identified in the MRI data, resulting in that a measurement cannot be provided, no segmented volume is visualized for that region in the coronal images.

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5: Fat Distribution

Measurements

The measurements of abdominal adiposity of the patient may assist in diagnosis and is given as complementary information in the MAsS Scan report, to give a full picture of the patient's body composition. The objective measurements presented in this section, Visceral Fat and Subcutaneous Fat, allows for assessment of body composition changes.

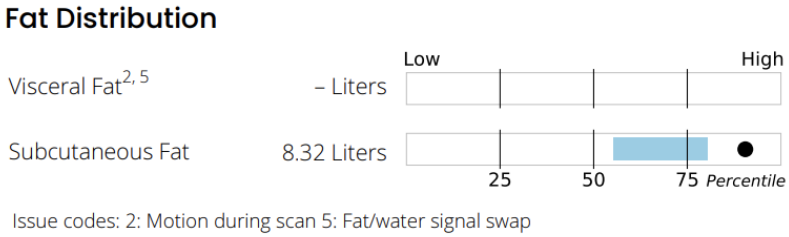
Bar plots

Each fat distribution measurement is visualized with a bar plot to help put the patient's measurement in a relevant context. The patient's measurement (black dot) is compared to the distribution of measurements within a sex specific reference population (white bar). The 25th, 50th and 75th percentiles of this reference population are presented as solid lines. The distribution within the patient's virtual control group (blue field) shows the expected range of the fat distribution measurement, given the provided patient's sex and body size at time of scan.

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.

Handling of identified input data issues

If issues in the MRI data are identified, the quality of the measurements cannot be guaranteed to be within the stated performance and the affected measurement(s) are therefore not reported. This is indicated by a dash, "–", instead of a value and a blank bar plot will be presented, with no patient marker or expected field visualized. A description of the identified issue(s) is presented below the bar plots.



Example: Issues with the MRI scan resulting in that Visceral Fat could not be measured within the stated performance. A dash is output instead of a value and the bar plot is blank. Issue 2: "Motion during scan" and Issue 5: "Fat/water signal swap" affected the Visceral Fat measurement, as can be seen by the super script numbers.

If there is an issue identified with the provided Patient Data, values will be presented, but the bar plots will be blank, with no patient marker or expected field visualized.

6: Quality of Input Data

This element gives a quick information on the quality status of the input data that lie as ground for the data presented in the report. To calculate measurements within the stated performance, the input data (MRI and Patient Data) need to be of sufficient quality.

APPROVED/REJECTED status

If the quality of input data was sufficient to calculate the MAsS, status is APPROVED. If the quality was not sufficient, status is REJECTED. In case of REJECTED, a notification is given, with the issue code and a short description of the issue. The possible issues that can be reported are listed and further explained in the *Issue categories explained* chapter.

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Example: Quality of input data was sufficient to calculate MAsS. Status is APPROVED.

Example: Quality of input data was not sufficient to calculate MAsS. Status is REJECTED.
Issue 3: "Region partly outside field of view" was identified.

Single leg used in case of identified issue in one of the legs

If there are any issues identified for any of the legs, only the leg with less severe issues is used for muscle composition calculations (Muscle Fat and Muscle Volume with corresponding bar plots). The informatics measurements that depend on these measurements (Muscle Fat Index, Muscle Volume Index, MAsS and the corresponding muscle assessment plot) is calculated from the dependent measurements if they are in compliance with the Performance Specification. In such cases, the quality status will be APPROVED but there will be a notification presented, on which leg was used. This information can be of importance if comparing two MAsS Scan reports from two different timepoints for the same patient. When this happens, it is also clear from the Detailed measurements section on page 2, that one of the legs has an issue.

Example: Issue was identified for one of the legs, so the calculation of MAsS is based on muscle composition calculations of one leg only. The status is APPROVED. There is a note telling which leg was used for muscle assessment.

7: Detailed Muscle Composition

Measurements

The detailed muscle composition section presents the separate muscle composition values for the anterior and posterior thigh muscle groups as complementary information, allowing for assessment of differences in muscle composition between the legs.

Bar plots

Each muscle composition measurement is visualized in a bar plot to help put the patient's measurement in a relevant context. The patient's measurement (black dot) is compared to the distribution of measurements within a sex specific reference population (white bar). The 25th, 50th and 75th percentiles of this reference population are presented as solid lines. The distribution within the patient's virtual control group (blue field) shows the expected range of the muscle measurement, given the provided patient's sex and body size.

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.

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Handling of identified input data issues

If issues in the MRI data are identified, the quality of the measurements cannot be guaranteed to be within the stated performance and the affected measurement(s) are therefore not reported. This is indicated by a dash, "–", instead of a value and a blank bar plot will be presented, with no patient marker or expected field visualized. A description of the identified issue(s) is presented below the bar plots.

If there is an issue identified with the provided Patient Data, values will be presented, but the bar plots will be blank, with no patient marker or expected field visualized.

8: Detailed Fat Distribution

Measurements

In this element, the fat distribution measurements from the front page are presented together with the Liver Fat measurement, as complementary information. This allows for full assessment between the different adipose tissue depots.

Bar plots

Each fat distribution measurement is visualized in a bar plot to help put the patient's measurement in a relevant context. The patient's measurement (black dot) is compared to the distribution of measurements within a sex specific reference population (white bar). The 25th, 50th and 75th percentiles of this reference population are presented as solid lines. The distribution within the patient's virtual control group (blue field) shows the expected range of the muscle measurement, given the provided patient's sex and body size at time of scan.

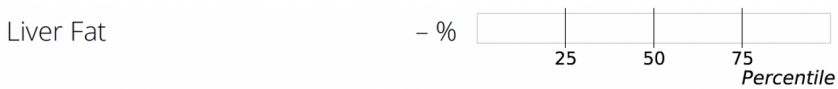
Liver fat has a skewed distribution in a general population, where most individuals have little liver fat. Therefore, the Liver Fat bar plot is scaled differently than the other bars plots, for easier interpretation.

⚠ **Caution:** The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy.

Handling of identified input data issues

If issues in the MRI data are identified, the quality of the measurements cannot be guaranteed to be within the stated performance and the affected measurement(s) are therefore not reported. This is indicated by a dash, "–", instead of a value and a blank bar plot will be presented, with no patient marker or expected field visualized. A description of the identified issue(s) is presented below the bar plots.

If no dedicated Liver images were received, a Liver Fat measurement cannot be calculated. This is indicated by a dash, "–", instead of a value and a blank bar plot will be presented, with no patient marker or expected field visualized. A notification will be presented below the bar plot, to inform about this.



Note: Liver Fat could not be calculated, since no Liver images were received.

Example: No dedicated Liver images were received for this patient. No Liver Fat value is presented and the bar plot is blank.

If there is an issue identified with the provided Patient Data, values will be presented, but the bar plots will be blank, with no patient marker or expected field visualized.

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Liver image

A representative slice of the liver is presented, with the ROIs placed in this slice visualized. The ROIs are a subset of the total number of ROIs used for calculation, which are evenly distributed within the liver. The image is either a Proton Density Fat Fraction (PDFF) image or a fat image, depending on which image was provided for Liver Fat calculations.

In case there is an issue identified in the MRI data of the liver, resulting in that a measurement cannot be provided, no ROIs are visualized in the Liver image.

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Issue Categories Explained

Input data issues can occur either in the MRI data or in the Patient Data. If the issue affects a measurement a short description of the identified issue will be presented. If the affected measurement is in compliance with the Performance Specification the measured value is reported, otherwise the value is omitted. The following sections explain more about the different issue categories. AMRA proposes remedial actions and how issues can be prevented going forward.

MRI Data Issues

Issue code	Short description given in report
1	Metal artifact
2	Motion during scan
3	Region partly outside field of view
4	Faulty alignment of adjacent slabs
5	Fat/water signal swap
6	Positive fat bias
10	Affected by strong negative fat signal
99	Other uncategorized issue

Table of issue categories used in AMRA® MAsS Scan report to identify issues in the MRI data.

Issue 1: Metal artifact

The measurable region contains an imaging artifact specific to the presence of metal within the imaging volume, with an adverse effect on image quality. This can occur if the patient has a metal implant/prosthesis/device, metal in their clothing or jewelry/piercings have not been removed.
Remedial action: Rescan all sequences if the metal is removable. If the metal is an immovable implant, prosthesis, or device, no rescan of the patient shall be done.
To prevent recurrence: Ensure all patients are free from metallic objects, jewelry and piercings and that clothing is metal free, prior to MRI acquisition.

Issue 2: Motion during scan

The measurable region contains motion imaging artifacts, with an adverse effect on image quality. This can occur if any part of the patient's body moves during the scan.
Remedial action: Rescan all sequences.
To prevent recurrence: Ensure the patient remains as still as possible during the scan and repeat affected sequences at MRI acquisition, paying particular attention to the patient's compliance with breath-hold instructions.

Issue 3: Region partly outside field of view

The measurable region is wholly or partly outside of the imaging field of view. This can occur if the patient is not positioned correctly or has moved during or in-between sequences.
Remedial action: Rescan all sequences.
To prevent recurrence: Ensure the patient is positioned centered and straight on the scanner table. Ensure the arms and legs are not abducted from the body and air gaps between the limbs are minimized as far as site procedures allow. Take extra

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care to ensure the patient is not given any support underneath the legs. Prior to finalizing the scan, ensure the images contain all measurable anatomy. Repeat all sequences when improved patient positioning is deemed necessary.

Issue 4: Faulty alignment of adjacent slabs

The measurable region encompasses several incongruent or misaligned imaging slabs. This can occur when the MRI sequences are manually planned/angled, table positions altered, slice thickness/number altered, or the patient has changed position during or in-between sequences.
Remedial action: Rescan all sequences.
To prevent recurrence: Ensure table positions match those provided at protocol installation. Ensure the slabs are not manually planned or angled. Ensure the patient does not move or change position and complies with breath-hold instructions.

Issue 5: Fat/water signal swap

The measurable region contains an imaging artifact specific to a fat and water signal swap, with an adverse effect on image quality.
Remedial action: Rescan all sequences paying particular attention to MRI imaging artifacts at acquisition. If a fat/water swap is identified at acquisition, rescan any affected sequences.
To prevent recurrence: Ensure the patient is positioned centered and straight on the scanner table. Ensure the arms and legs are not abducted from the body and air gaps between the limbs are minimized as far as site procedures allow. Take extra care to ensure the patient is not given any supports underneath the legs and clothing is metal free.

Issue 6: Positive fat bias

The measurable region contains an area where the fat signal has a positive bias, which results in an erroneously elevated muscle fat infiltration measurement. This occurs mainly with Philips' scanners with software versions < 5.4 (not supported), but can, on rare occasions, happen with other scanners.
Remedial actions: If this issue occurs, please contact AMRA support for further guidance.
To prevent recurrence: If this issue occurs, please contact AMRA support for further guidance.

Issue 10: Affected by strong negative fat signal

The measurable region contains a strong negative fat signal close to, or within, the region of measurement, which results in erroneously lowered volume measurements. This issue can occur if there is iron present in the abdomen/intestines.
Remedial actions: None. The patient shall not be rescanned.
To prevent recurrence: None.

Issue 99: Other uncategorized issue

There is an issue with the MRI data that does not fit into any of the above categories. For more information on the issue that has occurred, please contact AMRA support.

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Patient Data Issues

Issue code	Short description given in report
11	Missing patient data
12	Unreasonable height or weight

Table of issue categories used in AMRA® MAsS Scan report to identify issues in the Patient Data.

Issue 11: Missing patient data

Required patient data height, weight, or sex, was not provided at upload to InteleShare. The omitted patient data can be determined in the 'Patient Data' section of the report.
Remedial action: Provide the missing patient data, either by re-uploading the images with corrected metadata (in case of upload is done via InteleShare Gateway or InteleShare Share Code) or add it manually to the examination in InteleShare Webportal (in case of manual upload). Notify AMRA support that modification has been done, so that a re-analysis can be triggered and a new report generated. Always refer to the Patient ID when communicating with AMRA about a specific dataset. Note that the patient shall not be rescanned.
To prevent recurrence: Ensure patient data is complete and accurate at upload. If any further guidance is needed, please contact AMRA support.

Issue 12: Unreasonable height or weight

BMI calculated from the input height and weight value is outside the interval of 10-100 kg/m^2. This can occur if incorrect values are input at upload to InteleShare or the values are not represented in conventional SI units.
Remedial action: Check the height and weight values presented in the 'Patient Data' section of the report and update the numbers to the correct values, either by re-uploading the examination with corrected metadata (in case of upload via InteleShare Gateway or InteleShare Share Code) or modify it manually for the examination in InteleShare Webportal (in case of manual upload). Notify AMRA support that patient data has been modified, so that a re-analysis can be triggered and a new report generated. Always refer to the Patient ID when communicating with AMRA about a specific dataset.
Note that the patient shall not be rescanned.
To prevent recurrence: Ensure patient height and weight are correct at upload. If any further guidance is needed, please contact AMRA support.

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Machine-readable Format

There is an option to get the information from the MAsS Scan report delivered on a machine-readable format (JSON), in addition to the PDF report. If this is of interest, contact AMRA support at support@amramedical.com for more information.

⚠ **Caution:** The content of the machine-readable file shall always be used in conjunction with the PDF report delivered at the same time.

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Colored DICOM images

There is an option to get calibrated and processed colored DICOM fat and water images generated by AMRA Profiler 4, in addition to the PDF report, regulated by the contract. The PDF report includes representative coronal fat and water images of the patient (2D representation). With this add-on, full 3D volumes of the segmentations are provided, allowing the clinician to gain a better understanding of which regions have been analyzed.

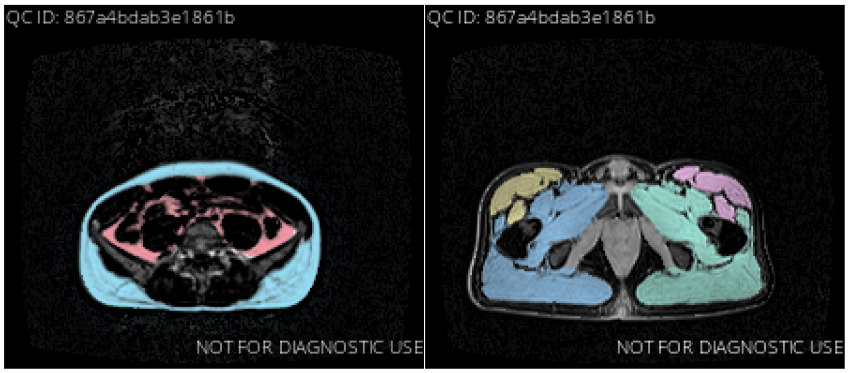
⚠ **Caution:** The colored DICOM images shall always be used in conjunction with the PDF report delivered at the same time.

⚠ **Caution:** The colored DICOM images are not for radiological diagnostic use.

The calibrated and processed colored DICOM images are not intended for radiological diagnostic analysis and must only be used as a supplementary visualization tool. The color of each segmentation is explained in the image legend next to the images on the front page of the PDF report.

In the PDF report there is a QualityControlD at the bottom of the report, the corresponding ID for the colored DICOM images can be found in the DICOM Derivation Description (0008,2111) information tag as well as at the top of each colored DICOM image (See example below). This ID shall always be used to ensure that the correct colored DICOM images are viewed with the correct PDF report.

The colored DICOM images gives the reader an overview of the muscle and fat status within the patient's body. In case there is an issue identified in the MRI data, resulting in that a measurement cannot be provided, no segmented volume is visualized for that region in the colored DICOM images.



Example: Calibrated and processed colored DICOM fat image (left) and water image (right). The fat example image shows the Visceral Fat in red and Subcutaneous Fat in blue. The water image shows the anterior and posterior left and right thigh muscles regions in different colors (see legend in the PDF report). On the top each image is the QualityControlD (QCID), which shall always be used to ensure that the correct colored DICOM images are viewed with the correct PDF report.

The colored DICOM images includes following information tags:

- Contributing Equipment Sequence (0018,A001)
  - Purpose of Reference Code Sequence (0040,A170) = 109102, DCM, "Processing Equipment"
  - Manufacturer (0008,0070) = AMRA Medical AB
  - Manufacturer's Model Name (0008,1090) = AMRA Profiler 4
  - Software Versions (0018,1020) = [*AMRA Profiler 4 software version*]
- Derivation Description (0008,2111) = "CAUTION: NOT FOR DIAGNOSTIC USE, QualityControlID: XXXXXX."
- SourceApplicationEntityTitle (0002,0016) = AMRA Profiler 4

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Reference Population Characteristics

	Total	Females	Males
N	30176 (100.0%)	15631 (51.8%)	14545 (48.2%)
Age (years)	64.7 (7.5)	64.1 (7.3)	65.4 (7.6)
Race [White] (No.)	29136 (96.6%)	15099 (96.6%)	14037 (96.5%)
Race [Black] (No.)	229 (0.8%)	130 (0.8%)	99 (0.7%)
Race [Asian] (No.)	354 (1.2%)	134 (0.9%)	220 (1.5%)
Race [Chinese] (No.)	95 (0.3%)	60 (0.4%)	35 (0.2%)
Race [Mixed] (No.)	139 (0.5%)	90 (0.6%)	49 (0.3%)
Race [Other] (No.)	154 (0.5%)	86 (0.6%)	68 (0.5%)
Weight (kg)	76.0 (15.2)	68.9 (13.1)	83.6 (13.4)
Height (cm)	169.5 (9.2)	163.0 (6.2)	176.4 (6.6)
Body mass index (kg/m²)	26.4 (4.4)	25.9 (4.7)	26.8 (3.9)
Waist circumference (cm)	88.7 (12.8)	83.1 (12.0)	94.6 (10.9)
Visceral Fat (L)	3.8 (2.3)	2.7 (1.5)	4.9 (2.4)
Subcutaneous Fat (L)	6.9 (3.2)	7.9 (3.4)	5.9 (2.5)
Liver Fat (%)	4.3 (4.0)	3.9 (3.8)	4.8 (4.1)
Muscle Volume (L)	10.2 (2.5)	8.2 (1.2)	12.3 (1.8)
Muscle Volume Index (SD)	0.0 (1.0)	0.0 (1.0)	0.0 (1.0)
Muscle Fat (%)	8.3 (2.0)	9.0 (1.9)	7.6 (1.9)
Muscle Fat Index (pp)	0.3 (1.9)	0.3 (1.9)	0.3 (1.9)
Left Anterior Thigh Muscle Volume (L)	1.7 (0.5)	1.3 (0.2)	2.1 (0.4)
Right Anterior Thigh Muscle Volume (L)	1.7 (0.5)	1.3 (0.2)	2.1 (0.4)
Left Posterior Thigh Muscle Volume (L)	3.4 (0.8)	2.7 (0.4)	4.0 (0.6)
Right Posterior Thigh Muscle Volume (L)	3.4 (0.8)	2.8 (0.4)	4.1 (0.6)
Left Anterior Thigh Muscle Fat (%)	8.4 (2.1)	9.1 (2.0)	7.6 (1.9)
Right Anterior Thigh Muscle Fat (%)	8.3 (2.1)	9.0 (2.0)	7.6 (2.0)
Left Posterior Thigh Muscle Fat (%)	12.2 (2.5)	12.9 (2.4)	11.4 (2.4)
Right Posterior Thigh Muscle Fat (%)	11.9 (2.5)	12.6 (2.4)	11.2 (2.4)
Metabolic disease free (No.)	7278 (24.1%)	3774 (24.1%)	3504 (24.1%)
Non-alcoholic fatty liver disease (No.)	3860 (12.8%)	1814 (11.6%)	2046 (14.1%)
Diabetes, type 2 (No.)	1557 (5.2%)	510 (3.3%)	1047 (7.2%)
Cardiovascular disease (No.)	2004 (6.6%)	535 (3.4%)	1469 (10.1%)
Coronary heart disease (No.)	1586 (5.3%)	402 (2.6%)	1184 (8.1%)
Cancer (No.)	3177 (10.5%)	1747 (11.2%)	1430 (9.8%)

Reference population characteristics. Values are mean (standard deviations).

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Performance Specification

Measurement	Accuracy	Precision	Reproducibility
Liver Fat	±2.0 pp	1.0 pp	2.0 pp
Visceral Fat	±0.5 L	0.10 L	0.15 L
Subcutaneous Fat	±1.0 L	0.20 L	0.25 L
Muscle Volume	±1.0 L	0.15 L	0.20 L
Left/Right Anterior/Posterior Thigh Muscle Volumes	±0.5 L	0.05 L	0.10 L
Muscle Fat	±2.0 pp	0.5 pp	1.0 pp
Left/Right Anterior/Posterior Thigh Muscle Fat	±3.0 pp	0.5 pp	1.0 pp
Muscle Fat Index	N/A (Indices are in relation to matched reference population)	0.5 pp	1.0 pp
Muscle Volume Index		0.10 SD	0.15 SD

L – Liter, pp – percentage point, SD – Standard Deviation.

Performance is derived from in-vivo experiments and represents limits of performance - measured performance is normally within the limits. Liver Fat represents AMRA's fat-referenced Liver Fat method. Accuracy was assessed by comparison with an established reference method, precision using a test-retest design, and reproducibility by scanning the same subjects on multiple different MRI systems. Accuracy is reported as outer limits of the limits of agreement, while precision and reproducibility are reported as upper limits of the within-subject standard deviation.

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Appendix A: Input of Patient Height on GE or Philips MRI Consoles

When registering the patient for the AMRA® BCP Scan Protocol, please insert the patient's height into the following fields on the MRI console:

GE: Additional Patient History (0010,21B0)
Philips: Study Comments (0032,4000)

Input the height in either meters or inches:

Meters: Type "HEIGHT *number* METERS", for example "HEIGHT 1.84 METERS"
Inches: Type "HEIGHT *number* INCHES", for example "HEIGHT 72.4 INCHES"

To convert feet into inches, multiply height in feet with 12.

For support, contact support@amramedical.com

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