Service User Guide

AMRA® MAsS Scan

Powered by AMRA Profiler 4

AMRA MEDICAL DEVICE

Europe AMRA Medical AB, Badhusgatan 5, SE-582 22 Linköping, Sweden

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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	Updated sections: • Data Export (Subsection *Input of patient height on the MRI console in case of GE or Philips* added) • Appendix A (New) General: Minor clarifications in text and typo corrections.

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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.	**Manufacturer:** AMRA Medical Badhusgatan 5 SE-582 22 Linköping SWEDEN www.amramedical.com support@amramedical.com
Clinical diagnosis should not be based solely on results shown in AMRA Profiler 4 reports. Results may vary slightly in different versions of AMRA Profiler 4. Any serious incident that has occurred in relation to the device should be reported to AMRA at support@amramedical.com and the competent authority of the Member State in which the healthcare institution and/or patient is established.	

Intended Purpose (Canada)

Intended Use

AMRA Profiler 4 is a product for classification and quantification of global and regional fat volumes, fat fractions, and lean tissue volumes in comparison to normal ranges or control groups, using magnetic resonance (MR) data acquired with the Dixon water-fat imaging method. The measurement results are intended to assist in the diagnosis and monitoring of metabolic diseases, muscle diseases and metabolic components of diseases in a general population. Additionally, the measurements are intended to assist in the prediction, diagnosis, prognosis, and monitoring of adverse muscle composition, sarcopenia, and cachexia in populations with hepatic cirrhosis, chronic kidney disease, cancer, as well as before and after surgery such as organ transplant and gastric bypass. The medical device is solely to be used by trained professionals, qualified and certified by AMRA. The results are delivered in the form of a report including quantitative measurements and visualizations providing information for physicians' evaluation.

Medical Indications

- Health and wellness,
- Metabolic diseases,
- Muscle diseases,
- Metabolic components of diseases,
- Adverse muscle composition,
- Sarcopenia, and
- Cachexia.

Metabolic diseases include

- Cardiovascular disease,
- Coronary heart disease,
- Liver inflammation and fibrosis,
- Metabolic syndrome and related comorbidities,
- Non-alcoholic fatty liver disease (NAFLD), and
- Type 2 diabetes.

Metabolic components of diseases

Several diseases may have an effect on the fat and muscle compartments in the patient. This is detectable when the precision of the measurements are sufficiently high to assess, for example, longitudinal changes and treatment follow-up.

Patient Population

- General population, as well as in populations with
- Hepatic cirrhosis,
- Chronic kidney disease,
- Cancer, and
- Before and after surgery such as organ transplant and gastric bypass.

Contraindications

Not applicable, software only.

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How to use AMRA® MAsS Scan service

Imaging Requirements

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

- Ambra Health platform (DG PACS, K152977), 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

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 1.75^3 mm³
- A voxel volume of maximum 4.5^3 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

For detailed information on the DICOM image requirements 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 Ambra Health.

- 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)

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.

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Input of patient height on the MRI console in case of GE or Philips

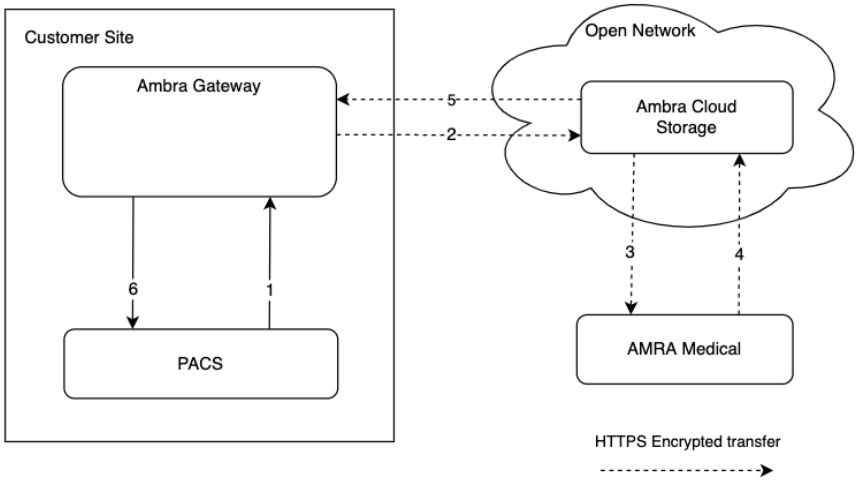
In case of GE or Philips scanners, there is no dedicated field to input patient height on the MRI console. The recommended solution is then to add the height information in the tags Study Comments (Philips) or Additional Patient History (GE) instead. See Appendix A in this document for a printable specification on how the information then needs to be typed in, in order for the information to be correctly interpreted and used by AMRA. If manual data transfer is done (see next chapter), the patient height can be input in the Ambra web portal instead.

Data Transfer

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

Upload via Ambra Gateway

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



Automatic data transfer via Ambra Gateway contains the following steps:

1. *Push of images, including sex, weight and height of the patient, from PACS to the Ambra Gateway*
2. *Automatic upload of de-identified DICOM images to Ambra Cloud Storage*
3. *Automatic download of DICOM images from Ambra Cloud Storage to AMRA*
4. *Automatic upload of a report to Ambra Cloud Storage*
5. *Automatic download of the report to Ambra Gateway*
6. *Automatic push of the report to the patient exam in PACS (based on Study Instance UID)*

SET-UP

For setup of the Ambra Gateway solution, contact your PACS or IT administrator.

The following procedures are needed for the setup of Ambra Gateway.

1. The Ambra Gateway is installed on a machine on the local network of the site
2. The Ambra Gateway is connected to the site’s PACS and the PACS is configured to push images to the Ambra Gateway (either manually or automatically)
3. The Ambra Gateway is configured in the AMRA account of Ambra Cloud Storage

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4. Configuration is added to convert the PDF report into a DICOM secondary capture, including Study Instance UID metadata.

Note that it is possible to get a notification if data was not successfully transfered from Ambra Gateway to the Ambra 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 Ambra Health at set-up.

DE-IDENTIFICATION

The data shall be de-identified before upload, so that it does not contain any unnecessary personal information. The site is responsible for de-identification of the data. When using the Ambra Gateway solution, the de-identification of data can be done either before the data is pushed to the Ambra Gatway, or within the Ambra Gateway. If it is done within the Ambra Gateway, the site needs to agree with Ambra at set up, on which DICOM tags shall be de-identified. AMRA will not actively screen for unnecessary personal information in the received data. If AMRA detects unnecessary personal information, the whole dataset will be deleted and the site asked to resend the images. The *DICOM Conformance Statement* states which DICOM tags are required in order to generate the MAsS Scan Report output.

PATIENT ID

When using upload via Ambra Gateway, the Patient ID tag needs to be populated with a string or number, unique for the examination, that is easily accessible for the site, such as the Accession Number (0008,0050).
The information in the Patient ID tag will be presented in the report, in the Patient Data section, and it will also be used to identify a specific dataset when AMRA communicates with you. Always refer to the de-identified Patient ID if there is a need to contact AMRA support about a specific dataset.

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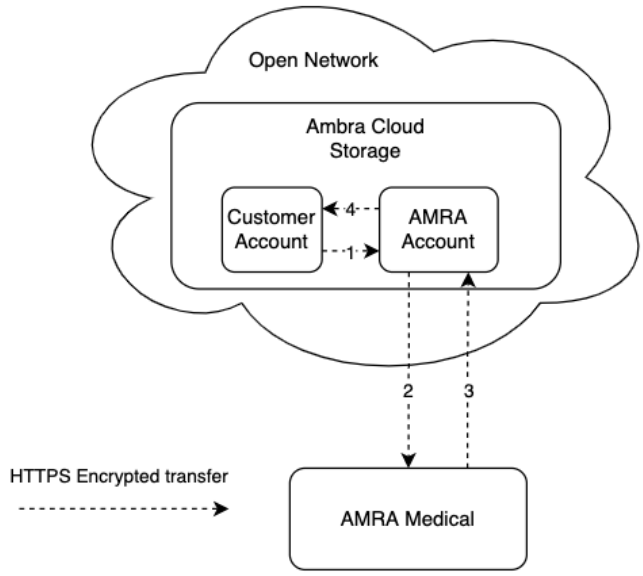
Upload via Ambra share code

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



Automatic data transfer via Ambra share code contains the following steps:

1. *De-identified 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 de-identified 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 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 Ambra cloud. Contact your local PACS or IT administrator.

DE-IDENTIFICATION

The data shall be de-identified before upload, so that it does not contain any unnecessary personal information. The site is responsible for de-identification of the data. When using the share code solution, the de-identification of data shall be done before data is pushed to the AMRA Account. The site needs to agree with Ambra at set up, on which DICOM tags shall be de-identified. AMRA will not actively screen for unnecessary personal information in the received data. If AMRA detects unnecessary personal information, the whole dataset will be deleted and the site asked to resend the images. The DICOM Conformance Statement states which DICOM tags are required in order to generate the MAsS Scan Report output.

PATIENT ID

When using upload via share code, the Patient ID tag needs to be populated with a string or number, unique for the examination, that is easily accessible for the site, such as the Accession Number (0008,0050).
The information in the Patient ID tag will be presented in the report, in the Patient Data section, and it will also be used to identify a specific dataset when AMRA communicates with you. Always refer to the de-identified Patient ID if there is a need to contact AMRA support about a specific dataset.

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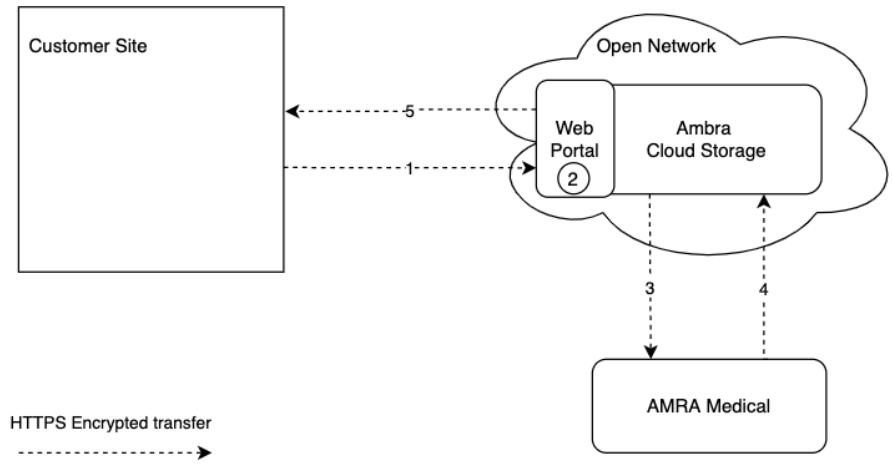
Manual upload via Ambra web portal

This is the flow-chart for manual upload to Ambra web portal.



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

1. *De-identified DICOM images, including sex, weight and height of the patient, are manually uploaded to the Ambra 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 de-identified report to Ambra Cloud Storage*
5. *Manual download of the report from the Ambra Web Portal*

SET-UP

The only requirement to upload images manually to Ambra 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.

DE-IDENTIFICATION

The data shall be de-identified before upload, so that it does not contain any unnecessary personal information. The site is responsible for de-identification of the data. AMRA will not actively screen for unnecessary personal information in the received data. If AMRA detects unnecessary personal information, the whole dataset will be deleted and the site asked to resend the images. The *DICOM Conformance Statement* states which DICOM tags are required in order to generate the MAsS Scan Report output.

PATIENT ID

When using the manual upload solution, a unique identifier must be used for each patient, in the Patient ID tag. The information in the Patient ID tag will be presented in the report, in the Patient Data section, and it will also be used to identify a specific dataset when AMRA communicates with you. Always refer to the de-identified Patient ID if there is a need to contact AMRA support about a specific dataset.

BROWSER REQUIREMENTS

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

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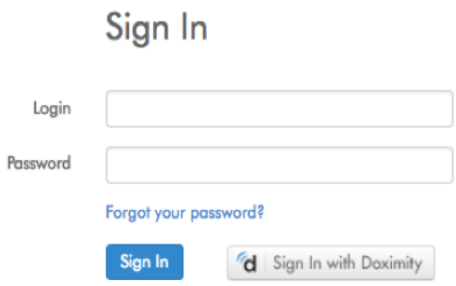
REGISTRATION

You will be sent an e-mail invite where you will be asked to register for the Ambra 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.

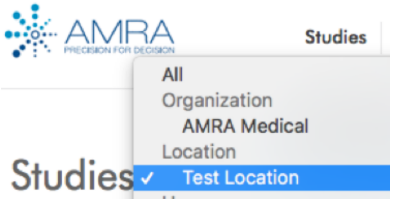
LOGGING IN

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

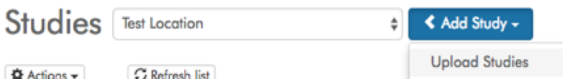


UPLOADING STUDIES

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.

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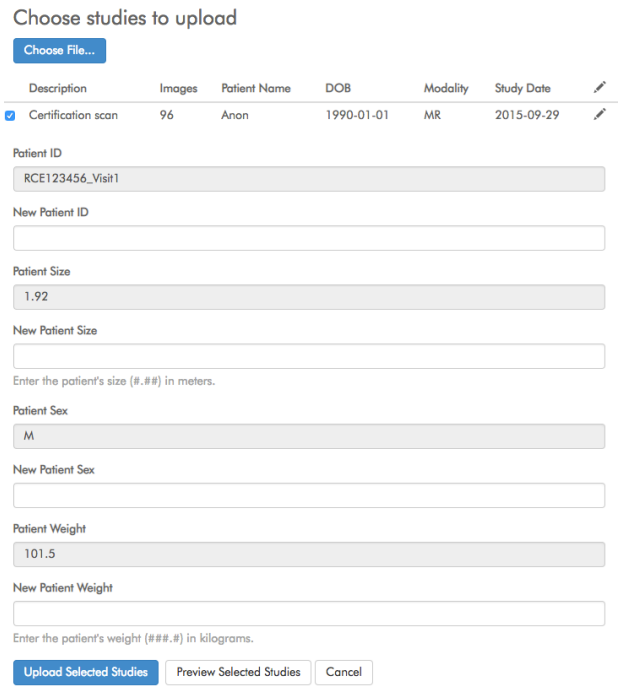

Please note, that any changes done after upload will not automatically be transferred to us. Please email support@amramedical.com alerting us to any changes.

For more help uploading, please consult Ambra's Help Center: support.ambrahealth.com

DOWNLOAD AND VIEW REPORTS

When patient 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 or download, 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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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 Ambra Health.

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.

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

Note: If a patient has been scanned at two different timepoints, and a comparison of reports between these timepoints are made, the virtual control group and thus the blue field in bar plots and MAsS plot can differ between the reports. For instance, if the patient has increased his/her weight between the two scans, the individuals included in the patient specific virtual control group will be slightly different between the timepoints and thus the resulting blue field will have a different distribution.

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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%. The 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. The 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. The Subcutaneous Fat is measured in liters (L).

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Liver Fat

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

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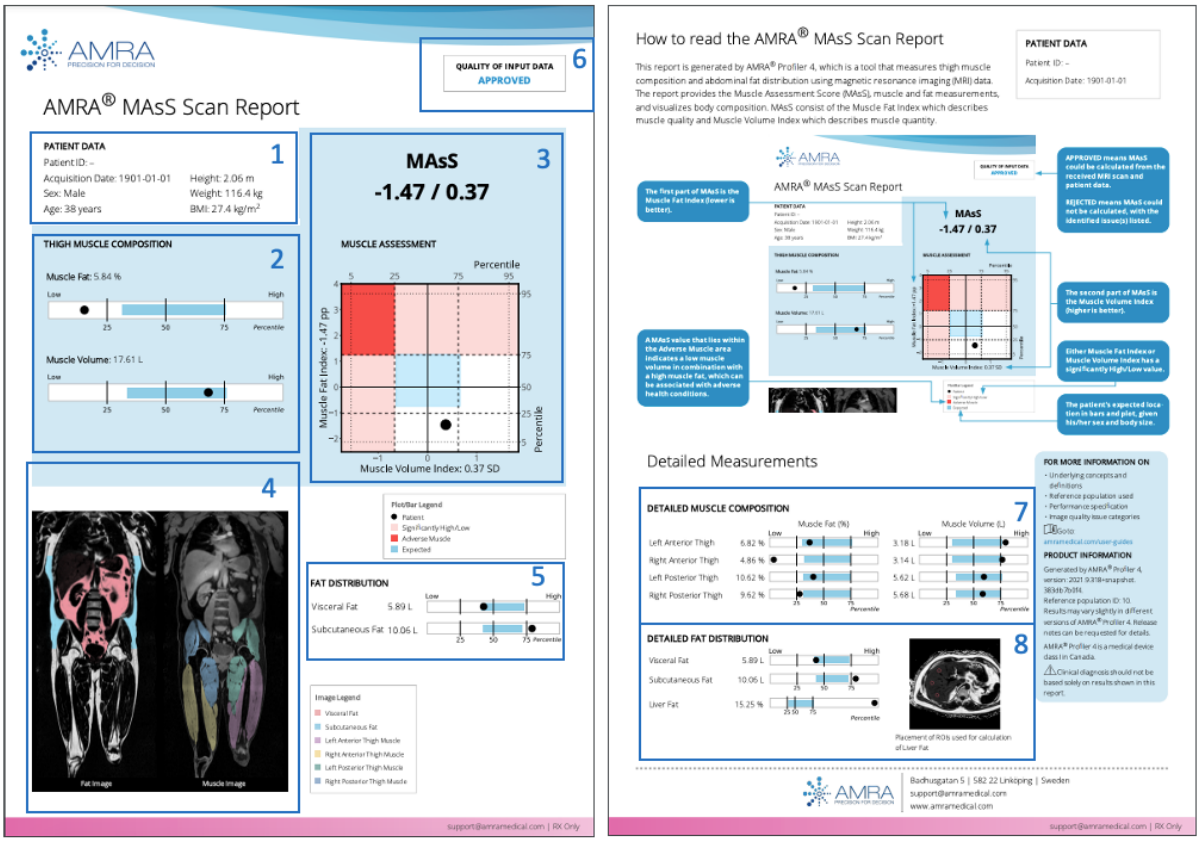
The different elements of the report

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: 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)**
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.

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

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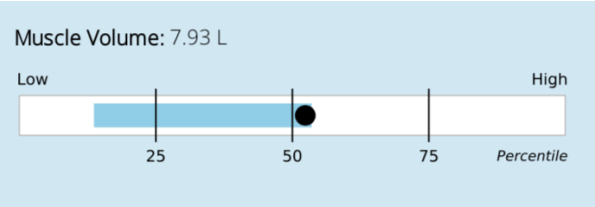
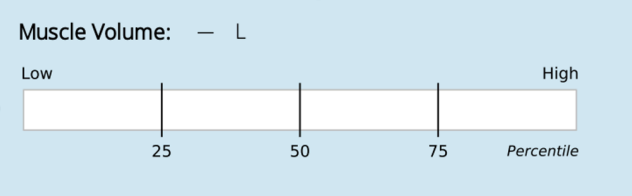


Example: The patient's Muscle Volume is slightly above the median among individuals in the reference population with the same sex (above the 50th percentile). The Muscle Volume is within what could be expected, given the patient's sex and body size (within the blue field), however, often individuals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

Note: 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 an empty bar plot will be output, 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 an empty bar plot is presented.

If there is an issue identified with the provided patient data, values will be presented, but an empty bar plot will be output, 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 allows for assessment of the muscle health, sarcopenic processes and the manifestations of disease in the muscles at an early stage, before the advent of frailty. The MAsS has a stronger association to poor activities and function of daily life and hospitalization than Muscle Fat and Muscle Volume alone and may assist a clinician with diagnosing sarcopenia 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 low 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 and function. 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, and thus indicates a lower muscle function. A Muscle Volume Index of zero corresponds to the mean within the reference population.

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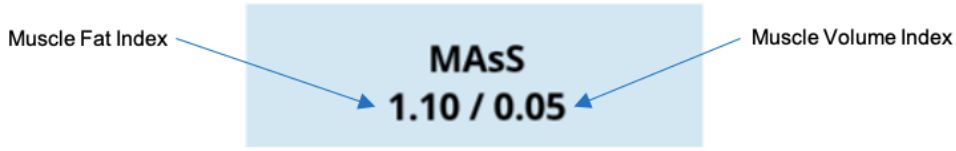


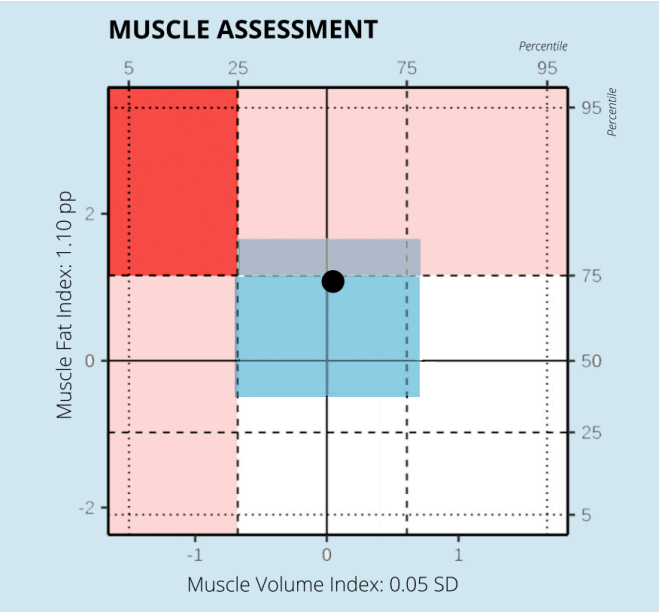
Example: A MAsS of 1.10 / 0.05 means that the patient has elevated muscle fat (1.10 percentage points higher than the median among individuals with the same sex) and an expected level of muscle volume (0.05 standard deviations higher than the mean within his/her virtual control group).

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 significantly high (above 75th percentile) or Muscle Volume Index is significantly low (below 25th percentile).

The red area marks the combination of significantly high Muscle Fat Index and significantly low Muscle Volume Index, which is defined as Adverse Muscle Composition. Patients presenting with an adverse muscle composition have a higher prevalence of metabolic co-morbidities including type-2 diabetes and coronary heart disease as well as a higher risk of all-cause mortality.

The blue field shows the patient's statistically expected location in the two dimensions (the interquartile range of the patient's virtual control group).



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 significant. 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).

Note: The patient marker being within the blue field, does not indicate if the patient is healthy or unhealthy. It means that the patient lies within the range of what one could expect, given the patient's sex and BMI. So, if the pink area and the blue area are overlapping as in the given example above, it means the patient has a significantly high Muscle Fat Index, which is common for individuals with same sex and similar BMI as the patient.

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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.

5: Fat distribution

Measurements

The measurements of abdominal adiposity of the patient may assist in diagnosis, prediction and monitoring of metabolic diseases and is given as complementary information in the MAsS Scan report, to give a full picture of the patient's body composition. Higher fraction of abdominal fat consisting of Visceral Fat indicates an unfavorable fat distribution associated with increased cardiac risk. Patients presenting with high Visceral Fat and low Liver Fat, have a higher risk for a cardiac event. Visceral Fat has further been associated with certain types of cancer, liver inflammation and fibrosis. The objective measurements presented in this section, Visceral Fat and Subcutaneous Fat, allows for assessment of body composition changes and early signs of treatment impact.

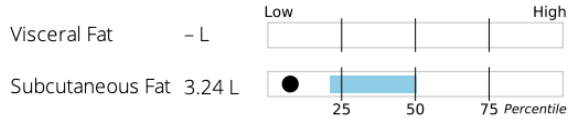
Bar plots

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 bar) shows the expected range of the fat distribution measurement, given the provided patient's sex and body size.

Note: 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 an empty bar plot will be output, with no patient marker or expected field visualized.



Example: Issues with the MRI scan resulting in that the Visceral Fat measurement could not be calculated within the stated performance. A dash is output instead of a value and there is an empty bar output next to the value.

If there is an issue identified with the provided Patient Data, values will be presented, but empty bar plots will be output, 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
Note: If there is an issue identified for one of the legs, only the leg without issues is used for muscle composition calculations (Muscle Fat and Muscle Volume with corresponding bar plots) and the informatics measurements that depend on these measurements (Muscle Fat Index, Muscle Volume Index, MAsS and the corresponding muscle assessment plot). 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 could not be assessed.

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 25^{th}, 50^{th} and 75^{th} percentiles of this reference population are presented as solid lines. The distribution within the patient's virtual control group (blue bar) shows the expected range of the muscle measurement, given the provided patient's sex and body size.

Note: 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 an empty bar plot will be output, with no patient marker or expected field visualized.

If there is an issue identified with the provided patient data, values will be presented, but an empty bar plot will be output, 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. Patients presenting with high Visceral Fat and low Liver Fat, have a higher risk for a cardiac event. Liver Fat may also be of interest in non-alcoholic fatty liver disease and non-alcoholic steatohepatitis.

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 25^{th}, 50^{th} and 75^{th} percentiles of this reference population are presented as solid lines. The distribution within the patient's virtual control group (blue bar) shows the expected range of the muscle measurement, given the provided patient's sex and body.

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.

Note: 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 an empty bar plot will be output, with no patient marker or expected field visualized.

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

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.

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Issue categories explained

Input data issues can occur either in the MRI data or in the Patient Data. 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	Body movement 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 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 jewelery/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, jewelery and piercings and that clothing is metal free, prior to MRI acquisition.

ISSUE 2: BODY MOVEMENT 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 care to ensure the patient is not given any support underneath the legs. Prior to

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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 of fat bias which results in an erroneously elevated fat fraction 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 SIGNAL

The measurable region contains a strong negative signal close to 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 Ambra Health. 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 Ambra Gateway or share code) or add it manually to the examination in Ambra 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 de-identified 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 Ambra Health 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 Ambra Gateway or share code) or modify it manually for the examination in Ambra 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 de-identified 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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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	Volume and muscle fat measurements are to be compared to the provided reference intervals	0.10 L	0.15 L
Subcutaneous Fat		0.20 L	0.25 L
Muscle Volume		0.15 L	0.20 L
Left/Right Anterior/Posterior Thigh Muscle Volumes		0.05 L	0.10 L
Muscle Fat		0.5 pp	1.0 pp
Left/Right Anterior/Posterior Thigh Muscle Fat		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: Patient Height Input - GE and Philips 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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