

Body Composition Profile Report

Conditions such as overweight and obesity are linked to increased risk of developing co-morbidities such as type 2 diabetes, stroke, heart attack and more. Today, body mass index (BMI) is an indirect, population-based measurement that is commonly used to assess degree of obesity and associated health risks. While a high BMI correlates with health risks on a population level, it may be a poor descriptor of the individual's health status. AMRA® Profiler directly measures, with high accuracy & precision, adiposity of an individual. AMRA® Profiler is a tool that assists in the diagnosis and monitoring of metabolic diseases, muscle disease and metabolic components of diseases.

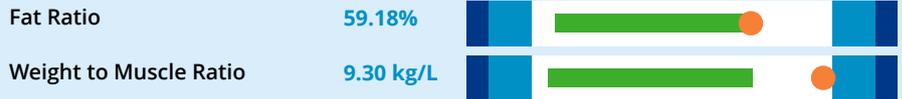
GRAPHS SHOWING INDIVIDUAL VALUES IN RELATION TO SEX-SPECIFIC REFERENCE DATA, NORMALIZED WITH HEIGHT IF AVAILABLE. *If sex is unspecified, reference data will include both male and female.*

- Individual value.
- General population region defined by our reference data.
- Metabolic disease free region. Defined by individuals reported to be asymptomatic of metabolic diseases.
- Low / high value. Among 15% lowest / highest in our reference data.
- Very low / high value. Among 5% lowest / highest in our reference data.

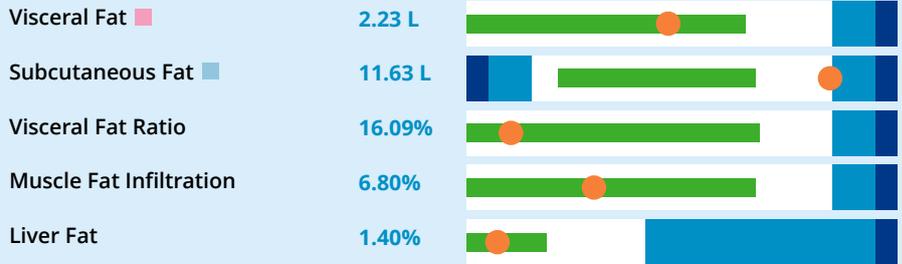
Patient Data

Sex: Female Height: 1.65 m
 Age: 55 BMI: 32.7 kg/m²
 Weight: 89 kg

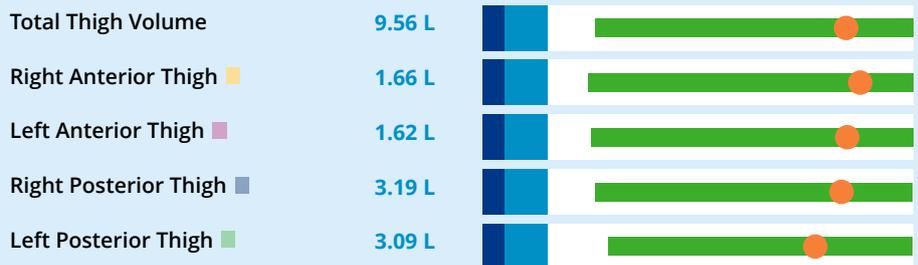
Body Ratios



Fat Measurements



Muscle Measurements



Biomarker Information

The information below is meant to provide a context to each of the biomarkers. An association between a low / high biomarker value and a disease does not necessarily mean that an individual with a low / high biomarker value has or will develop that disease. For additional information and scientific references, please see www.amramedical.com.

Fat Ratio

Describes the balance between fat and muscle tissue. A higher / lower value indicates a larger / smaller amount of fat in relation to muscles.

Details: $(VF + SCF) / (VF + SCF + Thigh\ Muscle\ Volume)$.

Weight to Muscle Ratio

This ratio compares the body weight to the amount of thigh muscle as a measure of the amount of muscle available to carry body weight. A higher / lower value indicates a smaller / larger amount of muscle in relation to body weight.

Details: $Body\ weight / Thigh\ Muscle\ Volume$.

Visceral Fat Ratio

The fraction of abdominal fat consisting of visceral fat indicating how the individual tend to store fat. Higher values indicate an unfavorable fat distribution associated with increased cardiac risk.

Details: $VF / (VF + SCF)$.

Visceral Fat (VF)

Visceral fat, or intra-abdominal fat, is stored around and between the abdominal organs. Increased visceral fat is associated with increased cardiac risk, type 2 diabetes, liver inflammation and fibrosis, and certain types of cancer.

Details: Measured as 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.

Subcutaneous Fat (SCF)

Subcutaneous fat is one of the main compartments in the body where large amounts of fat are stored. Subcutaneous fat by itself has only shown weak, or no, associations to adiposity related diseases and traditional risk factors.

Details: Subcutaneous adipose tissue in the abdomen from the top of the femoral head to the top of the thoracic vertebrae T9.

Liver Fat

Increased liver fat may lead to advanced fibrosis, cirrhosis, and hepatocellular carcinoma, and is also linked to the development of type 2 diabetes.

Details: Measured as the average proton-density fat fraction in regions of interest in the liver.

Thigh Muscles Volume(s)

A low or decreasing muscle volume has been seen in sarcopenia (age-related frailty) and cachexia (disease-related wasting).

Details: Posterior thigh include gluteus muscles, iliacus, adductor muscles, and hamstring muscles. Anterior thigh includes quadriceps femoris, sartorius, and tensor fascia latae.

Muscle Fat Infiltration (MFI)

MFI is also known as intramuscular fat, and is the fraction of inactive tissue in the muscle. Higher MFI indicates lower quality and functionality of the muscle and has been associated with reduced mobility and increased risk for type 2 diabetes.

Details: Measured as the average proton-density fat fraction in the anterior thigh muscles.

Performance Specification

Measurement	Accuracy	Precision	Reproducibility
Visceral Fat	<i>Volume and MFI</i>	0.10 L	0.15 L
Subcutaneous Fat	<i>measurements are to be</i>	0.20 L	0.25 L
Total Thigh Muscle Volume	<i>compared to the provided</i>	0.15 L	0.20 L
Individual Thigh Muscle Volumes	<i>reference values.</i>	0.05 L	0.10 L
Muscle Fat Infiltration		0.5 pp	1.0 pp
Liver Fat	±2.0 pp	1.0 pp	2.0 pp

L - Liter, pp - percentage point.

Performance is derived from in-vivo experiments and represent upper limits of performance - measured performance is normally within the limits. Liver fat performance represent AMRA's fat-referenced liver fat method. Accuracy was assessed using a clinical liver PDFF application as reference, precision using a test-retest design, and reproducibility by scanning the same subjects on multiple MRI systems. Precision and reproducibility are reported as upper limits of the within-subject standard deviation.

Image Quality Issues

If an image quality issue is indicated for a biomarker, the measurement is affected by one or several of the following image quality issues and the scan should be read before using the given value.

- 1) Metal
- 2) Body movements during the scan
- 3) Region being partly outside field of view
- 4) Faulty alignment of adjacent slabs
- 5) Signal swap
- 6) Positive bias of low fat concentrations

If the biomarker is not measurable, no value is given.

Intended Use

AMRA® Profiler is a product for classification and quantification of global and regional fat volumes, fat fractions and lean tissue volumes in comparison to normal ranges, 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. The medical device is solely to be used by trained professionals, qualified and certified by AMRA Medical. The measurement results are delivered in the form of a report providing information for physicians evaluation.

Product Information

This document was generated by AMRA Profiler 3. Version: 2022.11.420.

Clinical diagnosis should not be based solely on results shown in this report. Results may vary slightly in different versions of AMRA® Profiler. Release notes can be requested for details.