Perspectum

INTERPRETATION GUIDE

Interpreting Multi-Organ Multiparametric MRI Tissue Characterization [ENG]

For SG & US use only

CoverScanMD v1.2

CoverScan

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1. Preface

1.1. Symbols Key

	**Caution:** Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.
	**Date of Manufacture:** Denotes date of manufacture of the device.
 www.perspectum.com/our-products/pdf-library	**eIFU (electronic Instructions for Use):** Denotes that the instructions for use for this device is made available electronically.
	**Manufacturer:** Denotes the legal manufacture of the device.
	**Notice:** Is used to provide information on how to avoid operating errors or information emphasizing important details.
	**Indicates that the device is a medical device.**
	**Population:** Used to signify that CoverScanMD is suitable for the general population.
	**Email:** Our support team can always be contacted using support@perspectum.com.
	**Perspectum Hotline:** Our support team can be contacted via the Perspectum Hotline using +1 833 875 0862 (US) or +44 800 029 3049 (UK/EU).
Rx Only	**Prescription use only.**

1.2. Definitions and Abbreviations

AHA	American Heart Association
AWS	Amazon Web Services
CoverScanMD	CoverScanMD Medical Device software version v1.2

cT1	Corrected T1
DICOM	Digital Imaging and Communications in Medicine
FDA	U.S. Food and Drug Administration
LIC	Liver Iron Concentration
MDR	European Union Medical Device Regulation
MR or **MRI**	Magnetic Resonance or Magnetic Resonance Images
MultiScan	MultiScan software version v1.3
PDFF	Proton Density Fat Fraction
Perspectum	Perspectum Ltd.
QMS	Quality Management System
SaMD	Software as a Medical Device
srT1	Scanner Referenced T1
T1	T1 relaxation time – the longitudinal or spin-lattice NMR relaxation time
T2	T2 relaxation time – the transverse or spin-spin NMR relation time
T2*	T2* relaxation time – T2 combined with field inhomogeneity effects
UDI	Unique Device Identifier
v1.2.3	Software Version including major, minor and patch information. In this example, the Major version is 1, Minor version is 2 and Patch version is 3.

2. Use and Limitations

2.1. Intended Use and Indications for Use

CoverScanMD is a medical image management and processing software package that allows the display, analysis and post-processing of DICOM compliant medical images and MR data.

CoverScanMD provides both viewing and analysis capabilities to ascertain quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas and kidney.

CoverScanMD provides measurements in different organs to be used for the assessment of longitudinal and transversal relaxation time (T1, srT1, cT1, T2), fat content (proton density fat fraction or PDFF) and metrics of organ function (e.g., left ventricular ejection fraction and lung fractional area change on deep inspiration). These metrics derived from the images, when interpreted by a licensed physician, yield information that may assist in diagnosis, clinical management and monitoring of patients.

CoverScanMD is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T and Siemens 3T MRI scanners.

Federal law restricts the use of this device to patients referred to by licensed trained healthcare professionals.

2.2. Diagnostic and therapeutic restrictions

The following diagnostic and therapeutic restrictions apply. CoverScanMD is not intended to be used in any of the following circumstances and any such use is expressly forbidden by Perspectum.

- CoverScanMD should not be used as the sole basis for forming a diagnosis. To do so would constitute a misuse of the device.
- CoverScanMD should not be used for interpreting anything outside the specified organs. To do so would constitute a misuse of the device.
- CoverScanMD should not be used as a control mechanism for biopsy guidance. To do so would constitute a misuse of the device.
- CoverScanMD should not be used as the basis for surgical planning, the preparation, execution or post-operative assessment of surgical practices. To do so would constitute a misuse of the device.
- CoverScanMD should not be used as a control mechanism for the delivery of treatment. To do so would constitute a misuse of the device.
- CoverScanMD should not be used as the sole basis for evaluating the success or therapeutic response to treatment. To do so would constitute a misuse of the device.

CoverScanMD is not clinically validated for the above and would not be sufficiently accurate to allow safe and efficacious use.

2.3. Intended Population

CoverScanMD is intended for use in the general population and does not have any demographic or population restrictions.

2.4. Patient-Side Effects

There are currently no known side effects for the use of CoverScanMD.

2.5. Information to be conveyed to the Patient

The following information to patients should be part of the consenting process and to be reviewed at the time of the scan as part of local MRI safety protocol.

✓	✗
No **food or drink** for 4 hours before MRI scan.	Not necessary to abstain from alcohol.
Do not have a CoverScanMD shortly after another **contrast-related scan or procedure**, this will affect the results. Combining a contrast scan after the CoverScanMD acquisition is acceptable.	Light clothing (for those with personal or cultural vulnerabilities to undressing) can be worn during the test; **with no metallic belongings.**
Remove all **metallic belongings** in advance of an MRI examination *(incl. external hearing aids, watches, jewellery, cell phones, and items of clothing that have metallic threads or fasteners).*	Routine medications can be taken considering any diagnostic and therapeutic restrictions before the MRI scan.
Continuous glucose monitoring devices (CGMs) It is necessary to remove their glucose monitor prior to entering the MR Environment for the MRI to proceed safely. Please try to co-ordinate your scan around the time of sensor replacement or seek advice specific to CGM device model and manufacturer.	

2.6. Warnings and Precautions

CoverScanMD must not be used for direct diagnosis of patients.

CoverScanMD generated metrics must only be interpreted by trained healthcare professionals.

CoverScanMD output must not be used on its own to make any treatment decisions relating to any specific diseases or health conditions.

It is the responsibility of trained healthcare professionals to verify patient identifiers, ensuring they are reviewing the correct information.

2.7. Residual risks and safety

After a thorough analysis of all mitigated risks and residual risks pertaining to CoverScanMD, it has been determined that the benefits significantly outweigh the potential risks. Any safety cautions pertaining to the use of CoverScanMD and interpretation of its metrics are provided throughout this guide.

2.8. Intended Benefits

CoverScanMD is a safe and non-invasive imaging solution for multi-organ health assessment

CoverScanMD provides multi-organ assessment using a single MRI scan

CoverScanMD can aid in the diagnosis of patients with multi-organ impairment

CoverScanMD can aid in the clinical management of patients with conditions affecting multi-organ

CoverScanMD can aid in the monitoring of patients' multi-organ response to treatments

CoverScanMD provides comprehensive and visually enriched results

3. The CoverScanMD Device

CoverScanMD is a standalone, post-processing software as a medical device (SaMD) specifically designed for the processing and analysis of magnetic resonance imaging (MRI) data. It enables the visualisation, analysis and generation of quantitative metrics and composite images from MRI scans.

CoverScanMD consists of MultiScan software and a data consolidation software which reads results from compatible SaMD's that are independently authorised for use as medical devices. The data consolidation software compiles all the input data (metrics and image references) and produces a single JSON file output which are then used to generate quantitative multi-parametric MRI reports. The data consolidation software does not modify any input data, instead, it just appends all data into one single JSON file and a list of associated images for report generation. The report generation is done outside the CoverScanMD medical device and hence does not form part of the CoverScanMD medical device.

When a referring healthcare professional requests quantitative analysis using CoverScanMD, relevant images are acquired from patients using a single MRI scan at the MR clinic and are transferred to the Perspectum Portal through established secure gateways. Perspectum trained operators use the CoverScanMD software medical device to process the MRI images and produce the quantitative metrics and composite images. The device output information is then sent to the healthcare professionals for their clinical use.

CoverScanMD is only used within Perspectum's secure infrastructure by trained operators to process clinical images and generate metrics. The metrics and composite images output by CoverScanMD are then sent to trained Healthcare Professionals who then interpret the information to make informed decisions.

3.1. CoverScanMD Modules & Metrics

CoverScanMD offers metrics across multiple organs, but trained healthcare providers can choose, and order specific organ assessments tailored to the patient's needs. The available module options include:

- Cardiac
- Liver
- Kidney
- Pancreas
- Lung
- Spleen

3.1.1. Cardiac Metrics

- **Ventricle measurements:**

Metrics		Left Ventricle	Right Ventricle
Measurement	End Diastolic Volume	✓	✓
	End Systolic Volume	✓	✓
	Stroke Volume	✓	✓
	Muscle Mass	✓	
	Max Wall Thickness	✓	
Functional	Ejection Fraction	✓	✓
	Cardiac Output	✓	✓
	Cardiac Index	✓	✓
2D Global Strain	Longitudinal	✓	
	Circumferential	✓	
	Radial	✓	

- **Atrial measurements:**

Metrics	Left Atrium	Right Atrium
Minimum volume	✓	✓
Maximum volume	✓	✓

Left ventricular segmentations with

- **cardiac T1, T2, and wall thickness measurements:**
    - Global

1 - Basal Anterior
2 - Basal Anteroseptal
3 - Basal Inferoseptal
4 - Basal Inferior
5 - Basal Inferolateral
6 - Basal Anterolateral
7 - Mid Anterior
8 - Mid Anteroseptal
9 - Mid Inferoseptal
10 - Mid Inferior
11 - Mid Inferolateral
12 - Mid Anterolateral
13 - Apical Anterior
14 - Apical Septal
15 - Apical Inferior
16 - Apical Lateral

- **Aortic measurements:**
    - Ascending aorta diameter
    - Abdominal aorta diameter

3.1.2. Lung Metrics

- **Lung fractional area change** (right and left lungs)

3.1.3. Liver Metrics

- **Liver cT1**
- **Liver Fat** – PDFF
- **Liver Iron Concentration** – LIC

3.1.4. Pancreas Metrics

- **Pancreatic srT1**
- **Pancreatic Fat**

3.1.5. Kidney Metrics

- **Cortical T1** (right and left kidneys)
- **Kidney Lengths** (right and left kidneys)

3.1.6. Spleen Metrics

- **Spleen Length**

3.2. CoverScanMD Clinical Interpretation

3.2.1. Cardiac Metrics Interpretation

Cardiac magnetic resonance (CMR) imaging provides an unparalleled depth of insight into the structural and functional metrics of the heart and aorta, essential for understanding cardiovascular health and disease and monitoring of disease and treatments.

The parameters outlined in this guide cover key volumetric, functional, and tissue characteristics that are critical for diagnosing, monitoring, and treating cardiovascular conditions. They act as diagnostic and prognostic markers (1,2) which may aid identify at-risk and affected individuals, aiding clinical decision-making and individual cardiac risk assessment.

3.2.1.1. Cardiac Volumes

The measure of the maximum volume of blood present in the ventricle and atrium before the beginning of (EDV) or at the time of contraction (ESV).

3.2.1.2. Muscle Mass

The volume of tissue of the left ventricle between the endocardial and epicardial contours multiplied by the density of myocardial tissue (1.05g/mL).

3.2.1.3. Ejection Fraction

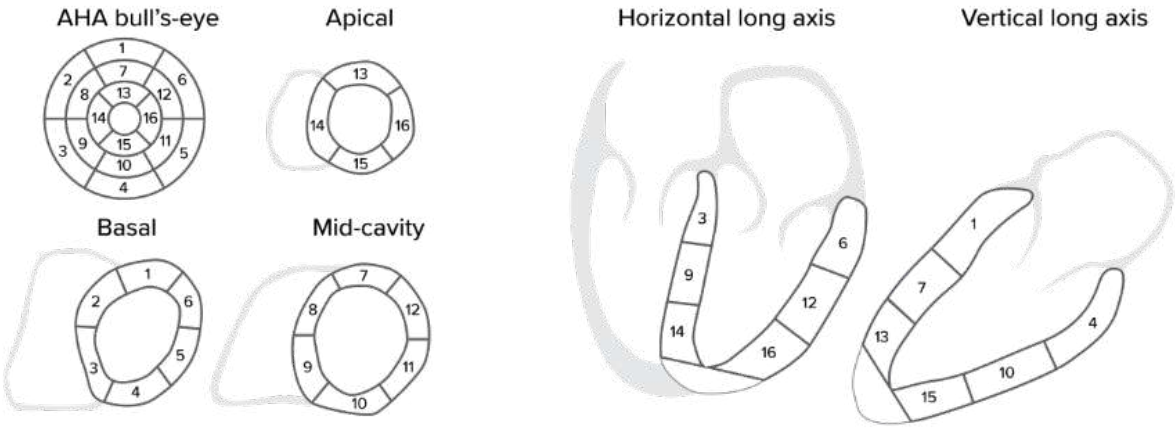
The Left Ventricular Ejection Fraction) is expressed as a percentage, of how much blood is pumped out of the left ventricle by each heartbeat. It is used to assess global heart function.

3.2.1.4. 2D Global Strain

Myocardial Strain is the change in myocardial fiber length over the cardiac cycle used as a measure of regional ventricular function (3,4). This myocardial deformation or percentage change in fiber length is provided in its different directions (longitudinal, circumferential and radial). This differs in its dominance in the phase

of the cardiac cycle, is unique to the affected layer of the heart or sensitivity to the stage of cardiac disease.

Global Longitudinal strain (GLS) holds guideline recommendations in the diagnosis and risk stratification of those individuals with suspicion of heart failure in routine clinical practice (5,6) GLS has been shown to be an early and sensitive marker of cardiac dysfunction and predictor of clinical outcomes, even before other traditional markers manifest e.g ejection fraction. GLS has superior reproducibility to LVEF measurements and therefore it can also be suitable for longitudinal cardiac monitoring (7)



The heart's anatomy is complex, and understanding its structure requires a standardized system to describe specific regions. The 16-segment model, as outlined by the American Heart Association (AHA) and visualized in the bull's-eye plot, provides a standardized framework for assessing the left ventricle in cardiac imaging. This model divides the left ventricle into basal, mid-cavity, and apical levels along its long axis and further segments the basal and mid-cavity regions into six circumferential slices (anterior, anteroseptal, inferoseptal, inferior, inferolateral, and anterolateral).

How Are the Segments Defined?

The 17 segments are organized based on two key axes:

1. **The Long Axis of the Left Ventricle (from apex to base):**
    - *Basal:* Closest to the base of the heart where the mitral valve is located.
    - *Mid-cavity:* The middle portion of the left ventricle.
    - *Apical:* The tapered portion of the ventricle near the apex.
2. **The Circumferential Orientation (360° around the short axis):**
    - The basal and mid-cavity slices are divided into *6 segments* of 60° each.
    - These segments correspond to anatomical regions: anterior, anteroseptal, inferoseptal, inferior, inferolateral, and anterolateral.

The apical region is narrower and includes 4 segments—apical anterior, apical septal, apical inferior, and apical lateral. The very tip of the heart, where no cavity exists, is called the apical cap (segment 17 not presented in the CoverScanMD cardiac

analysis).

Why Is This Model Useful?

- **Precise Localization:** The 17-segment model ensures abnormalities like ischemia, fibrosis, or wall motion
- issues are localized with high precision, enhancing diagnostic accuracy.
- **Standardization:** This model provides a universal language for reporting findings across modalities, including CMR, echocardiography, and nuclear imaging.
- **Pathophysiological Insight:** Different regions of the heart are supplied by specific coronary arteries. Using this segmentation, clinicians can map imaging findings to underlying vascular territories.
- **Functional Assessment:** Segments help quantify regional myocardial function, enabling advanced metrics such as strain analysis.

The CoverScanMD cardiac module provides detailed tissue characterization by delivering cardiac T1, T2, and wall thickness metrics across 16 heart segments according to the 17 AHA segment model. These measurements offer insights into the structure and function of the myocardium, enabling a comprehensive assessment of cardiac health.

3.2.1.5. Cardiac T1 (ms)

T1 is a time constant representing the recovery of longitudinal magnetization after a radiofrequency inversion pulse and provides a measure of the intrinsic properties of the myocardial tissue that can be shortened or prolonged by disease. For T1 mapping acquisition methods, T1 values are estimated by fitting a T1 recovery curve to each pixel in a series of images with different degrees of T1 recovery using a three-parameter fit (8,9).

Cardiac T1 has strong discriminatory ability to detect myocardial pathology, both in individuals with and without pre-existing cardiovascular disease (10-14). It is valuable in identifying cardiomyopathies, including diffuse fibrosis, and reliably diagnoses conditions such as myocardial infarction, myocarditis, amyloidosis, iron overload, and Fabry disease (15-18). Furthermore, T1 mapping has been adopted into clinical guidelines for the diagnosis of cardiac diseases (19).

	T1 can be measured by many methods. CoverScanMD uses a standardized MOLLI-T1 method. Other methods may differ from other T1 mapping and produce different results.
	CoverScanMD cannot provide cardiac T1 metrics if a contrast agent has been used.
	Cardiac T1 in apical segments is susceptible to partial volume artefact, thus these measures may not be available for quantification in all instances.

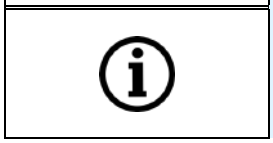
3.2.1.6. Cardiac T2 (ms)

T2 is a time representing the decay of transverse magnetization following a 90-degree radiofrequency pulse and it is used to measure the T2 relaxation time. T2

values are estimated by fitting a T2 decay curve to each pixel in a series of images with different degrees of T2 weighting on the 16 segments.

Cardiac T2 has good discriminatory ability to detect myocardial pathology in patients, whether without or with pre-existing cardiovascular disease (20-24).

CoverScanMD cannot provide cardiac T2 metrics if a contrast agent has been used.



Cardiac T2 in apical segments is susceptible to partial volume artefact, thus these measures may not be available for quantification in all instances.

3.2.1.7. Wall Thickness (mm)

Wall thickness is the distance between endocardial and epicardial contours at the end diastole. Wall Thickness is defined as the highest value of wall thickness measured at various cardiac segments.

3.2.1.8. Aorta diameter (mm)

Aortic diameter is the maximum external diameter of the ascending and abdominal aorta, this is measured at its widest point.

3.2.2. Lungs Metrics Interpretation

Lung fractional change for deep breathing is an MRI-derived proxy measure of relaxed vital capacity. This is calculated by the difference between the lung area, measured from images acquired in the coronal view, at maximum inspiration and expiration, which is divided by the maximum area at inspiration for normalization of patient size.

The change in lung area with deep breathing correlates with forced vital capacity measured from spirometry (25).

3.2.3. Liver Metrics Interpretation

3.2.3.1. Liver cT1 (ms) Interpretation

Corrected T1 (cT1) relates to the amount of extracellular fluid present in the liver parenchyma. cT1 is derived from T1 and T2* maps. T1 is a measure of the longitudinal (spin-lattice) relaxation time, measured in milliseconds (ms). The T1 of a tissue depends on its free water content, which relates to the proportion of the extracellular fluid in the tissue. Proton-dense tissues with a low water content, such as fat, have very short T1 values, while tissues with a high-water content, such as muscle, and the spleen have much longer T1 values. When tissue is inflamed or scarred (fibrotic), the water content increases, leading to longer T1 values. The application of T1 as a biomarker for inflammation and fibrosis in the liver is impeded by the liver iron. In a conventional T1 map, the local magnetic effects exerted by the iron artificially shorten the T1 measurement, leading to potential underestimation. CoverScanMD uses the T2* map to correct for signal changes related to iron deposits, producing a corrected T1 map, referred to as cT1. This iron-corrected T1 map compensates for the effects of elevated iron from T1 measurements. cT1 is sensitive to inflammation, fibrosis, and liver fat (PDFF). cT1 has been shown to correlate with liver parenchymal fibrosis, inflammation, and ballooning (26–29).

In cases of very high levels of hepatic fat (>35 %), Liver cT1 will not be reported. High levels of hepatic fat can confound the accuracy of cT1.

T1 can be measured by many methods. CoverScanMD uses a standardized MOLLI-T1 method. Other methods may differ from other T1 mapping and produce different results.

3.2.3.2. Liver Fat (PDFF) (%) Interpretation

Liver fat or Proton Density Fat Fraction (PDFF) is a ratio, expressed as a percentage, of the fraction of the MRI-detectable protons attributable to fat divided by all MRI-detectable protons in that region of the liver attributable to fat and water. The PDFF metric is an average of all the pixels within the contour generated by automatic liver segmentation.

PDFF imaging methods can be susceptible to fat and water components being erroneously swapped, leading to the water percentage reported as the fat percentage. CoverScanMD is robust against fat/water swaps, but in some cases this may still occur.

3.2.3.3. Liver Iron Concentration (LIC) (mg Fe / g) Interpretation

LIC, expressed in mg Fe/g dry tissue weight of the liver, provides the concentration of iron in hepatic tissues. LIC is derived from T2*, which is a measure of the transverse (spin-spin) relaxation of a given tissue in the presence of magnetic field inhomogeneities. The T2* of a tissue is affected by local magnetic susceptibility effects, including those caused by iron deposits, typically ferritin and hemosiderin. Hepatic tissues with high iron content have short T2* values, and tissues with low iron content have long T2* values. While T2* is field strength dependent, LIC is not affected by field strength.

3.2.4. Pancreas Metrics Interpretation

3.2.4.1. Pancreas srT1 (ms) Interpretation

As with cardiac T1, the T1 of the pancreatic tissue depends on its free water content, which relates to the proportion of extracellular fluid in the tissue. Increased T1 can be used in the diagnosis of edema (increased tissue water) or increased interstitial space due to fibrosis. Scanner make and field strength can introduce potential bias to the T1 measurement. The srT1 (scanner referenced T1) map relies on a modified look-locker inversion recovery (MOLLI) acquisition, enabling T1 maps from a single breath- hold acquisition to be generated. The T1 maps built from different scanner models and manufacturers may produce slightly different T1 values depending on the software implementation and hardware. The calculation of pancreas T1 maps using the MultiScan module uses the signal from supported scanners and MRI field strengths to simulate the data as it would be acquired on the reference scanner, providing improved reproducibility. The srT1 pipeline maps MRI-system dependent T1 images to MRI-system independent srT1 images and that allows comparison of srT1 values over a wide variety of MRI systems. srT1 is standardized to the MOLLI T1 measurement that would be made on a Siemens 3T scanner. It does not correct for any other potential confounders e.g. iron or fat.

T1 can be measured by many methods. CoverScanMD uses a standardized MOLLI-T1 method. Other methods may differ from other T1 mapping and produce different results.

3.2.4.2. Pancreas fat (PDFF) (%) Interpretation

Pancreatic fat or Proton Density Fat Fraction (PDFF) is a ratio, expressed as a percentage, of the fraction of the MRI-detectable protons attributable to fat divided by all MRI-detectable protons in that region of the liver attributable to fat and water. The PDFF metric is a summarized metric from the individual pixels within all of the ROIs (Region of Interest) placed on the PDFF parametric map (30).

PDFF imaging methods can be susceptible to fat and water components being erroneously swapped, leading to the water percentage reported as the fat percentage. CoverScanMD is robust against fat/water swaps, but in some cases this may still occur.

3.2.5. Kidneys Metrics Interpretation

3.2.5.1. Kidneys cortical T1 (ms) Interpretation

As with cardiac T1, the T1 of the kidney tissue depends on its free water content, which relates to the proportion of extracellular fluid in the tissue. Increased T1 can be diagnostic of edema (increased tissue water) or increased interstitial space due to fibrosis.

T1 can be measured by many methods. CoverScanMD uses a standardized MOLLI-T1 method. Other methods may differ from other T1 mapping and produce different results.

3.2.5.2. Kidneys length (cm) Interpretation

Kidney length (size) is a measure of the point-to-point length of each kidney and has been found to serve as surrogate for renal functional reserve (31).

3.2.6. Spleen Metrics Interpretation

3.2.6.1. Spleen Length Interpretation

The point-to-point length (size) of the spleen in the inferior to superior direction.

4. CoverScanMD Results

4.1. Cautions

If cautions are shown and results are still provided, Perspectum's analysts have identified and mitigated potential issue(s) and are confident in the accuracy of results presented.

All metrics reported by CoverScanMD should be interpreted only by a trained healthcare professional who can interpret MR examinations and the subsequently produced metrics.

CoverScanMD reported measurements should supplement and not replace a radiologist's interpretation and review.

CoverScanMD results should only be interpreted by a trained healthcare professional considering the totality of the information available on the patient, including a medical history of the patient. The trained healthcare professional remains responsible for the full clinical evaluation of the patient.

4.1.1. Patient Motion

Patient motion can affect the scan quality. However, if a metric is still provided, Perspectum's analysts have identified and mitigated potential issue(s) and are confident in the accuracy of results presented.

4.1.2. Low Patient Heart Rate

Accompanying cardiac metrics heart rate will be included as part of the cardiac evaluation when feasible. Patients with low heart rate can lead to issues that can affect the scan quality. However, if a metric is still provided, Perspectum's analysts have identified and mitigated potential issue(s) and are confident in the accuracy of results presented.

4.2. Perspectum Trained Operator Comments

During the analysis, Perspectum-trained operators can leave comments to provide additional information for the healthcare professional interpreting the results. These comments may highlight observations that are important for interpretation. These are found alongside the results to provide a quick and easily digestible summary.

If all quantitative results are present, Perspectum's analysts have identified and mitigated any data/image quality issue(s) and are confident in the accuracy of results presented.

4.3. Clinical Performance

CoverScanMD's clinical performance has been thoroughly tested using both retrospective and prospective data. The retrospective data included a wide variety of scanner models, subject types, and magnetic field strengths, ensuring robust and reliable performance across scanners. The prospective data was collected from 30 subjects using Siemens 1.5T and 3T MRI scanners at two different time points. This comprehensive testing helps ensure that CoverScanMD performs well across different

scenarios. Phantoms were also scanned in GE and Philips 1.5T and 3T to ensure the reproducibility of metrics across vendors.

The performance was tested for the following aspects:

1. Repeatability of metrics for a given magnetic field strength
2. Reproducibility of metrics across two different magnetic field strengths
3. Characterization of inter-operator variability
4. Characterization of intra-operator variability
5. 6 Equivalence testing between the operators' results and the gold standard (mean of 3 radiologists results)

The acceptance criteria for the performance tests were defined as below:

Organ	Metrics	Acceptance Criteria
Liver	T1	For Phantom Repeatability LoA +/- 15 ms For Phantom Reproducibility LoA +/- 5 % of the cT1 determined by the reference Siemens scanner For Phantom Accuracy ≥ 80 % of ground truth (Up to 20 % lower than ground truth)
	cT1	LoA +/- 150 ms
	Fat Fraction	LoA +/- 4 % being % absolute units
	LIC	LoA +/- 0.3 mg/g for iron < 3 mg/g LoA +/- 10 % for iron > 3 mg/g
Pancreas	T1	Phantom LoA +/- 8 % for all tests except accuracy. For accuracy, the criterium is (0.85 x IR-based T1) +/- 10 % of MOLLI-based T1
	srT1	LoA +/- 20 %
	Fat Fraction	LoA +/- 5 % if PDFF < 30 %, being % absolute units LoA +/- 15 % if PDFF > 30 % being % absolute units
Kidney	Right and Left Cortical T1	Phantom LoA +/- 8 % for all tests except accuracy. For accuracy, the criterium is (0.85 x IR-based T1) +/- 10 % of MOLLI-based T1 In-vivo LoA +/- 15 %
	Right and Left Length	LoA +/- 15 %

All aspects of in-vivo performance tests met the above acceptance criteria, thereby assuring robust clinical performance of the device across different scanners, field strengths and patient characteristics.

5. Data Transfer Infrastructure

Patients undergo a quick, non-contrast MRI scan at a Perspectum-cleared scanning center. This MRI captures an abdominal image, which is quality-checked and analyzed using the multiple devices that make up CoverScanMD by Perspectum's analysts. The results are returned for interpretation via a secure interface.

5.1. Secure Data Transfer

The Perspectum Portal, Perspectum's data transfer system, transfers data from the scanning site to Perspectum's analysts. The data security infrastructure is supported by an ISO 27001- and ISO 13485 compliant QMS designed around a defense-in-depth approach with multiple layers of redundancy, surveillance, physical access controls, and audit logs.

Access to the Perspectum Portal is controlled and secured by SSL encryption mandating an HTTPS protocol for web-based data transmissions to prevent eavesdropping, tampering, and forgery. All data is encrypted while in storage and routinely backed up to an alternative secondary physical location to ensure service continuity.

The Perspectum Portal is hosted by Amazon Web Services (AWS), a market-leading cloud platform solutions provider, which employs rigorous and sophisticated security processes to guard data privacy from malicious or accidental incidents.

5.2. Help and Assistance

If you have any questions regarding CoverScanMD, its components, the Perspectum Portal or the CoverScanMD results, please contact us via the following options.

Support@Perspectum.com

US: +1 833 875 0862

UK: +44 800 029 3049

The Perspectum Hotline is open from 9:00 am to 5:30 pm CT and GMT time zones excluding bank and federal holidays.

5.3. Frequently Asked Questions

Our FAQ's for CoverScanMD can be found on our website alongside this guide at: https://www.perspectum.com/our-products/coverscan.

6. Reporting an incident

6.1. Device Related Incidents

If you have a reason to suspect that a device incident has occurred, causing deterioration in the characteristics or performance of the device, or if the information supplied by Perspectum is inadequate, please email us immediately at safety@Perspectum.com and the competent authority in your country.

6.2. Cybersecurity Guidance

Cybersecurity is critical for ensuring the safety of patient information, healthcare networks, and the devices used to capture, analyze or view CoverScanMD data. The recommendations below are not comprehensive but rather a sampling of pointers that may help alleviate cybersecurity vulnerabilities.

- Keep your operating system and applications up to date.
- Protect your device with a strong and unique password.
- Use a secure network connection.
- Report suspected incidents to your administrator immediately.
- Protect your device with an up-to-date, reliable antivirus package.

Trained healthcare professionals should follow cybersecurity best practices when viewing CoverScanMD results.

6.3. Cybersecurity Related Incidents

If you believe a cybersecurity incident has occurred, please contact Perspectum's Information Security Team immediately to report the suspected incident at incidents@perspectum.com.

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8. Manufacturer Information

8.1. Regulatory Information

	Perspectum Ltd. Gemini One, 5520 John Smith Drive, Oxford, OX4 2LL, United Kingdom	
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8.2. Copyright

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