Perspectum®

A Guide to Interpreting MRCP+v1 Reports for Radiologists

PDM130

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Use and Limitation

This guidance is intended to be used as a reference guide for the reviewing radiologist using MRCP+v1 reports. It is expressly not intended to be relied upon by the reader for instruction as to the practice of medicine. Any radiologist reading this information is reminded that they must use their own learning, training and expertise in reporting on medical images. This material does not substitute for that duty and is not intended by Perspectum Ltd. to be used for any purpose in that regard. The reviewing radiologist bears the sole responsibility for the diagnosis of the patients.

MRCP+v1 does not make diagnostic recommendations. MRCP+v1 provides measurements derived from MR data which can be used for assessment of pancreatobiliary anatomy. Any conclusions arrived at can only be made by a trained radiologist interpreting such measurements. In this sense, the radiologist needs to take into consideration the modality, in this case MR, and MRCP+v1's limitations and accuracy when integrating the information from MR data, as presented by MRCP+v1, into a wider diagnostic process.

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THE MRCP+V1 DEVICE

MRCP+v1 is a software application for non-invasive assessment of the pancreatobiliary system that enables generation, display and review of three-dimensional quantitative pancreatobiliary system models, as well as display of three-dimensional MRCP and anatomical MR medical image data, in the form of a quantitative report, for review by a trained radiologist.

Is MRCP+v1 a medical device?

Yes. MRCP+ is an image processing system with reference to Section 21 CFR 892.2050 of the United States Code of Federal Regulations. As such, it is a Class II device with product code LLZ. It is cleared for commercial use in the United States under Premarket Notification 510(k) number K183133.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

In Europe, MRCP+ is classified as a Class I device using rule 12 in Annex IX of the Council Directive 93/42/EEC.

What is the intended use?

MRCP+v1 is indicated for use as an image processing system for non-invasive, quantitative assessment of pancreatobiliary system structures. MRCP+v1 enables generation, display and review of three-dimensional quantitative pancreatobiliary system models, as well as display of three-dimensional MRCP and anatomical MR medical image data.

MRCP+v1 is designed to utilize DICOM compliant MRCP datasets, acquired on supported MR scanners using supported MRCP acquisition protocols.

MRCP+v1 calculates quantitative three-dimensional pancreatobiliary system models that enable measurement of duct widths and automatic detection of regions of variation (ROV) of tubular structures.

These models and the physical parameters derived from the models, when interpreted by a trained radiologist, yield information that may assist in pancreatobiliary system assessment.

MRCP+v1 is suitable for all patients not contra-indicated for MRI.

Who is the legal manufacturer?

MRCP+v1 is manufactured in compliance with the Council Directive 93/42/EEC by

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

Apr 2022

CE 2797

In Europe, ***MRCP+*** is classified as a Class I device using rule 12 in Annex IX of the Council Directive 93/42/EEC

Basic UDI-DI for MRCP+:	B554MRCP10
Owner/Operator Number:	10056574
Establishment Registration Number:	3014232555
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What are the indications and contraindications?

MRCP+v1 should only be used in conjunction with abdominal MR images for visualization and quantification of pancreatobiliary system. MRCP+v1 is indicated for general use and does not have any specific demographic restrictions. MRCP+v1 is indicated for use where MRI is not contraindicated.

Caution: Routine MRI safety screening must be carried out to ensure patients are not contraindicated for MRI

What are the diagnostic and therapeutic restrictions?

The following diagnostic and therapeutic restrictions apply. MRCP+v1 or reports produced by MRCP+v1 are not intended to be used in any of the following circumstances and any such use is expressly forbidden by Perspectum Ltd.

- MRCP+v1 reports should not be used as the sole basis for forming a diagnosis – to do so would constitute a misuse of the device.
- MRCP+v1 reports should not be used as a control mechanism for biopsy guidance – to do so would constitute a misuse of the device.
- MRCP+v1 reports should not be used as a direct control mechanism for delivery of treatment – to do so would constitute a misuse of the device.
- MRCP+v1 reports should not be used as the sole basis for evaluating the response to treatment – to do so would constitute a misuse of the device.

Warning: MRCP+v1 is not clinically validated for the above and would not be sufficiently accurate to allow safe and efficacious use.

What does MRCP+v1 produce?

MRCP+v1 produces

- an enhanced three-dimensional MRCP volume; and
- a quantitative pancreatobiliary system model

from conventional MRCP images.

The enhanced MRCP volume, or surface model, is produced by segmenting and mathematically enhancing MRCP images for improved 3D visualisation of tubular structures, in this case, ducts.

The quantitative pancreatobiliary system model, or three dimensional (3D) parametric tree model, is produced using MRCP+v1's suit of tube-width estimation algorithms. The 3D parametric model enables the following.

- Visualisation of duct widths displayed in the form of a colour-coded tree image.
- Visualisation of individually selected ducts in a two dimensional (2D) unfolded view.
- Automatic detection of regions of variation (ROV) in quantified tubular widths.

MRCP data is processed by an internal operator located at one of Perspectum image analysis centres. The internal operator trained in radiological anatomy produces a report for use by an interpreting radiologist.

What does MRCP+ measure?

MRCP+v1 measures bile duct and pancreatic duct widths, pancreatobiliary duct volume and gallbladder volume.

MRCP+v1 produces quantitative models of the pancreatobiliary system which enable estimation of duct widths at any point of the modelled tree, as well as measurement of total pancreatobiliary duct volume and gallbladder volume. MRCP+v1 automatically detects regions of variation (ROV) of duct width in the biliary tree.

What is duct width?

Duct width is an estimated cross-sectional diameter of the lumen of a bile duct or pancreatic duct.

In MRCP+v1, duct widths can be measured at any point of the quantitative pancreatobiliary tree model. The model is computed from 3D MRCP images by state-of-the-art image processing techniques in order to create a three-dimensional representation of the pancreatobiliary tree. Each modelled duct consists of a series of estimated widths along its length.

Duct widths are measured in millimetres (unit mm). In MRCP+v1, duct widths are colour-coded in the range of [0-12] mm. The duct width metric on the quantitative analysis output is displayed as a median and interquartile range (IQR), as well as a minimum and a maximum value.

What is duct width ROVs?

By knowing duct width at each point of the duct, MRCP+v1 automatically detects regions of variation (ROVs) of duct width. Duct width ROVs are defined as areas where tubular width locally changes by 30% or more.

Duct ROVs are colour-coded as locations of duct width increase (orange) and duct width decrease (blue).

What is biliary volume and how is it measured?

Biliary volume is a summarised metric of all individual duct volumes in the quantitative biliary model (including all bile and pancreatic ducts). Volume of each duct is determined from its estimated width and length. Biliary volume is measured in millilitres (unit mL).

Caution: Biliary volume is calculated from the biliary structures present in MRCP images. If any of the biliary structures are outside of the field of view or are for other reasons not captured or visible in MRCP data, biliary volume will likely be underestimated.

What is gallbladder volume and how is it measured?

Gallbladder volume is the total volume of the gallbladder as seen in MRCP images. Gallbladder volume is measured in millilitres (unit mL).

Caution: The gallbladder volume is calculated from the gallbladder modelled in MRCP+v1. If a part of the gallbladder is outside of the field of view or is for other reasons not captured or visible in MRCP data, the gallbladder volume will likely be underestimated.

What is the accuracy and precision of MRCP+v1?

It is important to understand the limitations in the performance of MRCP+v1. The table below provides a summary of performance testing in-vivo and in phantoms. Values provided are limits of agreement.

Metric	Accuracy	Repeatability	Reproducibility
Biliary Volume (ml)	N/A	± 3.5	± 6.9
Gallbladder Volume (ml)	N/A	± 9.4	± 18.4
Bile Duct Width (mm)	± 1.1	± 2.0	± 2.8

Table 1 MRCP+v1 accuracy and precision

From the above, the following definitions apply:

Biliary Volume

- Repeatability is defined as the worst LoA achieved from in vivo scans (test-retest) of the tree volume metric on the reference scanner (Siemens Prisma 3T).
- Reproducibility is defined as the worst LoA achieved for the tree volume metric from the reference scanner (Siemens Prisma 3T) against another tested scanner manufacturer (GE Optima 450W).

Gallbladder Volume

- Repeatability is defined as the worst LoA achieved from in vivo scans (test-retest) of the Gallbladder Volume metric on the reference scanner (Siemens Prisma 3T).
- Reproducibility is defined as the worst LoA achieved for the Gallbladder Volume from the reference scanner (Siemens Prisma 3T) against another tested scanner manufacturer (Siemens Avantofit 1.5T).

Bile Duct Width

- Accuracy is defined as the worst-case limits of agreement (LoA) achieved from clinical phantom acquisitions across the scanners supported. Measurements from the GE Optima 450W 1.5T scanner were used.
- Repeatability is defined as the worst LoA achieved from in vivo scans (test-retest) of the CD Median metric on the reference scanner (Siemens Prisma 3T).
- Reproducibility is defined as the worst LoA achieved for the CD Median metric from the reference scanner (Siemens Prisma 3T) against another tested scanner manufacturer (Siemens Avantofit 1.5T).

Key take home points can be summarised as follows:

- MRCP+v1 width measurement algorithm accuracy is ± 1.1mm
- Test-retest for biliary tree volume is ± 3.5ml

- Cystic duct was the worst performing duct identified during performance testing. Repeatability measurements of duct width for cystic duct is ±2.0mm, and the reproducibility measurements were ±2.8mm
- Repeatability of all other ducts is between ±0.5 and ±2.0mm, and reproducibility between ±0.5 and ±2.8mm
- Reproducibility of biliary tree volume is ±6.9ml
- Repeatability of gallbladder tree volume is ±9.4ml, and reproducibility of gallbladder tree volume is ±18.4ml.
- Gallbladder Volume is the least precise measurement produced by MRCP+v1.

Please refer to the Appendix for a summary of comparative metrics found from scientific literature from different studies and imaging modalities.

Which MRCP Protocols are supported in MRCP+?

To generate a three-dimensional heavily T2-weighted volumetric image, we make use of specific 3D multi-shot fast/turbo spin echo acquisitions with very long echo train lengths and short echo spacing.

The 3D multi-shot FSE/TSE pulse sequences are unique to the individual MRI manufacturers.

- Philips MRI systems require a 3D multi-shot FSE/TSE pulse sequence (*sMRCP_3D_HR)*.
- Siemens MRI systems require a 3D multi-shot FSE/TSE pulse sequence (*SPACE)*.
- GE MRI systems require a 3D multi-shot FSE/TSE pulse sequence (*3D frFSE)*.

The pulse sequences are released clinical products.

MRCP+ protocols are defined using parameters that vary depending on the manufacturer.

Table 2 summarises the acquisition protocols supported for the three main MRI manufacturers at 1.5T and 3T.

MRI Manufacturer	Siemens	Philips	GE
In Plane FOV (X x Y)	180x180 - 475x475		
Native Resolution (X x Y x Z, mm)	0.25x0.25x0.25 - 2.5x2.5x2.5		
Slice Gap	0 (Contiguous)		
Slices	32 - 1024		
In-Plane Acquisition Matrix	72x72 - 1024x1024		
Acquisition plane	Acquisition should primarily coronal.		
Voxel size relationship	The native voxel size should not be larger, by a factor of two, in one direction compared to the other.		

Table 2 – MRCP+ supported acquisition parameters summarised for each manufacturer.

What are the MRCP+ recommended protocols?

Please refer to the following documentation.

- MRCP+v1 Supported MR Systems – MRA758
- MRCP+v1 Image Acquisition Protocols – MRA450

Please refer to the following documentation.

- MRCP+v1 Patient Acquisition Checklist – MRA481
- MRCP+v1 Patient Acquisition Manual – MRA460

THE MRCP+V1 REPORT

MRCP+v1 is provided to the reviewing radiologist as a quantitative report. It gives summary metrics for the whole biliary tree (including any pancreatic ducts modelled), the gallbladder, and selected individual ducts.

How can I view the MRCP+ report?

MRCP+ report can be opened by a standard PDF viewer software. It is recommended that your PDF viewer is kept up to date.

How is the report structured?

The MRCP+v1 report is at least three pages long. It always contains a biliary tree summary page, an acquisition details page and a MIP page. Optionally, the MRCP+ report may contain any additional number of single duct pages for any ducts of interest which the operator has added to the report for review.

Note: Figure 1-4 are for demonstration only. The MRCP+v1 report shall reflect the corresponding MRCP+v1.x.x and candidate release information according to the software manufacture details on the About MRCP+ of the version in use.

Biliary system page

The biliary system page contains the results of the quantitative analysis of the biliary system. An example biliary system page is shown in Figure 1.

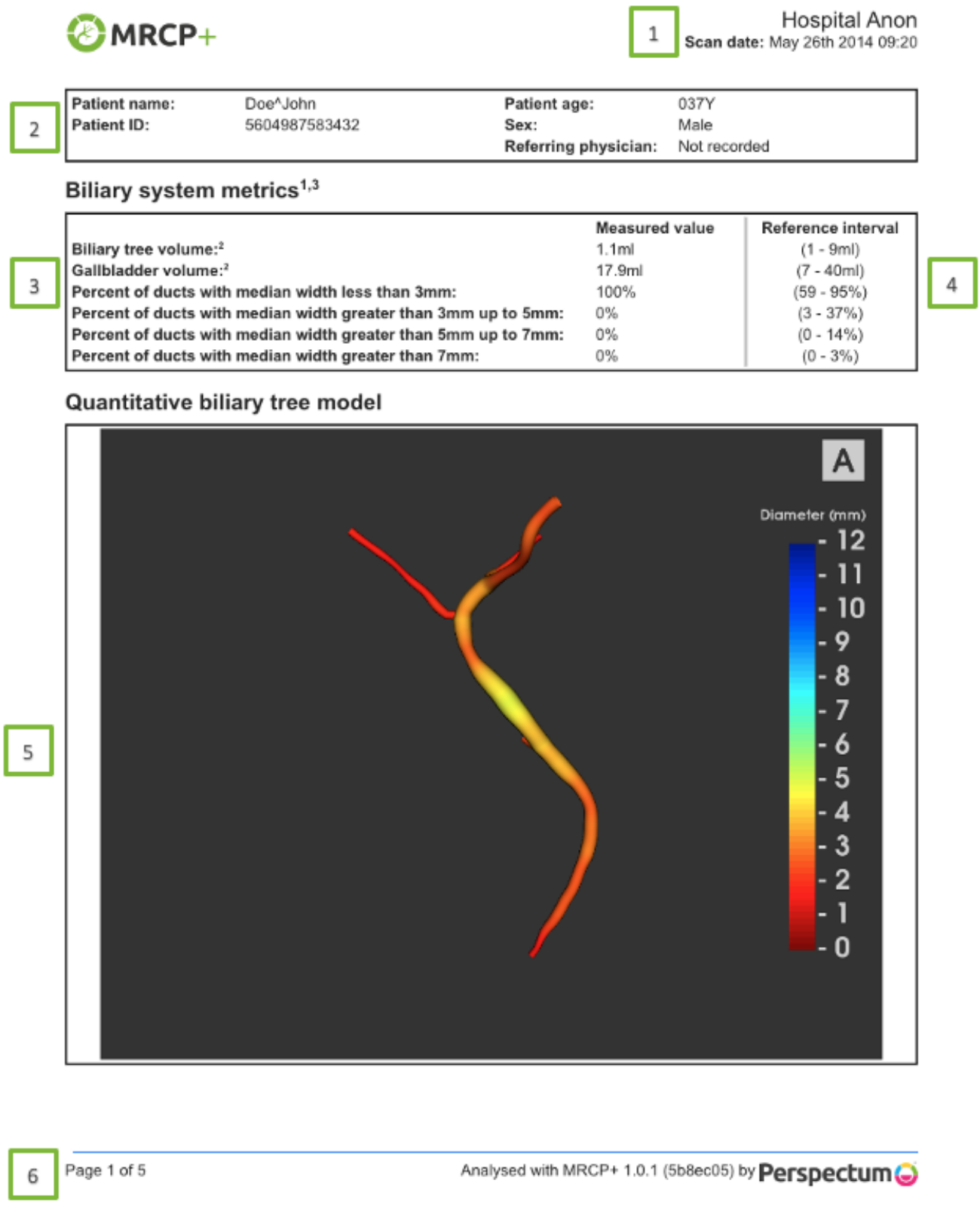


Figure 1 MRCP+v1 report; Biliary System Page

The explanation of the metrics in this guide is intended exclusively for use by Radiologists.

The key features are denoted numerically.

Feature number	Feature content	Feature description
1	Header	Acquisition centre name and date of the acquisition
2	Patient information	Patient identifiers and referring clinician details
3	Biliary system metrics	Biliary tree and gallbladder volumes. Distribution of bile duct widths throughout the biliary tree
4	Reference intervals	Reference intervals calculated from 95% confidence intervals on whole tree metric distributions in N=30 healthy subjects (BMI<26 kg/m^2, mean age 35y) scanned during performance testing
5	Biliary tree model	An image of the quantitative biliary tree model. Colour codes available: Duct width; or ROV of duct width
6	Footer	MRCP+v1 software version used to perform quantitative analysis

Table 3 Biliary system page contents

Information: Responsibility for entering the correct patient identifiers lies with the acquisition centre.

Caution: MRCP+v1 uses validated algorithms to produce a mathematical model of the biliary system. Modelling inaccuracies at branching points may be possible in some cases. The radiologist may utilise conventional methods alongside MRCP+v1 to confirm diagnosis, if deemed necessary. The radiologist should be cautious when interpreting quantitative measurements reported at suspicious branching points.

Bile duct page

The Bile duct page contains information about an individual bile duct and its morphology. An example Bile duct page is shown in the igure 2.

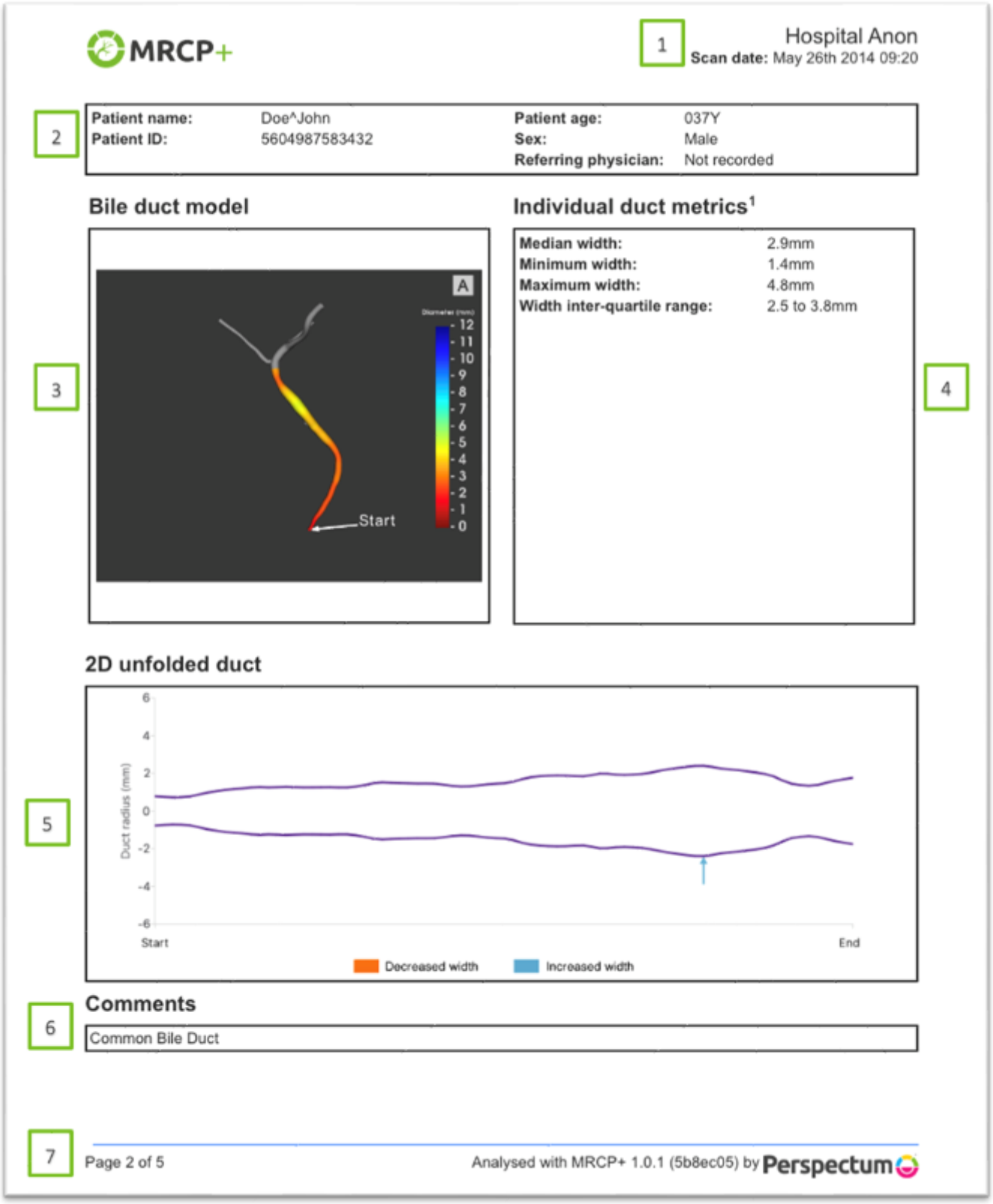


Figure 2 MRCP+v1 report; Bile duct page

The explanation of the metrics in this guide is intended exclusively for use by Radiologists.

The key features are denoted numerically.

Feature number	Feature content	Feature description
1	Header	Acquisition centre name and date of the acquisition
2	Patient information	Patient identifiers and referring clinician details
3	Bile duct model	An image of the quantitative biliary tree model, where the selected duct is displayed in a selected colour code, and the rest of the tree is shaded in grey. Colour codes available: - Duct width: [0-12]mm - ROV of duct width: orange = decreased width; blue = increased width
4	Bile duct metrics	Bile duct width median and interquartile range (IQR). Minimum and maximum bile duct width
5	2D unfolded duct	A graphical representation of the selected bile duct model unfolded in 2D for easier understanding of the variation of duct width. If present in the duct model, the location of duct width ROVs will be indicated on the graph by arrows: • orange = decreased width • blue = increased width
6	Operator's comments	Comments added by operator for an individual duct; may contain anatomical naming of the duct
7	Footer	MRCP+v1 software version used to perform quantitative analysis

Table 4 Duct page contents

Reference intervals for single duct metrics

The MRCP+ report will typically contain the following single ducts, if present in the model:

- Common Bile Duct (**CBD**)
- Right Hepatic Bile Duct (**RHBD**); In some variations the report may contain:
  - Right Anterior Bile Duct (**RABD**)
  - Right Posterior Bile Duct (**RPBD**)
- Left Hepatic Bile Duct (**LHBD**)
- Cystic Duct (**CD**)
- Pancreatic Duct (**PD**)

Reference intervals for all metric reported for these ducts are shown in Table 6.

	Median (mm)	Minimum (mm)	Maximum (mm)	IQR (mm)
CBD	2.6 – 6.4	1.7 – 4.1	3.3 – 8.9	0.1 – 2.3
RHBD	2.3 – 5.3	1.7 – 5.1	2.6 – 6.2	0.1 – 1.5
RABD	1.9 – 4.2	1.3 – 3.9	2.5 – 5.1	0.0 – 1.5
RPBD	1.9 – 3.3	1.0 – 2.9	2.6 – 4.6	0.2 – 1.5
LHBD	2.3 – 5.2	1.8 – 4.7	2.9 – 6.2	0.0 – 2.3
CD	1.3 – 4.7	0.7 – 3.6	1.9 – 7.5	0.0 – 3.5
PD	1.4 – 4.2	0.6 – 3.2	1.7 – 5.8	0.2 – 1.5

Table 5 Reference intervals calculated from 95% confidence intervals on whole tree metric distributions in N=30 healthy subjects (BMI<26 kg/m², mean age 35y) scanned during performance testing

Please refer to the Appendix for a summary of comparative metrics found from scientific literature from different studies and imaging modalities.

Acquisition details page

The Acquisition details page provides details of the acquisition, including any cautions or acquisition quality comments. An example acquisition details page is shown in Figure 3.

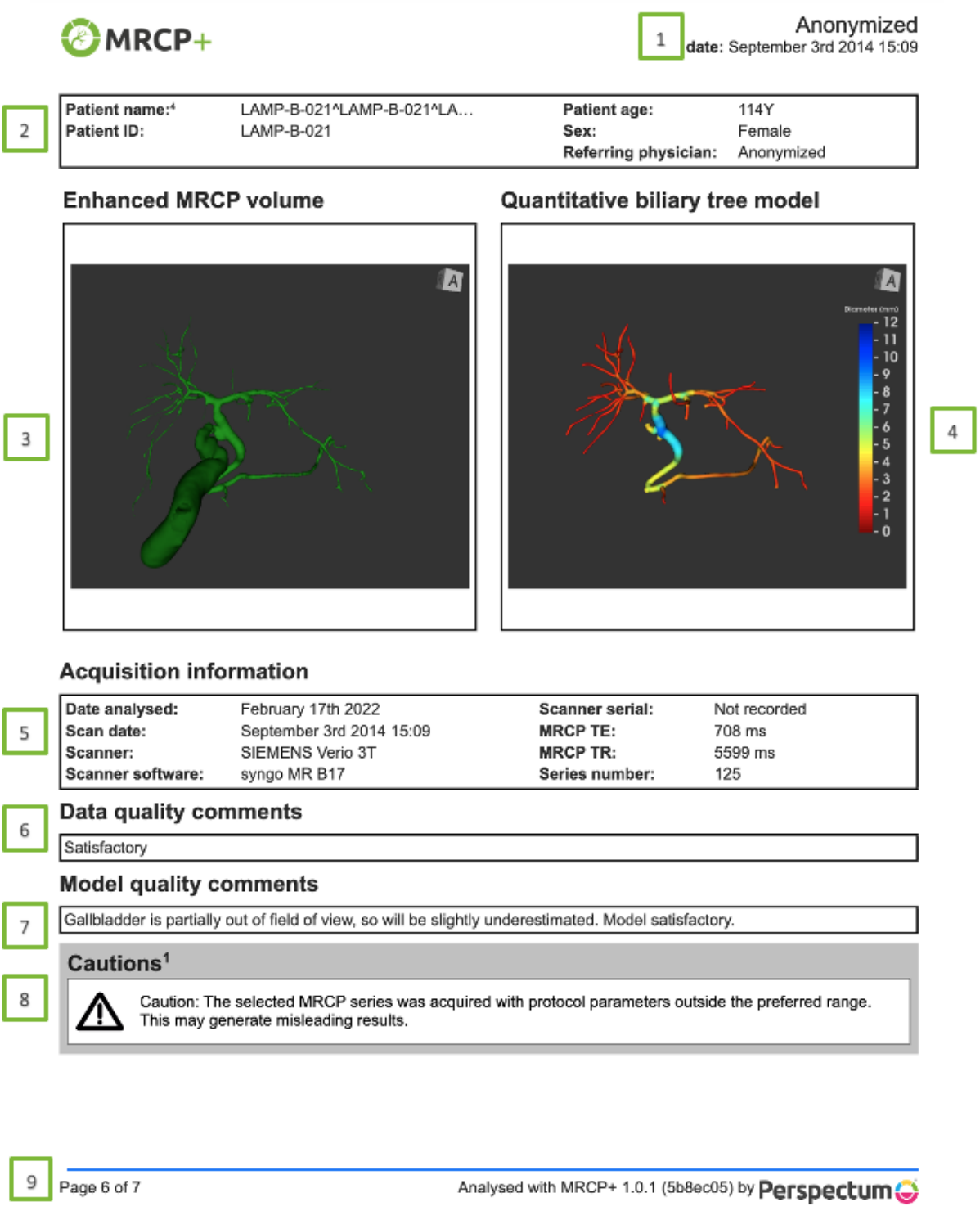


Figure 3 MRCP+v1 report; Acquisition details page

The contents are described in Table 7.

Feature number	Feature content	Feature description
1	Header	Acquisition centre name and date of the acquisition
2	Patient information	Patient identifiers and referring clinician details
3	Enhanced biliary tree	An image of the enhanced biliary tree, including the gallbladder, if present
4	Biliary tree model	An image of the quantitative biliary tree model. Same image as in the biliary system page; shown next to the enhanced biliary tree image for reference
5	Acquisition information	Scanner details and date of MRCP+v1 analysis
6	Data quality comments	Data quality comments added by the operator
7	Model quality comments	Model quality comments added by the operator
8	Cautions	Cautions generated by MRCP+v1
9	Footer	MRCP+v1 software version used to perform quantitative analysis

Table 6 Acquisition details page contents

Caution: In the case of unusual anatomy observed in MRCP+v1 images, the radiologist may utilise conventional methods alongside MRCP+v1 to confirm diagnosis, if deemed necessary.

Caution: In the case that a duct appears to be disconnected in MRCP+v1 model, the radiologist may utilise conventional methods alongside MRCP+v1 to confirm diagnosis, if deemed necessary.

MIP page

The MIP page contains a Maximum Intensity projection of the MRCP data, as well as any caution messages and footnotes. An example MIP page is shown in the Figure 4.

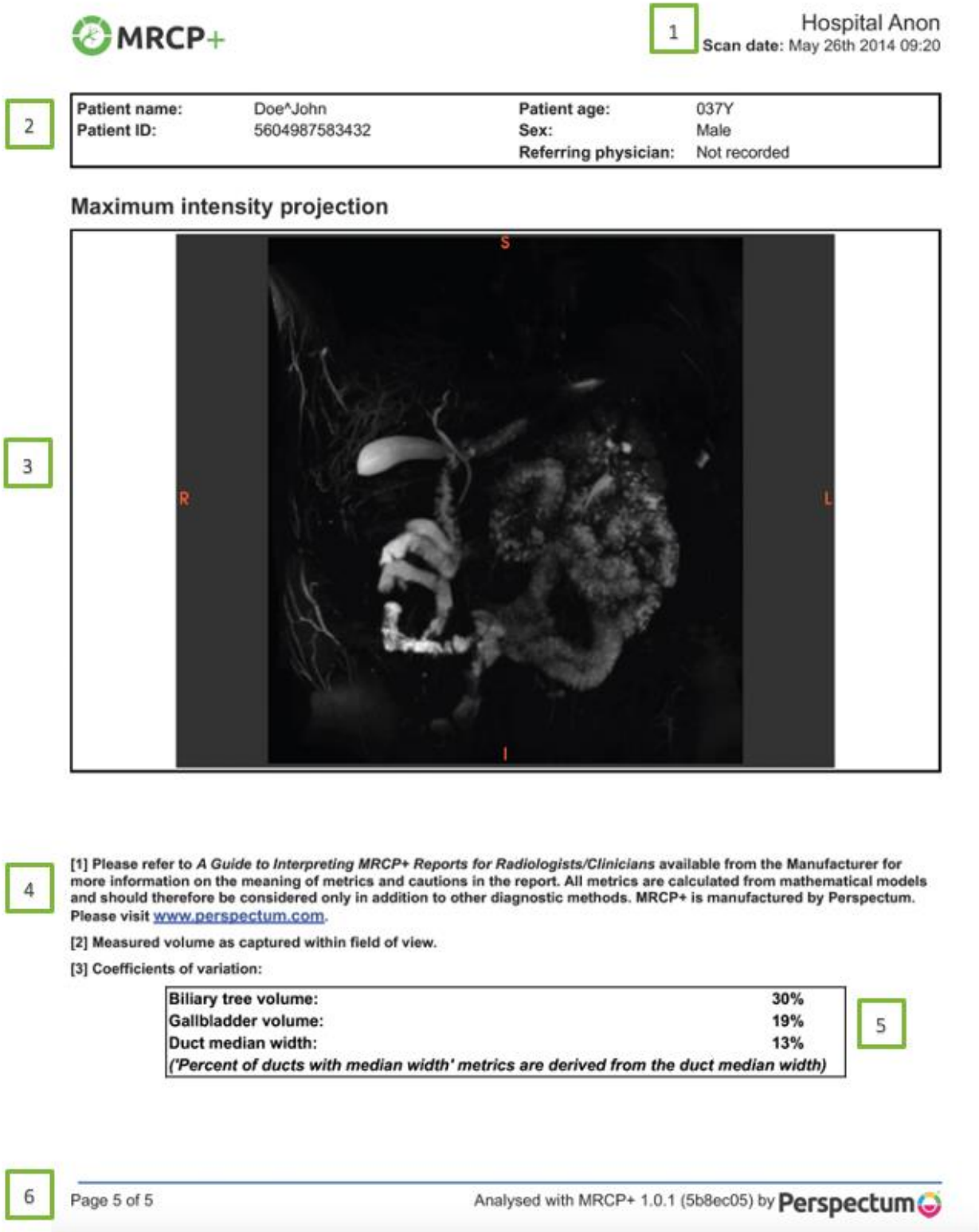


Figure 4 - MRCP+v1 Report; MIP Page.

The key features are denoted numerically.

Feature number	Feature content	Feature description
1	Header	Acquisition centre name and date of the acquisition
2	Patient information	Patient identifiers and referring clinician details
3	MIP image	Maximum Intensity Projection image in coronal orientation
4	Footnotes	Additional information on references referenced from elsewhere within the report
5	Coefficients of variation	Coefficients of variation calculated from N=40 performance testing scans, representing the service repeatability (same person scanned twice on the same scanner, data analysed by different operators)
6	Footer	MRCP+v1 software version used to perform quantitative analysis

Table 7 - MIP Page Contents.

Which factors associated with image acquisition can affect the quality of metrics reported?

The use of MRCP+v1 is contingent on the acquisition of data of sufficient quality. As part of the Quantitative Analysis Service (QAS), data quality is assessed both automatically and manually. Typical acquisition problems are detailed in Table 8, together with exemplar report comments.

Exemplar Report Comment	Why?	Impact on Quantitation
 Caution: The selected MRCP series was acquired with protocol parameters outside the preferred range. This may generate misleading results.	MRCP series used for analysis was acquired with resolution different than the preferred resolution (specified in MRA450).	Where resolution is too low, partial volume effect artefacts can occur. Where resolution is too high, long acquisition time may lead to motion artefacts.
 Caution: The selected MRCP series was acquired with protocol parameters outside the preferred range. This may generate misleading results.	MRCP series used for analysis was acquired with TE (echo time) outside the preferred range (specified in MRA450).	Where TE is too low, there can be vessel contamination. Where TE is too high, signal from the biliary structures can be too low to be quantified.
 Caution: The selected MRCP series was acquired with	MRCP series used for analysis was acquired with a non-coronal acquisition.	Non-coronal resolution may lead to incorrect display of data dimensions.

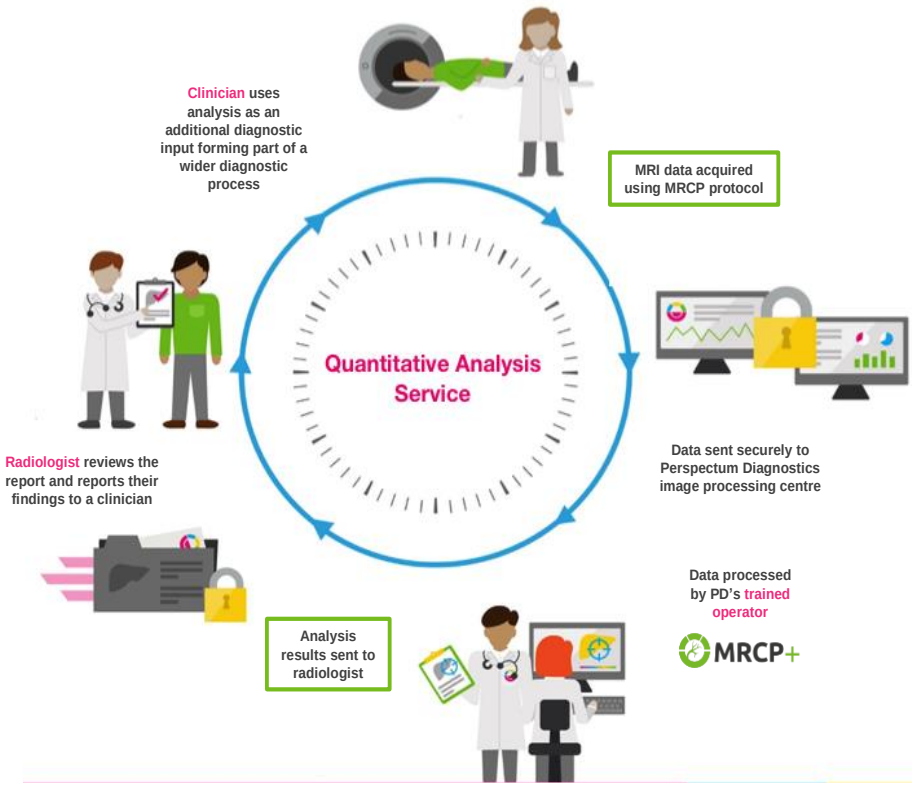
Exemplar Report Comment	Why?	Impact on Quantitation
protocol parameters outside the preferred range. This may generate misleading results.		
 Caution: The selected MRCP series was acquired with protocol parameters outside the preferred range. This may generate misleading results.	MRCP series used for analysis was acquired with number of slices outside the preferred range (specified in MRA450).	Where number of slices is too low, a desirable coverage of the biliary tree may not be achieved. Where number of slices is too high, long acquisition time may lead to motion artefacts.
 Caution: The selected MRCP series was acquired with protocol parameters outside the preferred range. This may generate misleading results.	MRCP series used for analysis was acquired with echo train length outside the preferred range (specified in MRA450).	Where echo train length is too low, long acquisition time may lead to motion artefacts. Where echo train length is too high, spatial blurring and a decrease in overall signal-to-noise-ratio and contrast-to-noise ratio can occur.
Evidence of motion	Whilst the patient acquisition manual stresses the importance of controlled breathing to minimise the likelihood of motion, breathing and moving to get comfortable may occur. This is typified as blurring and/or ghosting in the image.	If motion is minimal, biliary tree can be quantified in unaffected regions. Where motion is severe, it may not be possible to perform quantitation.
Low SNR (signal to noise ratio)	Reduced signal can be caused by mechanical issues, e.g. incorrect coil selection or biological issues. Images affected by low SNR contain high amounts of non-biliary structures, causing difficulty in identify biliary structures.	If noise is too severe, it may not be possible to perform quantitation.
Vessel contamination	Evidence of several hepatic vessels in the MRCP data can conduct to misidentification of biliary structures. Usually appears where TE is too low.	If vessel contamination is minimal, biliary tree can be quantified in unaffected regions. Where vessel contamination is severe, it may not be possible to perform quantitation or

Exemplar Report Comment	Why?	Impact on Quantitation
		biliary tree could be overestimated. In the presence of vessel contamination TE should be increased to preferred range; [450 - 750] ms
Gastrointestinal contamination	Evidence of several gastrointestinal structures with hyperintense signal that could affect biliary tree thresholding method and biliary tree identification.	If gastrointestinal contamination is minimal, biliary tree can be quantified in unaffected regions or some gaps in biliary tree ducts may occur due to connection between gastrointestinal structures and biliary tree in the 3D model. Where gastrointestinal contamination is severe, it may not be possible to perform quantitation or biliary tree could be modelled with several issues in the final model (eg. gaps in biliary ducts, erroneous ducts morphology).
Aliasing (phase wrap-around)	Evidence of structures outside the FOV projected into the area of interest. Usually it is manifested by an overlapping of the structures outside the FOV on the opposite side of the image. In the presence of aliasing phase oversampling should be increased to 100% in order to avoid wrap-around artefact.	If aliasing is minimal and the structures do not project onto the biliary tree, it can be quantified in unaffected regions. If aliasing is severe and the structures project onto the biliary tree it may not be possible to perform quantitation.
Poor fat suppression	Poor fat suppression is characterized by presence of hyperintense signal of structures with fat content (e.g. visceral fat or subcutaneous fat). In the presence of poor fat suppression, it should be confirmed that fat suppression techniques are enabled, and system frequency adjustment should be checked to confirm if the excitation frequency is in the proton water range.	If fat suppression is suboptimal and there exists some signal from visceral and/or subcutaneous fat, the biliary tree can be quantified with minor issues regarding biliary tree segmentation quality. If poor fat suppression is severe, it may not be possible to perform quantitation.

Table 8 Potential acquisition issues

Quantitative Analysis Service

Perspectum offers a Quantitative Analysis Service (QAS). Patients undergo an MRI scan at a Perspectum cleared scanning centre. The MRI scan will capture an abdominal image which includes the liver. The images are then analysed using MRCP+v1 in Perspectum dedicated image analysis centre. A quantitative report on biliary system metrics is generated and sent to a reporting radiologist. The radiologist uses the report, as well as the MRCP data, in conjunction with standard radiological tools, in order to produce a radiological report. The results are subsequently returned to the scanning centre for interpretation by a clinician. The clinician uses the information, as well as other diagnostic tests or procedures, to make a diagnosis.



Who performs the analysis on the acquired data?

Perspectum use trained operators based in our dedicated data analysis centre. Operators, for example radiographers or radiologists, are the intended users of the MRCP+v1 device and is necessarily trained in radiological anatomy.

How is the quality of the data acquired assessed?

All data goes through both automated and manual quality control (QC) checks. Once a dataset passes the automated QC checks, our operators are trained to identify potential problems or artefacts.

If a dataset appears severely affected by acquisition artefacts, the case is escalated to specialist teams within Perspectum to evaluate and recommend further action, if at all possible. In some cases, the recommendation will be to reject the study.

How is the clinician informed of the quality of the acquired data and confidence in the reported metrics?

Operators are trained to report on the quality of the data acquired. The acquired MRCP DICOM data is reviewed, processed and analysed using conventional radiological tools and the MRCP+v1 device. The reviewing radiologist produces a radiological report for use by an interpreting clinician. The MRCP+v1 report serves as an additional quantitative report for consideration by the radiologist.

Any concerns regarding MRCP+v1's ability to reliably quantify biliary system metrics are communicated as comments along with the reported metrics. Repeated issues with image quality may lead to a remedial QC visit from Perspectum to identify the root cause of the problems, and retrain the MR radiographer, if required.

How is quality assured?

Perspectum operate an independently certified ISO 13485 and 9001 quality management system. Our team installs the MRCP+v1 MRI protocols and provides training to MR Radiographers at scanning centres. Sites are then cleared to ensure that both the MR scanner and MR radiographer(s) are able to produce images that meet our quality standards. The data undergo automated quality checks prior to analysis by trained operators at our dedicated analysis centre. Results are re-checked prior to returning the analysed metrics to the scanning centre.

Perspectum holds an ISO 13485 certificate with the following scope:

> "The design and manufacture of a software system for quantitative image analysis of MRI data and the provision of a quantitative analysis service."

How secure is the service?

Perspectum is in compliance with the UK Data Protection Act of 1998, and as such, is a registered data controller with the Information Commissioner's Office. In addition, our QAS infrastructure is compliant with the US Health Insurance Portability and Accountability Act (HIPAA) and the US Health Information Technology for Economic and Clinical Health Act (HITECH).

Data analysis is performed under a certified ISO 13485 compliant QMS. Perspectum holds an independently assessed ISO 27001 information security certificate with the following scope:

> "The protection of information for:
>
> (i) the provision of a quantitative analysis service covering confidentiality, integrity, and availability, including the appropriate handing of information pertaining to competing clients; and
> (ii) the management of information pertaining to the operation of Perspectum.
>
> This is in accordance with our Statement of Applicability."

How do I get in touch with Perspectum in case I have additional questions or need support?

For support and advice please contact:

Perspectum Ltd

Telephone: +44 1865 655343 (UK) | + 1 650 392 0987 (US)

Email: support@perspectum.com

CYBERSECURITY

Cybersecurity is a critical part of ensuring that patient safety, patient information, healthcare networks, as well as your own devices are not compromised. The recommendations provided below are not a comprehensive list, but rather a sampling of issues that may be helpful in alleviating cybersecurity vulnerabilities. Keeping your operating system, as well as the viewer used to view the pdf report produced by MRCP+ up to date is strongly recommended. Other controls, such as firewalls or virtual private networks may also be appropriate. Please contact your system administrator if you believe this to be the case.

The use of antivirus software is recommended. It is important that your antivirus software is kept up to date and routine scans are performed at appropriate intervals. This may aid in protecting your device from malware, as well as other devices on your network.

Malware is a general term that refers to many types of threats, such as these:

- Virus: Harmful software that replicates itself and spreads itself to other devices
- Adware and spyware: Embedded in free software, such as weather trackers and screensavers; this type of malware generates ads and tracks user behaviour
- Phishing: Seemingly safe links take users to malicious sites that gather personal data and login credentials, and can be found within websites, emails or triggers inadvertent downloads of malware
- Pharming: Similar to phishing attacks, pharming attacks redirect users from a legitimate site to a malicious one
- Ransomware: When downloaded, ransomware blocks access to files and programs until users pay a set fee

Antivirus software may also be useful in identifying and blocking incoming threats and scanning your device for existing malware. Reliable, tested malware protection aims to get to the root of an infection and completely remove it.

Information: If you believe your device had been infected or that the data transfer has been insecure, please contact your system administrator and email incidents@perspectum.com immediately.

What are the Cybersecurity recommendations for viewing reports produced by MRCP+?

- 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

Information: Immediately stop and contact your system administrator if you suspect data has been transferred in an insecure manner, for example error messages regarding SSL certificates.

Appendix: Summary of comparative metrics

Image modality	Study size (n)	Normal CBD diameter (mm)		Abnormal CBD diameter (mm)		Duct	Duct measurement	Ref
		Mean	SD	Mean	SD			
US	200	4.1				CBD		Parulekar, 1979
US	600	3.4	Range (2-11)	4.5	Range (2-15)	CBD		Kaude, 1983
				6.2	Range (2-21)	CBD		
US	256		Range (1-10)			CBD		Wu, Ho, & Chen, 1984
US	1018	3.6	0.26			CBD		Perret et al., 2000
		4	0.25			CBD		
US	258	3.5	1			CBD	Proximal-transverse	Horrow et al., 2001
		2.9	1.1			CBD	Proximal-anteroposterior	
		3.9	1.2			CBD	Proximal-anteroposterior	
		3.4	1.2			CBD	Proximal-anteroposterior	
		4.1	1.2			CBD	Distal-transverse	
		3.5	1.2			CBD	Distal-anteroposterior	
US	251	3.39	1.14			CBD	Proximal	Bachar, Cohen, Belenky, Atar, & Gideon, 2003
		3.72	1.28			CBD	Middle	
		4.28	1.18			CBD	Distal	
		3.66	1.15			CBD	Overall mean for all measures	
		3.128	0.862			CBD		
		4.19	1.15			CBD		
US	830	2.5	1.1			CBD	At porta hepatis	Niederau et al., 1983
		2.8	1.2			CBD	Widest point	
				3.8	2	CBD	At porta hepatis	
				4.8	2.2	CBD	Widest point	
				5.2	2.3	CBD	At porta hepatis	
				6.2	2.5	CBD	Widest point	
US	24			3.95		CHD		Hunt & Scott, 1989
				4.48		CHD		
US	92	6.2	2.3	8.7	2.9	CBD		Kaim et al., 1998

				6	1.6	CBD		
US		4	1.02			CBD	Proximal	Lal, Mehra, & Lal, 2014
		4.1	1.01			CBD	Middle	
		4.2	1.01			CBD	Distal	
		4.1	1.01			CBD	Overall mean for all measures	
ERCP	20			12.9	3.9	CBD		Wachsberg, Kim, & Sundaram, 1998
US				13.1	3.1	CBD		
ERCP	30			8	Range (3-28)	CBD		Varghese et al., 1999
ERCP	10243	6.1	1.8			CHD	Maximal	Kim et al., 2002
		5.3	1.6			CHD	Midportion	
		6.4	1.8			CBD	Maximal	
		5.5	1.7			CBD	Midportion	
MRCP	29			9	Range (2-26)	CBD	Upper duct	Varghese et al., 1999
ERCP				8	Range (3-25)	CBD	Upper duct	
MRCP	40			10.2		CBD		Rösch et al., 2002
ERCP				12		CBD		
CT				10.4		CBD		
US				9.8		CBD		
MRCP	187	4.6	1.8			CBD		Chen, Hung, Huang, Lii, & Chen, 2012
		5	1.7			CBD		
MRCP	23			13.6	9.1	CBD		Park et al., 2004
MRCP	862	4.13	1.11			CBD		Peng et al., 2015
MRCP	51			20.7	5.7	CBD		Yu, Huang, Zhang, Li, & Geng, 2014
				16.5	5.2	CBD		
MDCT	398	6.7	2.41			CBD		Park, Lee, Jeong, & Cho, 2009
Anatomical	100	4.77	1.07			CBD		Mahour, Wakim, & Ferris, 1967
MRCP	6			9.1	Range (4.1-15.4)	CHD	Proximal to stricture	Kitazono et al., 2007
ERCP				8.2	Range (4-15)	CHD	Proximal to stricture	