Constellation V2 - TELUS
User Manual

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1. Device Overview

Constellation V2 is a cloud-based post-processing software application that processes magnetic resonance imaging (MRI) data acquired using the Q Bio Whole Body MRI Protocol (Q-Protocol). It automatically converts imaging data into standardized formats, stitches multi-station images into whole-body images, performs anatomical segmentation, and calculates quantitative measurements.

Constellation optionally integrates information from radiology reports and cardiac health metrics reports for display alongside imaging outputs.

1.1. Device Information

Q Bio, Inc

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San Carlos, California 94070

Device Name: Constellation V2™

Identifier: SW005

Contact Email: support@q.bio

2. Indications for Use

Constellation V2 is intended for the non-invasive labeling and calculation of quantitative measurements for anatomical regions using DICOM MR images acquired with the Q Bio Whole Body MRI Protocol on Health Canada licensed MRI scanners. It is intended to be used for healthy adult patients aged 18–80 years. Clinicians may use Constellation as a clinical decision support tool; however, it is not intended for use in triage, emergency medicine, or critical care. A clinician retains ultimate responsibility for making the pertinent diagnosis based on their standard practices.

3. Intended Users, Uses, and Use Environment

Constellation V2 is a software application that processes MRI images by stitching multi-station inputs into whole-body images, automatically labeling anatomical regions, and calculating quantitative measurements. Constellation V2 is intended for use by licensed healthcare professionals, including radiologists, physicians, and trained clinical staff who are experienced in the interpretation of magnetic resonance imaging (MRI) studies. Constellation V2 is a clinical decision support tool and is not intended to be used as the sole basis for diagnosis or patient management decisions. It is not intended for use in triage, emergency medicine, or critical care.

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Constellation V2 is intended for use with adult patients aged 18–80 years. The software is not intended for use by patients or untrained individuals.

Users of Constellation V2 include both technical operators and clinicians. Software operators are expected to be Q Bio employees or trained staff responsible for executing the Constellation workflow. These users must be familiar with operating a computer and, where applicable, using command-line functions or initiating processing through the cloud-based service. Clinician users are the end-users of Constellation outputs. Both operator and licensed healthcare professionals are required to review and understand the information in this User Manual prior to use. Licensed healthcare professionals are expected to exercise professional clinical judgment when interpreting Constellation outputs.

Constellation V2 is intended for use in hospitals, imaging centers, and clinics where MRI examinations are performed or evaluated. The device operates in a secure, HIPAA-compliant cloud computing environment and is accessed through standard computers with internet connectivity. Use of Constellation V2 requires MRI data acquired using the Q Bio Whole Body MRI Protocol (Q-Protocol) on Health Canada licensed 1.5T MRI scanners (GE and Siemens).

4. Warnings, Contraindications and Precautions

4.1. Warnings

- Constellation outputs do not provide a sole diagnosis or diagnostic recommendation. Licensed healthcare professionals may use Constellation in conjunction with other clinical findings as part of a broader clinical assessment process.
- Patient management decisions should not be made based solely on results from Constellation.
- Constellation outputs should only be reviewed and interpreted by licensed healthcare professionals trained in radiology and the interpretation of quantitative imaging results.
- Image artifacts, motion, noise, incomplete coverage, or other quality issues may affect segmentation accuracy and quantitative results.

4.2. Contraindications

- Constellation is not intended for use with populations outside the cleared intended use (healthy adults aged 22–80 years). Accuracy and reliability of outputs have not been established for patients outside this population.

4.3. Precautions

- Constellation has been developed and validated using imaging data from a healthy, normal population. Performance in patients with significant anatomical alterations (e.g., large lesions, surgical resections, tumors, or abnormal variants) has not been established. Licensed healthcare professionals should use judgment when determining whether Constellation outputs are appropriate for interpretation in unaffected anatomical regions.

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- Constellation is intended to be used only in professional healthcare settings by trained personnel.
- Constellation must be installed and configured by trained Q Bio technical staff. Installation or modification by end-users is not approved.
- All users must review the User Manual in full prior to using Constellation.
- The software is intended to run only on datasets acquired using the Q Bio Whole Body MRI Protocol (Q-Protocol) on Health Canada licensed, supported MRI scanners.

4.4. Important notes

- Constellation is a software tool that supports clinical decision-making but does not replace professional judgment. Results must be interpreted by qualified healthcare professionals.
- Users must comply with all applicable laws, regulations, and institutional policies when using Constellation in a clinical setting.

5. Definitions

This section provides definitions for terms, and abbreviations used throughout this User Manual.

Abbreviations and Terms

- **DICOM** – Digital Imaging and Communications in Medicine; the international standard for handling, storing, and transmitting medical imaging information.
- **NIfTI** – Neuroimaging Informatics Technology Initiative; a file format commonly used for storing MRI and other neuroimaging data.
- **JSON** – JavaScript Object Notation; a lightweight data format used for structuring quantitative measurement outputs.
- **HL7** – Health Level Seven; a set of international standards for transferring clinical and administrative data.
- **Q-Protocol** – Q Bio Whole Body MRI Protocol; the set of MRI sequences required for Constellation V2 processing.
- **QA** – Quality Assurance; the process within Constellation to verify completeness, accuracy, and correct mapping of outputs.
- **Segmentation Label Map** – A NIfTI-formatted file in which each voxel is assigned to a labeled anatomical region.

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6. System Requirements

- **Input Data**: DICOM files generated using Q-Protocol MRI sequences.
- **Supported Scanners**: Health Canada licensed GE and Siemens 1.5T MRI scanners.
- **Input Formats**: DICOM (Enhanced MR Image Storage or MR Image Storage), HL7 or RTF radiology report (optional), PDF cardiac health metrics report (optional).
- **Outputs**: NIfTI images, NIfTI segmentation label maps, JSON measurement files, JSON manifest and findings files, original source reports (if provided).
- **Environment**: Secure HIPAA-compliant cloud environment.

7. Operating Instructions

7.1. Preparing the Input

MRI data must be acquired using the Q-Protocol sequences. All images should meet quality standards before upload to ensure completeness and adequate image quality. If available, a radiology report in HL7 or RTF format and/or a cardiac health metrics report in PDF format may be included with the imaging data to enable integration of these findings into the Constellation output.

7.2. Uploading Data

The acquired DICOM study data should be uploaded to the secure cloud location configured for Constellation processing. A triggering message must be passed correctly to initiate the workflow. If input data is incomplete, invalid, or corrupted, Constellation will automatically log an error and processing will not proceed until the data issue is resolved.

7.3. Processing Workflow

Once initiated, Constellation executes a defined sequence of steps to process the input data. The DICOM images are first converted into standardized NIfTI file formats (3D or 4D). Multi-station NIfTI files are then stitched together to create a whole-body reconstruction. Anatomical segmentation is applied to generate label maps of relevant structures (NIfTI format label maps), and quantitative measurements are computed to produce a JSON file containing organ and tissue volumes. If provided, radiology reports and cardiac health metrics reports are parsed and integrated into the output set to create a consolidated view of imaging and clinical information.

7.4. Quality Assurance Process

Constellation incorporates a quality assurance (QA) process designed to ensure that outputs meet clinical standards before being finalized. The QA process first verifies the completeness of

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stitched images and confirms that all expected segmentation labels are present. The QA process also evaluates segmentation accuracy; when necessary, segmentations may be manually corrected, and any corrections are logged and reapplied iteratively until results meet the accepted clinical standards. Finally, if a radiology report is included, the QA process verifies correct mapping of findings and impressions to the appropriate image slices to ensure accuracy and consistency in the consolidated output.

7.5. Review of Outputs

The resulting outputs should be validated by licensed healthcare professionals through review of the Constellation machine-readable outputs in JSON and NIfTI formats presented on the Gemini Health Dashboard. If included, parsed radiology and cardiac reports are incorporated into the outputs and linked to the relevant imaging slices to facilitate interpretation. These consolidated outputs allow the reviewer to evaluate quantitative measures alongside clinical impressions.

8. Performance Characteristics

Constellation V2 has been validated to demonstrate accuracy and repeatability of segmentation and quantitative measurement outputs in accordance with Q Bio's Product Development and Quality System procedures. Validation was conducted using datasets acquired under the Q Bio Whole Body MRI Protocol (Q-Protocol) on FDA-cleared 1.5T MRI scanners (GE and Siemens).

Accuracy

- For thoracic, abdominal, and musculoskeletal structures, segmentation accuracy was assessed using the **Dice Similarity Coefficient (DSC)** and **Mean Percent Absolute Difference (MPAD)** compared to ground-truth segmentations (expert manual annotation or predicate device outputs).
- For brain cortical and subcortical structures, accuracy was assessed using **MPAD** and **Pearson's correlation coefficient** compared to predicate device outputs.
- Validation confirmed that Constellation V2 meets predefined acceptance criteria for all anatomical structures tested.

Repeatability

- **Device repeatability** was evaluated by reprocessing the same datasets twice through Constellation and comparing outputs.
- **Test–retest repeatability** was evaluated by comparing scans from the same participants acquired in repeat imaging sessions.
- In both cases, MPAD and correlation analyses demonstrated repeatable performance within acceptance thresholds.

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8.1. Residual Risks and Limitations

Constellation V2 has been designed, validated, and verified to meet its intended use. However, certain residual risks and limitations remain that users must be aware of:

- **Data Quality Dependence**: Performance is dependent on MRI data quality. Motion artifacts, noise, incomplete coverage, or deviations from the Q-Protocol may reduce segmentation accuracy and measurement reliability.
- **Population Limitations**: Performance has only been validated in healthy adult patients aged 22–80 years. Accuracy and reliability outside of this age range have not been established.
- **Anatomical Alterations**: Constellation has been developed using data from a normal population. Segmentation and volumetric analysis in patients with significant anatomical alterations (e.g., large lesions, resections, or tumors) may be inaccurate. Licensed healthcare professionals must determine whether outputs are appropriate for interpretation in unaffected regions.
- **Scope of Use**: Constellation is not intended for triage, emergency medicine, or critical care. It is intended only as a clinical decision support tool and must not be used as the sole basis for diagnosis or patient management.
- **Software Environment**: Constellation is validated only in its secure, HIPAA-compliant cloud environment. Use outside of this controlled environment (e.g., on unapproved systems) may compromise data integrity or performance.
- **Updates and Versions**: Using outdated or unverified versions of Constellation may lead to performance inconsistencies. Users must verify current version status with Q Bio Support.

These residual risks have been assessed as acceptable when Constellation is used in accordance with its intended use, by trained users, and under the specified conditions described in this User Manual.

9. Constellation Output Access

Constellation V2 outputs are intended to be accessed within a secure clinical environment. Clinical sites and licensed healthcare professionals may use image viewers or web-based dashboards capable of displaying NIfTI images and parsing JSON files to review outputs. Access methods, user provisioning, and navigation shall be defined by the site.

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For technical questions about output formats and integration, contact Q Bio Support by email at support@q.bio or by phone at +1-(415) 967-7622.

10. Maintenance and Updates

Constellation V2 is a cloud-based software application and does not require routine maintenance by end users. All software maintenance, configuration, and updates are managed exclusively by Q Bio technical staff under Q Bio's quality management system and product development procedures. End users are not permitted to modify, service, or configure the software.

Users will be notified of new software versions or updates through email or other official communication channels. To verify that the installation is current, users should contact Q Bio Support. Only authorized Q Bio personnel are permitted to apply software updates or make changes to the system configuration.

No preventive maintenance is required by the user. If Constellation V2 is suspected to be malfunctioning, users should discontinue use and contact Q Bio Support for assistance.

11. Contact Information

For technical support or questions related to the Constellation, please contact a Q Bio Administrator by email at support@q.bio or by phone at +1-(415) 967-7622.

If you are a clinician using Constellation outputs and have questions related to the Quality Assurance (QA) process, please contact a Q Bio Administrator and request to be connected with a Q Bio QA Team member. The QA Team will address inquiries related to quality assurance of the outputs.

If you are a clinician and have clinical or medical questions regarding Constellation outputs, please contact a Q Bio Administrator and request to be connected with the Q Bio Medical Team. The Medical Team will address inquiries related to clinical interpretation and use of Constellation outputs.

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