Patient QA with myQA iON CyberSecurity Leaflet

The purpose of this leaflet is to provide CyberSecurity information on the myQA iON software to IT personnel. This information will help ensure the secure and safe use of the system in clinical practice.

What is the system used for?

For cancer treatment, treatment machines such as Linear accelerators or Particle Therapy (PT) accelerators apply treatment plans to a patient, by delivering a Dose with different energies, patterns and from different angles.

- The purpose of the system is to perform quality assurance on a treatment plan, that is, verify whether the treatment plan is correctly delivered to the patient.

- These quality assurance activities are performed by certified medical physicists or dosimetrists before and during patient treatment for all patients undergoing radiation therapy.

- myQA iON is a web-based software application providing means for the verification of:

  a) The patient treatment plan prior to the first treatment fraction by:

     - Using an independent dose algorithm to compute a dose map based on the treatment plan,

     - Performing machine log analysis during a treatment dry run session,

     - Performing measurements using QA measurement tools (2D arrays, 3D detectors, chambers...) and analyzing the results.

  b) The patient treatment delivery by performing treatment machine log analysis for each treatment fraction.

- The results of above activities are compared to the treatment plan in the myQA iON software. If there are significant deviations, it can be assumed, that the plan cannot be delivered to a patient as expected. The plan will be recomputed, or the treatment machine will be checked for errors.

What if the imported or computed data is corrupted?

In this case, the comparison to the treatment plan will fail, the patient will not be treated, and the medical physicists will start a root cause investigation.

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How does the system architecture look like?
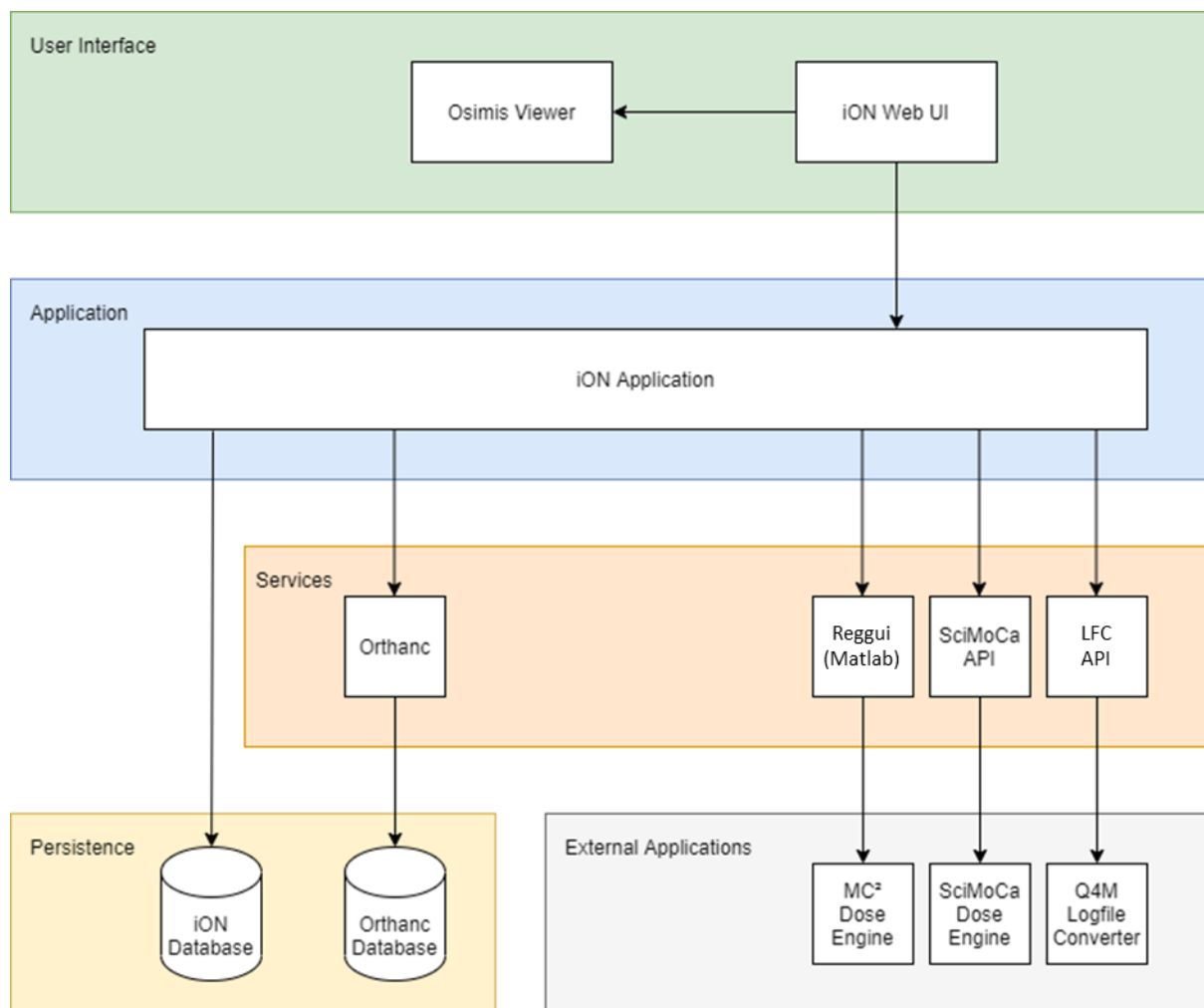
Are there any operating systems or application software supplied?

- The myQA iON software package runs on Hardware / OS provided by the hospital IT (Windows).
- The myQA iON is a web-based software composed of a backend and a web-based user interface.
- Depending on configuration, the myQA iON software package includes following SOUPs and Third-Party software:
  - Orthanc DICOM server, used as a base for DICOM handling functionalities. It also implements a convenient 'triggering' system when new patient plans are received.
  - OpenReggui providing 2D/3D Gamma (and other) algorithms used for patient QA.
  - MCSquare (Particle Therapy) which is a proton dose calculation engine.
  - SciMoCa (conventional radiotherapy) which is a dose calculation engine for RT.
  - Qualiformed (Q4M) log file converter to convert RT log files to DICOM plans.

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What kind of data is stored and handled?

■ The myQA iON Software package handles patient related data, including data which is used to identify the patient (such as name, date of birth). This data is saved in the myQA iON **SQL database.**

■ The **myQA Workstation** itself stores the following data:
- Software error logs (error and activities).

■ The **myQA iON SQL Server** stores the following data:
- Parameters used in any simulation.
- Pass / Fail decisions.
- Partial patient related data (as mentioned above).
- Event logfile (audit log).
- Tasks to be performed.
- User management.

■ The **Orthanc SQL Server** stores the following data:
- Patient data/treatment plans/Structure/CT, imported via DICOM from the treatment planning system.
- Computed doses

■ The **following data are transmitted** between:
- workstation and myQA iON SQL database:
  - Comparison / plan verification results.
  - Pass / Fail decisions.
  - Patient related data (as mentioned above).
  - Event information (stored in the audit log).
  - Tasks to be performed.
  - User management
- between workstation and Orthanc SQL data base:
  - Treatment Plans imported manually from the treatment planning system (transmission is direct between TPS and Orthanc when automated).
  - Computed doses

■ **Ports** of myQA iON:
- 8080/tcp   Apache Tomcat web server (webapp: UI, API)
- 443/tcp   Secured Apache Tomcat web server (webapp: UI, API)
- 8042/tcp   Orthanc server REST API / dashboard
- 4242/tcp   Orthanc dicom listener
- 8085/tcp   proxy used when displaying DICOM in a 3D viewer within the UI

  (Communication between the UI and Orthanc DICOM server)

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- 5432/tcp   PostgreSQL database

Interfaces

- DICOM interface, used for the import of patient treatment plans and forwarded / converted logfiles.

- It is recommended to secure the connection between myQA iON and the SQL server(s) either by a VPN or by TLS 1.2 / 1.3.

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Which measures are implemented by IBA Dosimetry to support safe and secure operation?

- An MDS-2 form is published for the myQA iON Software package and is available from our customer support team.

- Our source code is continuously scanned for vulnerabilities. We are employing software to regularly assess and improve the code quality during development.

- For ensuring the authenticity and integrity of software updates or upgrades, IBA will provide the SHA-256 checksums via a separate help center article.

- Access to SQL servers requires authentication, with credentials different from those for accessing the software application.

- User authentication for the myQA iON Software package, requiring the use of strong passwords.

- The myQA iON configuration files are signed with a hash value. At the startup of the web application, myQA iON verifies that those files have not been modified between the startup of the software and the use of the files. If the software detects a mismatch, the software will switch to non-clinical, and the user will be warned.

- Event logging (audit log) is implemented for patient related operations (patient delection, plan approval, etc.).

- All code is running on the Java Virtual Machine, which protects against many typical CyberSecurity vulnerabilities (like buffer overflow, memory corruption).

- All SOUPs are validated for functionality, analyzed for possible risks, and the list of anomalies / vulnerabilities published by the manufacturer of the SOUP is evaluated.

- Orthanc is integrated in its most recent version at the time of release of myQA iON.

- All SOUPs are running on the same server as myQA iON.

- All OWASP Top 10 have been considered.

Which CyberSecurity measures are expected to be implemented by the operator (health-care provider)?

- General requirements expected:

  - State of the art virus scanners and firewalls for the tablet and PC must be used.

  - Prescribed maintenance is done as required, including installation of security patches.

  - Windows session timeout for web application session is configured according to local policy.

  - Access control to the medical devices and network access points is established (physically and electronically). Internet access is appropriately protected. Adequate password policy is implemented.

  - A server not directly connected to internet.

- myQA iON specific:

  - Establish secure connection between myQA iON and the SQL server(s) using TLS 1.2 / 1.3.
  - Adequate use of the layered authorization model implemented in myQA iON, by differentiating privileges based on the user role, to prevent unauthorized access to, and modification of relevant data.

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We care: what happens in the case of a CyberSecurity incident?

- IBA Dosimetry is available for you 24/7. We welcome any notification about any CyberSecurity event or suspected vulnerability involving IBA hardware or software products.

- Please feel free to call our customer support team or file a request in our helpcenter (see contact information and link below).

- We will handle such reports with high priority, and you will be continuously informed about the progress.
  If necessary, we will publish a security patch.

Please contact the: IBA Dosimetry Help Center (helpcenter.iba-dosimetry.com) with any further questions

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