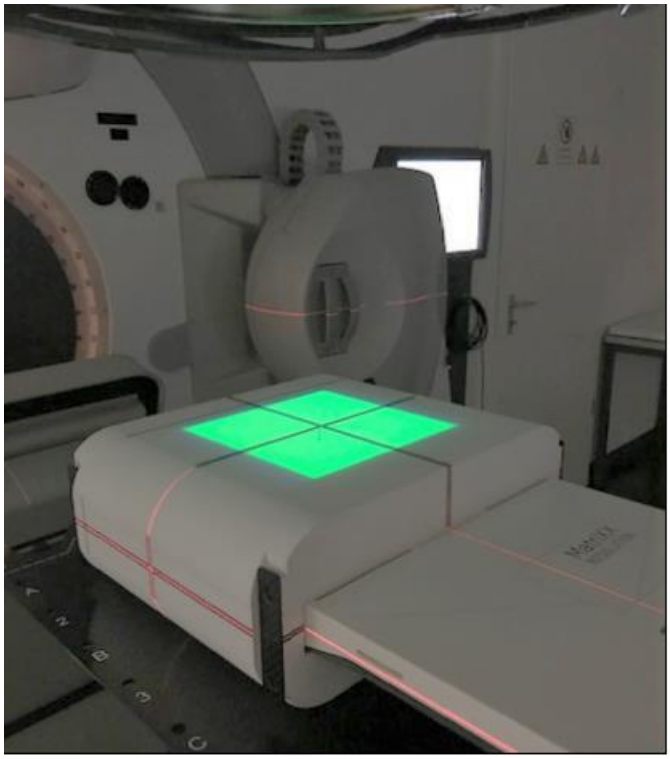
Patient QA with MatriXX Resolution CyberSecurity Leaflet

The purpose of this leaflet is to provide CyberSecurity information on the MatriXX Resolution and myQA software for 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, Linear accelerators apply treatment plans to a patient, by delivering a Dose with different energies, patterns and from different angles.

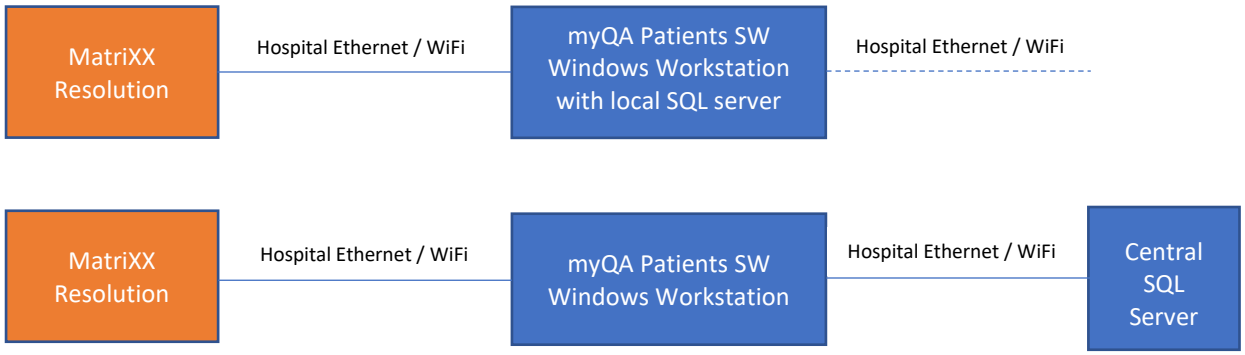
- The purpose of the system is to record a simulated treatment and to compare it versus a treatment plan.
- The MatriXX Resolution is placed on the couch instead of a patient, and the treatment plan is applied. The device records the treatment dose distribution and corresponding angles. The result is compared to the plan in the myQA Patients 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 Linear accelerator will be checked for errors.



What if the measurement device fails or measured data is corrupted?

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

How does the system architecture look like?



Are there any operating systems or application software supplied?

The MatriXX Resolution is used with the myQA Patients Software package which is delivered together with the detector.

- The myQA Patients Software package runs on Hardware / OS provided by the hospital IT.
- The MatriXX Resolution firmware contains an operating system based on Linux kernel 4.19. For updates (including any security patches), only firmware files supplied by IBA Dosimetry must be used.

What kind of data is stored and handled?

- The myQA Patients 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 SQL database.
- The MatriXX Resolution stores the following data:
  - Configuration data.
  - Calibration file.
- The myQA Workstation stores the following data:
  - Uniformity Correction file.
  - Software error logs.
- The Central SQL Server stores the following data:
  - Measurements acquired with the MatriXX Resolution.
  - Treatment Plans imported from the Planning System.
  - Comparison / plan verification results.
  - Pass / Fail decisions.
  - Patient related data (as mentioned above).
  - Event logfile (audit log).
- The following data are transmitted between workstation and MatriXX Resolution:
  - Measurements acquired with the MatriXX Resolution.

- The following data are transmitted between workstation and SQL data base:
  - Measurements acquired with the MatriXX Resolution.
  - Treatment Plans imported from the Planning System.
  - Comparison / plan verification results.
  - Pass / Fail decisions.
  - Patient related data (as mentioned above).
  - Event information (stored in the audit log).
- Ports:
  - myQA Patients: the port for the DICOM listener is 998, and configurable by the user.
  - myQA Cockpit: this viewer application uses port 52803 which is configurable by the user.
- Encryption
  - All data which is used to identify the patient (such as name, date of birth) is encrypted in the SQL database. This also applies to the event logfile.

Interfaces

- DICOM interface, used for the import of patient treatment plans.
- Import of “path.xml” files in case a Cyberknife system is used.
- If the optional viewer application myQA Cockpit is used, particularly when used from outside the clinical premises, it is strongly recommended to secure the connection between myQA Cockpit and the SQL server either by a VPN or by TLS 1.2 / 1.3.

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

- All patient personal related data are encrypted.
- Access to SQL server requires authentication.
- User authentication for the myQA Patients Software package, requiring the use of strong passwords.
- Use of TCP/IP as transport protocol.
- Communication between workstation and MatriXX Resolution uses our proprietary Hermes protocol and is secured with TLS.
- Both factory calibration and user uniformity correction files are secured with a hash value.
- Event logging (audit log) for patient related operations (Read, Write, Update, View, Backup / Restore).
- The connection to the optional viewer application myQA Cockpit can be secured with TLS 1.2 or 1.3.
- MDS-2 forms are published for both the MatriXX Resolution and the myQA Software package, and are available from our customer support team.
- Updates to the myQA Patients Software package are protected with a hash value (SHA-256). This hash value can be used to verify the authenticity of the update file received.
- Our source code is continuously scanned for vulnerabilities using SonarQube.
- The installers have a digital signature.

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 are 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.
  - An Adequate password policy is implemented.
- Device specific:
  - None.
- While no CyberSecurity issues are known at the time of release of the Dose-X we cannot completely rule out that in the future previously unidentified vulnerabilities or security issues might arise. It is therefore recommended that the customer's risk management team performs a risk assessment related to the use of the device and the myQA Software in the IT network.

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 hard- 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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