

The friendly PACS solution

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Authentic document archiving with **dicomPACS**[®]

The medical documentation obligation is grounded in the Model Professional Ordination for Medical Practitioners (Musterberufsordnung für Ärzte, § 11 Abs. 1 MBO) as a legal duty, thereby attaining the status of secondary contractual obligation deriving from the concluded treatment agreement. Watertight, evidentially secure documentation retained during the legally required periods of custody is advisable from a legal point of view and leads to a reversal of the onus of proof, i.e. that it is not for the doctor to prove that the submitted document is unfalsifiable, but for the plaintiff to present proof to the contrary.

In order for the documents to retain the legal status of an "Item of High Authenticity" that very closely approximates the original document, which clearly increases its evidential integrity, demanding standards are set for the authenticity of archived electronic documents, which need to satisfy the requirements regarding patient care as well as the administrative-legal requirements as well as queries relating to quality management and/or education and research. In accordance with the principles of duly applied DP-assisted accounting systems (GoBS¹), files must, in order to fulfil their function as records, be complete, factually and chronologically correct, properly ordered and unable to be modified.

dicomPACS[®] fulfils these requirements inter alia by means of the following internal system functionalities and procedures:

- All digital data is stored in the internationally valid DICOM (Digital Imaging and Communications in Medicine) standard. This standard was developed to create a communications platform for the transfer of medical images and image-related information, which platform is independent of any single producer. DICOM was released in 1993 and has been accepted in Europe since 1995 as the formally recognised standard. A DICOM image consists of a list of data elements containing a multitude of ancillary information relating to the image, which information requires a high degree of data security, for instance:

- Information on the patient, e.g. name, date of birth and ID number
- Information on the modality and nature of the recording, e.g. apparatus parameters, calibration, radiation dosage and contrast media?
- Image information, e.g. resolution and windows.

In accordance with the needs of the DICOM standard, all documents (own and imported images, videos, scans, faxes, patient data etc.) are basically always archived in the DICOM format. Thereby

¹ Grundsätze ordnungsgemäßer DV-gestützter Buchführung

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both the document information as well as the administrative information (number of pages, date, unique document number) are stored in a file. Each file is given a universally unique ID number, which is always retained for accessing the contents of the document as well as its respective inspection.

- It is possible to access patient data from the practice management system or directly from the **dicomPACS**[®] data bank, whereby allocation and literal errors are avoided. Date access is handled by using standardised interfaces (e.g. BDT, GDT).
- In accordance with the requirements of an internal control system (ICS) no deliberate modification of data is impossible (security against falsification). All required amendments of archived data (correction, deletion, blocking²) are completely minuted in a tamper-proof fashion and are therefore immediately accessible in an amendment register. In this way it can be immediately determined by whom, by what means and for what reason amendments were done.
- The SQL document data bank cannot be processed by means of conventional Windows[™] software, which avoids any accidental modifications. Access to the SQL data bank is secured by passwords. Long-term archiving is done by means of non-rerecordable CDs or DVDs, which means they cannot be modified.



Bernd Oehm
Distribution/Marketing partner



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Development/Technology partner

² e.g. according to the rights of the affected party, in terms of . §§20 &.35 BDSG, erasure is compulsory on termination of the documentation obligation.