Clinical and Scientific Documentation
Online & offline data entry

The MEMdoc Platform
Data Collection & Management

Preface

In keeping with their reputation as a center of excellence in orthopaedic surgery, documentation, and continuing education, the Institute for Evaluative Research in Orthopaedic Surgery (MEM-CED), University of Berne, has reinvested its resources in broadening its documentation system. A joint venture was undertaken, in early 2001, along with several renowned partners from the academic and orthopaedic medical devices industry, with the common goal of streamlining orthopaedic documentation. The objective of such an endeavour is the design and development of an international orthopaedic platform consisting of comprehensive services for the entire orthopaedic community. The MEMdoc portal will contain, at its core, a standardized international documentation system (clinical, radiological, epidemiological, and implant data), a patient-oriented information site, an orthopaedic research and educational site, as well as a tracking tool for the quality control and distribution of surgical instrumentation.

Within the portal, MEM-CED represents a neutral academic institution, which acts as a scientific clearinghouse for the anonymous collection, administration, and analysis of medical and scientific data. MEM-CED is also entrusted with industrial data pools, as several industry partners require an independent body to preside over the integrity of their data. It is worth mentioning at this stage that tremendous efforts have been undertaken to segregate apart the academic and industrial data pools. In fact, several routines ensure that no industrial application has access to academic data. On the contrary, academic tools, such as documentation of patient implants, have unrestricted access to limited views of industrial data pools for the linking of essential datasets.

Status & Prospective

Current Release

The MEMdoc portal includes three major sites: documentation, SEDICO, and patient forum.

The documentation site encompasses all online and offline data collection, archiving, and distribution tools. Registries are hosted within this section for all orthopaedic disciplines, such as knee arthroplasty, hip arthroplasty, spine surgery, in addition to various multicenter studies and patient scores.

The SEDICO site is a quality assurance tool for hospitals to mine their own implant data collected via the SEDICO barcode scanner interface. This includes several unique functionalities, such as implant tracking, usage statistics, and order confirmation.

The patient forum is a source of premiere quality information about conventional joint interventions and orthopaedic rehabilitation. All information within the patient forum is either written by MEM-CED medical staff or obtained from renowned academic sources.
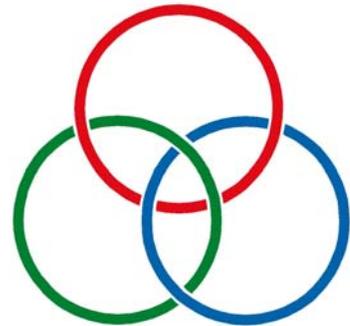
Future Enhancements

As a preamble to the European-wide launch of MEMdoc release 3.0 scheduled for the Fall of 2004, numerous prototype features will be bundled as core additions to existing functionalities. These features will include new cutting edge solutions in medical informatics to further ease the collection and distribution of medical data. Among the many tools currently in development are a few cutting-edge applications, such as a dedicated research and educational site for the real-time mining of data for academic and scientific purposes, as well as the seamless integration of national registries and other medial systems via standardized interfaces. Finally, it is worth mentioning that significant efforts are being dedicated to the development of enhanced local data collection systems. The concept is simple: to alleviate the technology burden on hospitals with client-side interfaces and applications.

A New Documentation Concept

The Basic Idea

The basic idea behind a documentation system is the creation of a centralized application that is accessible 24 hours a day 7 days a week by all registered users from anywhere in the world. Several online as well as offline tools are employed to accomplish such a task. Consequently, data from ongoing studies is pooled immediately and anonymously in the MEM-CED database hosted by MEMdoc. The anonymous data pool serves as a source of benchmarks to establish standards in Orthopaedic surgery, and gives surgeons and institutions the possibility to gauge their performance in real-time by comparing themselves against an aggregate of their peers. Nonetheless, data is shared on the clinic level. This means that all physicians and surgeons registered within one and the same hospital see their cases and those of their colleagues.

Although the application does not require personalized identifiers, any archived personalized data submitted to MEM-CED is securely stored in separate and isolated data pools. Obviously, all archived data belongs to participating hospitals or those societies under whose auspices the respective study was set up, and hence can be permanently removed via either the tools provided or a formal written request.

Process Optimization

In order to further optimize data collection and reduce workload, a new scheme of real time retrospective and prospective documentation is implemented to best emulate clinical workflow. As such each study questionnaire is divided into subforms, which is composed in the case of a primary-intervention-form, for example, of at least an admission subform, a surgery subform and a discharge subform. Depending on the length and content of a given form type, it is broken down into one or more subforms that best fit the data collection workflow in hospitals. Hence, a single subform makes up the smallest possible amount of data that needs to be documented and submitted in a particular instance. The overwhelming advantage of such a model is that subforms can potentially be filled out independently of each other using different interfaces. Nevertheless, validation rules built within the generic system ensure that data is logically and medically validated before submission.
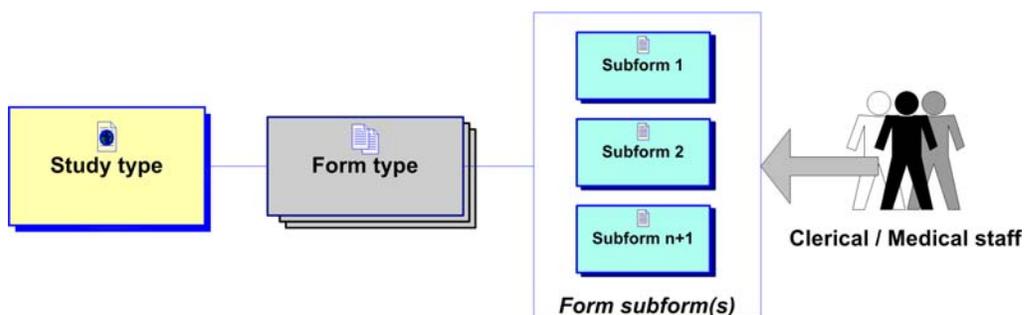
Approval of collected data

Subforms reside in meta-storage (buffer state) within the database, and are as such editable by all authorized users until all subforms defining a certain form type are completed. Only then, the "submit" state is activated, and a surgeon can submit the completed form. Once a form is submitted it is no longer editable, and is stored in the database under the name of the surgeon that submitted it. This structure makes it possible to enter data when it most easily accessible (upon admission, after surgery, or at discharge), and hence render data collection a team effort. The concept is that the responsible staff surgeon receives help from secretaries or residents, and is only required to fill out the surgery subform, review completed subforms, and finally edit the case before final submission.

Unprecedented Features (1)

Modularity & Flexibility

A modern documentation system needs to give as much flexibility as possible to users and participating clinics to ensure acceptance. With this in mind, MEM-CED developed a unique proprietary application that enables the quick implementation of clinical studies, emulates daily clinical workflow, and adds many features and functionalities to reduce the documentation workload. This modular technology facilitates the generic integration of three distinct yet complimentary solutions: an online application based on the most advanced web technologies, a paper solution using Optical Mark Recognition (OMR) scanners, as well as a mobile interface using a barcode scanner.
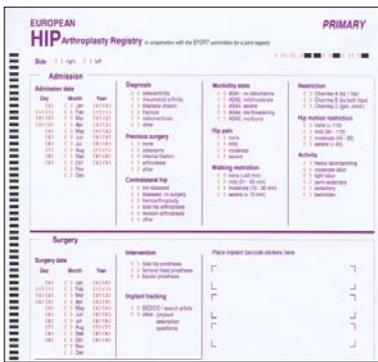
WWW Interface   **Paper Interface**   **Barcode Interface**

Interface	Modality	Requirements
WWW	Internet-based with all functionality, including data export & analysis tools	Web browser with reliably fast & encrypted Internet connectivity
Barcode	Mobile scanner for one-way transmission of data	Dedicated cradle station for battery recharge and data upload to central server
Paper (OMR)	Client or Internet enabled application with bidirectional communication	OMR application running on a networked workstation connected to an OMR scanner

External Interfaces

The MEMdoc platform is empowered with several propriety interfaces that integrate authoritative third-party systems, such as a content management system provided by Obtree Technologies Inc., Basel Switzerland, a standardized Picture Archiving & Communications System by Intelerad Medical Systems Inc. Montreal, Canada, a barcode data collection solution provided by ClusterTec, AG, Zug, Switzerland, as well as a statistical engine powered by SAS Institute Inc., North Carolina, USA. Combined with three online & offline data collection mediums, these interfaces render MEMdoc applications capable of delivering premiere data acquisition solutions.

Unprecedented Features (2)

Data Sharing

The fact is that physicians/surgeons as well as patients alike do move around from and to multiple clinics. A stable documentation system must be able in these difficult scenarios to track down both physician and patient, and still be able to correctly link the corresponding clinical data from the various hospitals.

MEMdoc has implemented a data sharing feature that spans across users as well as clinics and is compatible with all data collection modalities. This is accomplished by establishing distinct roles that a given user can overtake. Additionally, it is mandated that a given intervention is anchored to the specific clinic where such an intervention took place. Hence, both physician and patient alike can acquire multiple MEMdoc roles without adversely affecting the documentation linking of data from various sources as well as locations.

Nevertheless, given that only non-identifiable patient information is required as opposed to the personalized physician information collected, the linking of patient medical record numbers from different hospitals must be submitted to MEMdoc on a per clinic basis. This needs to done only once for a given patient record within a specified hospital.
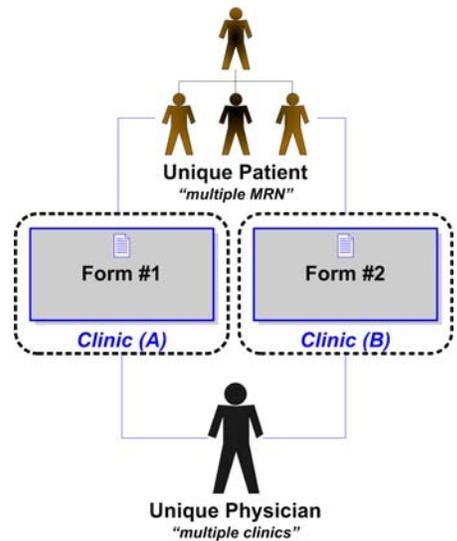
Data Validation

As an additional feature that maximizes the quality of collected data, three types of customizable data validation sets are implemented at the question, subform, and form levels. Hence, only complete and medically valid information can be submitted to the database rendering obsolete the retrospective correction of incomplete and incorrect datasets. Validation rules extend to all integrated online & offline solutions.

The first level of validation ensures that, for example, single answer questions can only be answered with a single answer. This level also ensures that, within a given subform, answers that medically or logically exclude each other are corrected before a subform can be saved. A second level of validation comes into play when a subform is submitted. As a result, a second validation mask across subforms is activated, as the submitting person might be asked to make corrections before the form is accepted for final submission. Finally a third level of validation maintains data integrity by negating the possibility of opening patient form types that conflict medically. For example, it prevents users from creating two right primary hip interventions or opening two right 3-month follow-up forms within the same 3-month period.

Online Question(s) Generator

A cornerstone of the online documentation site is a tool that allows clinics to create their own customized subform questionnaires with single, multiple, and text answer options. Although there is a limit of one active added-on subform per study form type, there are no limits to the number of questions permitted per subform. This entails a very modular and dynamic documentation system that enables the collection of datasets on three levels – an international, a national, and a hospital or even departmental level.

Unprecedented Features (3)

Patient Questionnaires

A modern documentation system needs to also offer the possibility to document patient derived information with standard questionnaires like the WOMAC, Oswestry, subjective patient health, etc. It also needs to offer standard clinical questionnaires like the Harris Hip Score or the Merle D'Aubigné Score. Therefore, all these questionnaires are offered in a separate section called additional subforms where they can be selected and added to a respective form. Such a configuration gives users the ultimate freedom in assigning optional patient studies and scores to current open cases.

The current version of the documentation system does not yet offer patients the possibility of filling out online patient based questionnaires. Alternatively, a barcode form or a paper version is available that patients can use to answer these scores. In future releases patients will be able to independently access the documentation system from home or from a patient kiosk and submit their forms. In an alternative data entry mode, patients will be able to send paper-based forms (SF, WOMAC, etc.) to their hospital where they are read-in with MEMdoc OMR scanners and linked to the respective clinical data.

Online Visual Analog Scales (VAS)

In order to provide users with a realistic depiction of clinical examinations as well as a standardized patient satisfaction questionnaire, MEMdoc integrated a dynamic online generator of Visual Analog Scales (VAS). Defined as part of a study form type, VAS questions can be easily and generically implemented. Furthermore, several questions can be linked to a single VAS definition, which enables the utilization of a single scale of symmetrical examinations.

An example would be the internal and external rotation measurements with a Harris hip score, or even the standard 10 cm line patient pain assessment questionnaire for back and leg pain.

6
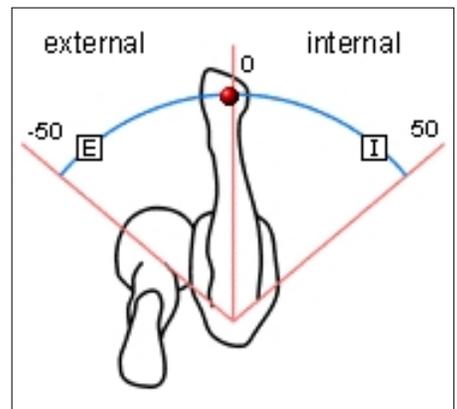
Clinical Data Collection – Paper-based

OMR Paper Forms

Due to the varying organizational and hardware infrastructures in clinics, paper-based forms are sometimes still preferable to other online and handheld documentation systems. Paper-based forms are inexpensive to produce, quickly scanned, and easily passed around the hospital to gather information.

While interested hospitals would still have to independently purchase a supported OMR scanner, no local software has to be installed or maintained. Instead, any local software necessary for scanning and validating collected data would be freely delivered from the MEMdoc centralized server.

Completed paper forms can be scanned from a single remote yet networked workstation in the clinic, or even mailed back to a data collection center. Scanning is performed while connected to the central database to provide immediate validation. On-screen messages from the centralized database allows form editing and rescanning for error correction and annotation. Once accepted, the data is instantly accessible for retrieval, statistics, and linking of further case relevant information, such as previous study, implant, and radiographic data, in the same way as data entered through web and barcode based forms.
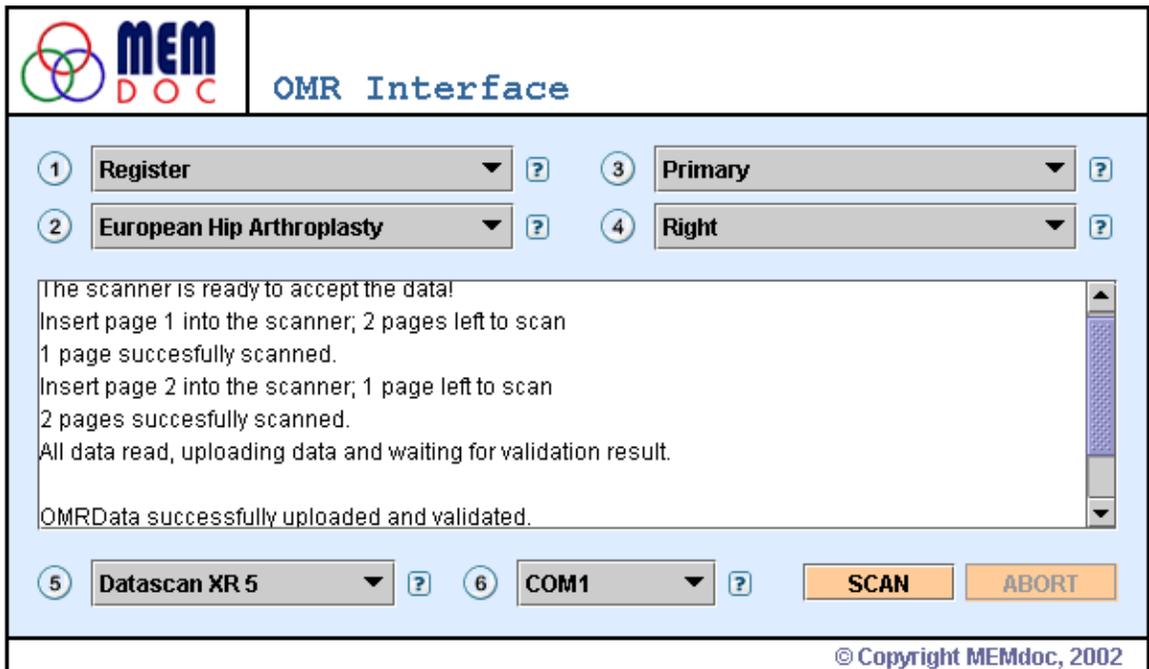
Clinical Data Collection – Barcode-based

Barcode Reader

The obvious advantage of the barcode solution is its portability, handling, and flexibility. Each surgeon carries a barcode-reader-pen (DocPen) in a pocket size format. After a patient is opened using the online interface, questions can be answered using the DocPen laminated forms. These laminated barcode forms can also be assembled into books that are distributed strategically to appropriate locations in the hospital (OR, out-patient clinic, wards, etc.).

The subform approach with several validation levels is ported to the barcode solution, which means that a subform remains the smallest amount of information that needs to be documented in a single instance. Hence, a mixed entry mode using the web interface and the DocPen is also possible.

The DocPen can be shared by several users within a clinic, and can easily carry the caseload of an entire day. As soon as it is placed in its recharge cradle, which is connected to a telephone modem, the DocPen automatically dials a toll-free number to transmit it's data to the MEMdoc database. In less than 10 minutes, the data is visible on the online interface, where it can be corrected, completed, or submitted.
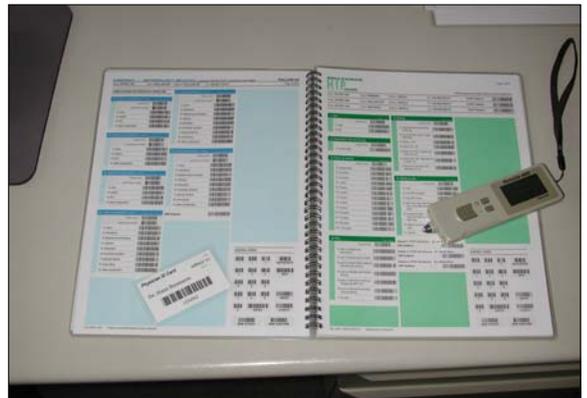
Implant Tracking Using SEDICO

Implant tracking (SEDICO)

The number and diversity of implants available on the market, in addition to the fact that many of them are not sufficiently clinically tested before they enter the market, makes it highly desirable to precisely document the implant used (article number & lot number), and to correlate it with the clinical and radiographic outcome in short-, mid-, and long-term follow-ups. Numerous variables are needed to describe an implant so precisely as to be able to accurately identify it. This is a very time consuming effort, and hence is not possible for daily use in a clinical setting. Therefore, MEM-CED has interfaced a barcode-based implant tracking system, which is capable of accurately identifying and tracking orthopaedic implants. This system, called Secure Data Integration Concept (SEDICO), is based on an open partner concept with an ultimate goal to integrate all major implant producers into the system. Currently Centerpulse, Aesculap, DePuy/J&J, and Zimmer form the growing SEDICO community.

With SEDICO, all main components used and implanted in a patient are scanned by the OR staff and automatically identified to the respective case using the medical record number when they are unpacked and handed to the surgeon. The scanner downloads the data overnight while it sits in its recharge cradle. One set of the data is used for ordering and inventory purposes, and another copy, consisting of article and lot numbers with other linking parameters, is sent to the clinical documentation system.

In the event that the SEDICO system is not available in a hospital, the documentation system also offers an updated electronic catalogues of the major implant producers where the implanted components can be searched and linked. Last but not least, possibilities to simply type-in article numbers or fill-in the implant description of other producers are also available online.

The Sedico Implant Data Collection Process

1. SCAN
Scanning of the implant barcode

2. TRANSMIT
Transmission of the scanned data

3. RECEIVE
Reception of the scanned data at the clearing center

7. PROCESS
Order processing by the supplier

6. DOCUMENT
Linking of implant data to clinical documentation

4. CONFIRM
E-mail or fax confirmation sent to the operating theatre or purchasing department

5. INTEGRATE (optional)
Integration of the order into the hospital's ERP

Online Functionalities (1)

Print tool

Forms can be at any time printed from the web for use in the clinic or to put in the patient file. Currently, the format is a rough question-answer format. In a later version, the information generated in the questionnaires will be embedded in a reporting format. The clinical administrator will have tools to individually design the layout of the questionnaire, and create text templates wherein clinical information is placed. Hence, printed forms would contain the individual layout of individual clinics (headers, logos, etc.), and the text content can be adapted to departmental requirements.

Download Data

Surgeons can any time download their own data in Excel-compatible or ASCII format for personal data modification, administration and analysis. Patient-specific incomplete or submitted cases and cases entered in a certain time range can also be downloaded in a single request. In future releases, a compiled CD of personal and clinical cases, including copies of digitized radiographic data, reports, and statistical results, can be requested online.

Online Statistics

A potent functionality of the documentation system is a "live" online interface to a powerful statistical package called SAS. This unique interface to data pools provides real-time complex statistical queries to be performed on any set of collected information.

For public registries, physicians/surgeons can monitor their cases by querying the database with certain predefined parameters provided by MEM-CED. This view is also customizable to display statistical results from own cases versus hospital and registry-wide filters. For multicenter studies this feature is also available, but is subject to individual agreement and setup as part of initial study definition.

MEM Center Epidemiology

Epidemiological online services is a feature offered to orthoglobe exclusively by the Institute for Evaluative Research in Orthopaedic Surgery, University of Berne. Note that only patients with submitted form(s) and those submitted data are taken into account in producing statistical results

Please select global settings:

Filter: [please select ▾]   Demographics: [please select ▾]

Please select statistical parameter(s):

Admission

☐ Diagnosis	☐ Contralateral hip
☐ Morbidity state	☐ Hip pain
☐ Walking restriction	☐ Restriction
☐ Hip motion restriction	☐ Activity

Surgery

| ☐ Side | ☐ Surgeon |
| ☐ First assistant | ☐ Previous surgery |

Patient Demographics, Age at Primary Operation
all cases

	Age (years)		
	N	mean	median
Gender			
female	55	58.64	62.00
male	80	51.62	51.93
All	135	54.48	55.59

EFORT registry

Distribution of Contralateral hip
all cases

Contralateral hip	Frequency Count	Percent of Total Frequency
not diseased	68	55.74
diseased, no surgery	31	25.41
hemiarthroplasty	7	5.74
total hip arthroplas	14	11.48
revision arthroplast	1	0.82
other status	1	0.82
	122	100.0

EFORT registry

Distribution of Contralateral hip
all cases

Contralateral hip	Frequency	Percent
not diseased	68	55.74
diseased, no surgery	31	25.41
hemiarthroplasty	7	5.74
total hip arthroplas	14	11.48
revision arthroplast	1	0.82
other status	1	0.82

EFORT registry
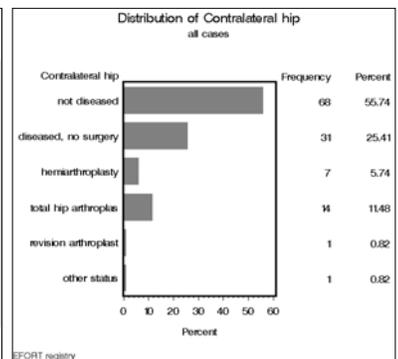
Benchmarking

Benchmarking allows comparison of one's own data against an anonymously aggregated data pool with predefined parameters similar to those of the online stats section. Presently this feature is not enabled, as no available medical benchmarks exist for the various hosted registries and multicenter studies.

Online Functionalities (2)

Multicenter Studies

In addition to registries, the documentation engine is also able to handle the generic implementation of multicenter studies. These closed-group password-protected studies are designed especially to meet the needs of clinical study groups as well as industrial post market surveillance and CE approval studies. As an added value, special administrative tools are available to multicenter coordinators that help define study access and monitor user activity.

Every individual user involved in a multicenter study receives a special password to gain access to study forms. This password is part of a single one-time extended registration step. Only users with special access to a certain study can see or enter data into these data pools. Standard access rights are also imposed onto multicenter users, in such a manner that an individual participant can only see his own and his clinics cases.

Digital X-rays

In addition to clinical data, the documentation system offers an online tool to upload digitized x-rays with automated linking to their respective case. Surgeons have the freedom to decide which radiological cases they deem acceptable for upload into registry and/or multicenter studies. Once a completed form is reviewed and submitted by the responsible surgeon, uploaded digitized x-rays are automatically transformed to the Digital Imaging and Communication in Medicine (DICOM) format, and directly stored on a medical picture archiving and communication system (PACS) server. Digitized radiographs are then immediately available for viewing using an online viewer that also includes standard image manipulation features. A maximum limit of 6 x-rays of 5Mb each is imposed on all cases.

⊛MEMDOC

Notes of Importance

Privacy Policy

Due to the nature of the doctor/patient relationship and the sensitivity of healthcare data, exchanging and collecting information on the web brings with it many concerns regarding privacy and confidentiality. As such, the official privacy policy of MEMdoc is to take every measure possible to guarantee that the traditional physician/patient relationship, based on trust, is still the number one priority. This is done by dealing with the issue of Physician/Patient confidentiality at every level.

> **Security features:**
> ✓ ISO compliant computer systems
> ✓ Segregated network setup with firewalls
> ✓ Data transfer via secure socket layers (SSL)
> ✓ Java object signing digital ID's
> ✓ 24-hr secure physical environment

Technical requirements

Any personal computer, Macintosh or IBM compatible, connected to the Internet running Internet Explorer 5.5 or Netscape 6.1 and higher. In addition, browsers must be compatible with 128-bit encryption. Please refer to the "About" section under the "Help" menu of browsers in order to ensure a compatible browser. Moreover, Acrobat Reader 3.0 and higher is required for the viewing of online documents placed on various content-based sections of the MEMdoc portal.

For software download and installation information, please refer to each respective vendor website.

Microsoft Internet Explorer: http://www.microsoft.com
Netscape Communications Corporation: http://www.netscape.com
Adobe Acrobat Reader: http://www.adobe.com/

The MEM-CED documentation system hosted on MEMdoc complies with all standard Internet applications. In the event that all system specifications comply with the technical requirements mentioned above yet browsers are still unable to gain access, then the first step would be to consult the online helps provided by the software vendors at the above URL addresses. For users accessing the Internet from hospitals, private clinics, and university research institutions, please note that connections to the World Wide Web are usually limited by the setup of local hospital networks. Hence, it is strongly recommended that those users consult their local system administrators before seeking online help or contacting MEM-CED.

> **Local system checklist**
> ☑ Compatible browser (IE 5+ or Netscape 6+)
> ☑ 128-bit enabled system / browser
> ☑ Network proxy setting (if applicable)
> ☑ Access to Internet ports (if applicable)