

MEM Research Center

Memdoc Manual for Entering and Querying Data















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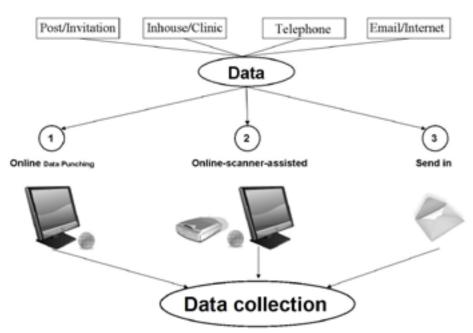
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Introduction

Data Entry

There are 4 possible ways forms and questionnaires can be transferred to the database (Fig. 1)

- 1) Online data entry via the web-interface (no software to be installed)
- 2) OMR (Optical Mark Reader) i.e. scanner-assisted entry of paper forms
- 3) Paper based data capture with mailing to the IEFM or other partner institutions for OMR scanner-assisted entry of paper forms
- 4) Hybrid method of online data entry and OMR scanner-assisted entry of paper forms (not pictured)



In the rectangles multiple methods of gathering patient and physician generated data are shown (per mail, in house, outpatient clinics, telephone and new electronic media). The goal to generate a comprehensive database is achieved by collecting data of the patient layer and the clinic/physician layer. Having created a consistent data set the options of analyses are almost unlimited. Outcome evaluation can now be done in particular.

Security

Memdoc Manual

The model of the MEMdoc and MEMdoc-Module system is designed around the principle of data separation. The MEMdoc central server, housed at the MEM Research Center (MEMcenter) in Bern, hosts the main application and the central database containing all study definitions and clinical study data. Satellite MEMdoc-Module servers located throughout the world store all personal data about users, institutions and patients. At the core of the system is an innovative and patent-pending architecture in which the web

browser of the client is used as a hub to seamlessly segregate and integrate the data between the MEMdoc-Module and the MEMdoc central server.

This design provides tightly integrated communication between the servers while increasing the security and privacy of both systems. This has been accomplished using a light weight JSON server and incorporation of SSL encryption on each module. Flexible data sharing options have been designed to restrict or expand data access to suit individual needs. Finally, data consistency is controlled through systematic validation of received data and a rollback in case of errors.

Each module server contains a local MySQL database, an Apache web server and the custom MEMdoc-Module application. This server can sit within the same clinic as the user or in some remote location depending on the needs of the group hosting the module. The physical and network security of this server is left up to the hosting entity. Some groups choose to restrict access to the module to users within the local subnet while others allow open access from anywhere. The module database contains all user and clinic information as well as the basic demographic data of patients. No medical data is stored on the module server.

All users from every MEMdoc-Module make their initial connection to the MEMdoc central server that houses the core MEMdoc application as well as all clinical study definitions. The MEMdoc application then recognizes the URL of the connection to determine which MEMdoc-Module to utilize and delivers the appropriate custom module application to the user's web browser. Each time a user requests data the application contacts both the local MEMdoc-Module and MEMdoc central database (Oracle) to seamlessly integrate the data from each for display. Newly entered data is likewise split so that only internal numeric identifiers for the user, patient, clinic, department and module are stored on the MEMdoc central database. All medical data is retrieved from and stored directly to the MEMdoc central server and linked to the module by these internal identifiers. Medical data never passes through the MEMdoc-Module server and is never stored on the MEMdoc-Module server. The birth year and gender of each patient are the only pieces of personal information stored on the MEMdoc central database for performing pooled statistics.

The physical and network security of all the MEMdoc servers is maintained by IEFM at the MEM Research Center. This includes the MEMdoc central (web) server, the MEMdoc database server and the MEMdoc statistics (SAS) server. All servers are physically housed at the MEMcenter in a dedicated, locked, climate controlled and monitored server room. The network is protected by a enterprise level firewall with real-time gateway antivirus, anti-spyware, anti-spam and intrusion prevention. The firewall only allows access to the servers from the outside via port 443. Additional access is restricted to connections from within the MEMcenter. Web security is controlled by a DigiCert certified SSL web server certificate with 256-bit encryption on the MEMdoc central server and on each satellite module. Each server is continuously monitored to log all connections and to detect any suspicious activity. Additionally, any modules that are hosted at the MEMcenter fall within the same security parameters.

Introduction

Online Data and Entry Tools: Registration - Enter Data - Clinical Tools - User Tools

Current chapter:

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ntroduction

Online Data and Entry Tools: Registration - Enter Data - Clinical Tools - User Tools

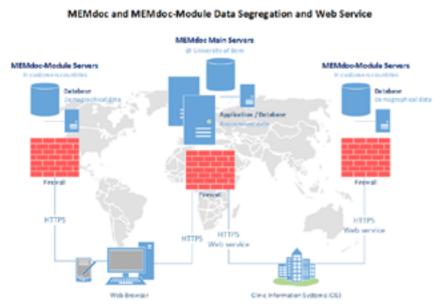


Fig. 29. Data segregation

Optional Hardware/ Scanner

By scanning the OMR forms by oneself we use the OMR 50E Scanner (datawin). The OMR 50E mark reader is an optical mark reader designed for manual feed. It reads marks, crosses, bars, dots and various other types of markings. It processes automatically printed documents (e. g. laser printouts) as well as blind color forms and qualitatively high-grade (dimensionally accurate) copies.

The read head can be folded back without the use of tools in order to carry out cleaning or maintenance operations. The compact structure of the device allows it to be positioned at a slant as an ergonomic desktop model.

For further technical data we refer to the Company link:

http://www.datawin.de/fileadmin/user_upload/datawin/prospects_eng/OMR50E_E.pdf

General Marks

Orange marks are not found on the papersheets or online, they are added in this manual for explanation.



This sign marks very important things you should read and remember.

Registration

If already registered, log in with your username/password and proceed to Chapter "Enter Data"

User-ID and Password

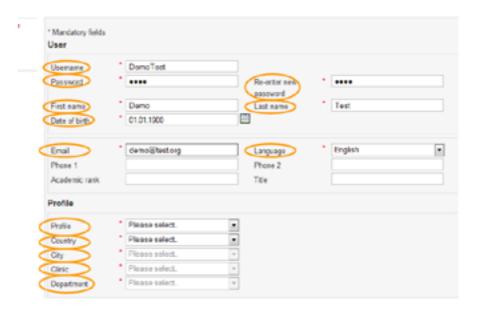
If you want to become a new user of the Spine Tango Registry you need to register in the module.

For entering a new account go to new user.



You can choose your User I.D. and you password! Fill out all fields marked with a star.

Please make sure that your email is correct for contact data.



Determine your profile

With entering a new user profile your account profile needs to be determined. If you are the first person registering for one clinic you need to be the clinical administrator.

Profile		
Profile	* Please select.	<u> </u>
Country	Please select. clinic_admin	
City	docteur	
Clinic	• infirmier	
Department	* Please select.	~

If you register for a clinic which is already registered in the spine tango you have to choose this clinic at the profile menu. If your clinic does not exist in the module yet, you have to enter all the required data and add the clinic.

Clinic name	Street	
Street number	Zip code	
Contact person	Phone	
Fax	URL	
City		
Department name	Contact person	
Phone	Fax	

In details this means you have to enter the whole clinic profile with all of the required information on country, city, clinic and department as following: country:

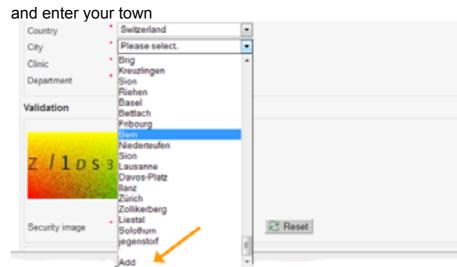
Country	Switzerland	
City	Seychelles Sierra Leone	*
Clinic	Singapore	
Department	- Slovakia Slovenia	
/alidation	Solomon Islands Somalia South Africa	
z / 1 o s	South Korea Spain Sri Lanka Sudan Suriname Swaziland Sweden	
Security image	Switzerland Syria São Tomé and Principe Talwan Talikistan	E Reset
Save 25 R	eset	

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Online Data and Entry Tools: Registration - Enter Data - Clinical Tools - User Tools
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_	
City	
City	

If the given possibilities do not apply, select:

 \rightarrow Add



Clinic:

If the given possibilities do not apply, select:

→ Add		
Profile	docteur	•
Country	* Switzerland	•
City	* StGallen	•
Clinic	* TestClinic	<u> </u>
Department	Please select. TestClinic	
Validation	Add	

If you add a new City / Clinic, fill out all mandatory fields (marked with a star) and select:

→ Add

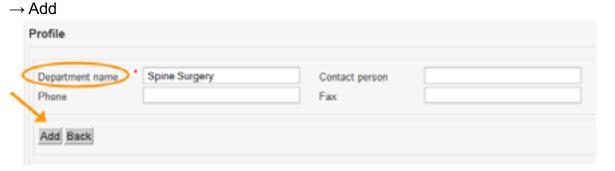
Clinic name	TestClinic	Street	
Street number		Zip code	
Contact person		Phone	
Fax		URL	
City	Test Town		
Department name	spine surgery	Contact person	
Phone		Fax	

Surrent chapter:	Registration
	Tools: Registration - Enter Data - Clinical Tools - User Tools
ntroduction	

Department: If the given possibilities do not apply, select: → Add and specify Profile Country City Test Town City Clinic Department Validation Departmen

If you

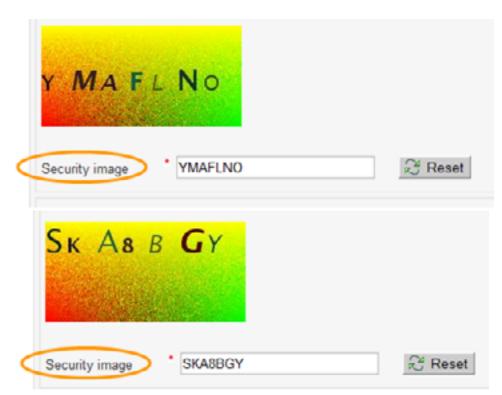
add a new Department, fill out the marked fields and select:



Next validate with the secuity Image:



Please read the "code" in the Validation-Field and write it into the requested field. Example:



At the end, please read the "Statement of Permission and Confidentiality" carefully and tick the field to go on. Then select:

 \rightarrow Save



If erverything was entered correctly the following window opens:



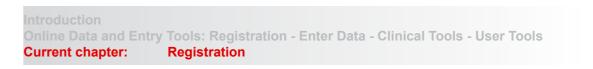
You will recieve a confirmation mail of your registration.

That's why it is very important to enter a correct email address!

For now you cannot enter data. You need to wait for activation from the module administrator.

If your account is activated you will receive another confirmation email.

Then you can login with you self chosen User ID and password and start entering.



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Forgotten password

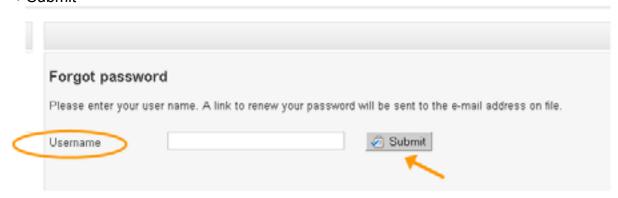
In case you forgot you password, select:

→ Forgot password at the login page

Swiss/Internation	onal SSE Spine Tango Module		
Usemame		Password	🔊 Login
			Forgot password New user

Now enter your Username and select:

→ Submit



An e-mail with a link will be sent to the address you entered in your registration. Click on the link and the following window will open:

Welcome	Reset password
Login Forgot password	Username
 New user 	New password
	Re-enter new password.
	Save

Enter your username and the new password in the required fields and save.

Username	testaccount	Password	🔑 Login
			Forgot password New user

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Enter Data

Document a patient record

Enter data for a new patient - create a new mask.

Enter data for an existing patient - search the patient and create a new e-form.

Create a new Patient Select: → Enter Data → New Patient Clinical tools

New patient
 Search patient

Clinical tools

Admin tools

User tools

Logout

Please fill out at least the mandatory fields marked with a star (*): Department; MRN - Medical Record Number; Date of birth; Gender

New patient			
M.R.N.	111	Date of birth	* 01.01.1960
SSN/SIN		Gender	* Male Female
First name		Last name	
Family name at birth			
City of birth		Country of birth	Switzerland
Phone		E-mail	
Street name		Street number	
City		Zip code	
Country		v	
Language	English	•	

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Click on: → Save

to store the information and proceed to the form list:



Search a Patient

Select:

- \rightarrow Enter data
- → Search patient

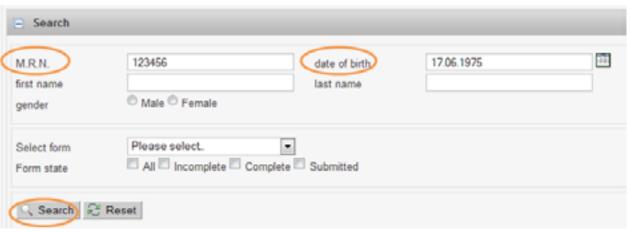
 New patient Search patient 	\leftarrow
Clinical tools	
Admin tools	
User tools	
Logout	

The easiest way to search is the quick search by simply clicking the search button or entering one clue.

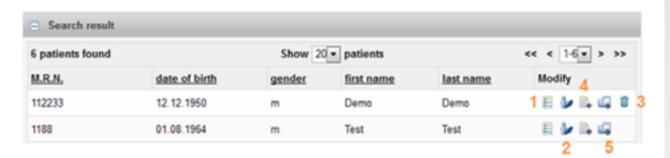
Search patient	
Quick search 123	Search
Search Se	
Search result	

You can also limit your search with MRN or date of birth, or you can search with every shown criterion

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You can also show all patients with a special form or with a special form state. The search results shows all the patients which match your search criteria. If there is only one patient, the details will appear automatically.

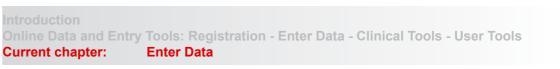


- 1: to open the form list click:
- 2: if you click this, you open the demographic data of a patient and can add more information or change them
- 3: you can only delete a patient file when there are no e-forms existing
- 4: Click here to directly open a new e-form for this patient.
- 5: Click here to directli scan a new OMR form for this patient.

Formlist

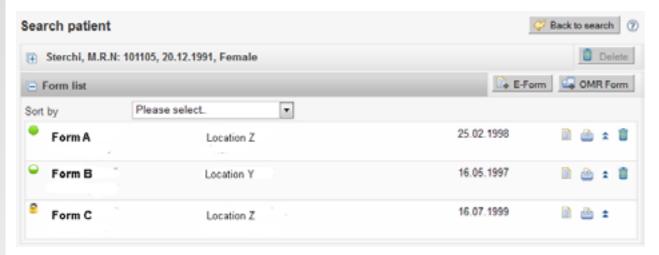
The Form List shows all the existing forms for this patient. There are 3 possible states (Status) for the e-forms:

- incomplete: not all the subforms are filled out and saved

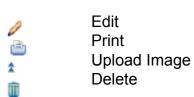


- to submit: all the subforms are filled out and saved and the e-form can be submitted.
- submitted: you can only view the data and not edit them anymore.

There is no possibility to change the data or add data to a submitted e-form (except by contacting the data center).



The legend to the various symbols of the form list looks as followed:





Upload Image:

With this function you can upload a x-ray image. Just choose the location, the date and browse it on your computer. Select:

→ Upload image



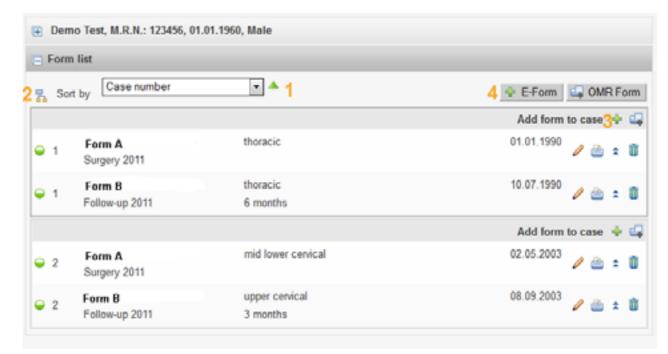
To view your image, delete it or add a new one, now select:



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Case-ID

The Formlist is normally sorted by cases. A case includes all forms regarding one injury eg. A fracture. All treatments like surgery or follow-ups should be integrated in this case. This is very useful for evaluating purposes, overview and also for users to keep records of their Follow-ups etc. Cases will be numbered from 1 upwards.



Under the header you have the option to sort all your cases and forms (1). The sorting will always be conducted within the cases first and after that in general, but the cases will stay. The green arrow allows to switch the sorting direction, eg. Date descending or ascending.

The Icon to the left lists the patient forms independently of the cases (2).

Now to add a new form to a case, for example a follow-up-form, please click the green + in the corresponding case (3). The location will be completed automatically and after you apply the date of the FU, also the follow-up-interval will be calculated.

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1. Follow-up date 21.12.1991	
Primary form date 01.01.1990	Time difference with primary form date 1 Year, 11 Months, 20 Days
2. Level of intervention thoracic	
3. Follow-up interval 2 years	Specify other interval in years (ex.4 months = 0.33 yrs.(4/12))

A new case is generated when a different problem/injury occurs, that is not related with the first whatsoever -> Button E-Form (4).

If you create a new Form with "E-Form" (e.g. a Follow-up Form) you will be shown all options of cases (Filtered by location, study etc.). If you choose one, your FU-form will be integrated in this case, click -> "Add".

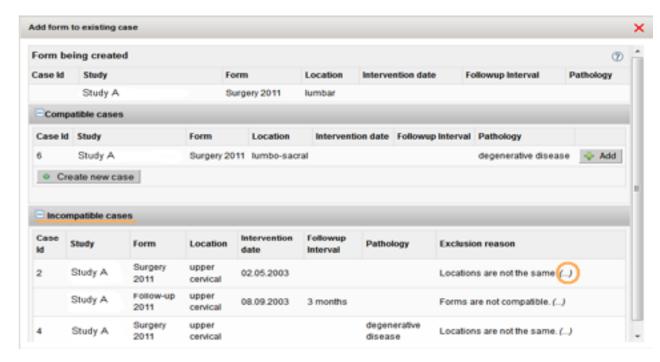
If you would like to create a new case because the treatment is not connected with any other case before, click -> Create new case.

Form be	ing created						
Case Id	Study	Form	Loc	ation In	tervention date	Followup Interval	Pathology
	Study A	Follow-up	2011 upp	er cervical			
Comp	atible cases						
Case Id	Study	Form	Location	Intervention da	te Followup Interval	Pathology	
2	Study A	Surgery 2011	upper cervical	02.05.2003			Ad
	Study A	Follow-up 2011	upper cervical	08.09.2003	3 months		
4	Study A	Surgery 2011	upper cervical			degenerative disease	- Ad

If you mistakenly add a form to a wrong case, you can move it again by clicking on the case number in front of the form (circle). All possible cases will be shown in a pop-up window for you to choose.

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Some cases in the form list will be incompatible for various reasons (not same study, not same level etc.). You see these cases by clicking on the grey bar saying "incompatible cases". On the left side, there is a short explanation why the case is incompatible which can be extended by clickling on the brackets (...).



Create questionnaire

New e-Form

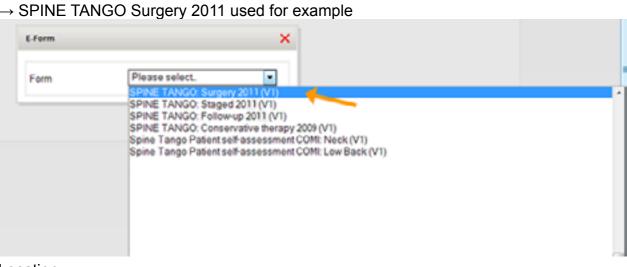
To enter data, create a new e-form:

- \rightarrow + E-Form
- → Choose Form:

Online Data and Entry Tools: Registration - Enter Data - Clinical Tools - User Tools **Enter Data** Current chapter:

Pack to search (7

A OMR Form



w

Location:

Search patient

Form list

No forms available for patient

Sort by

F Sterchi, M.R.N: 101105, 20.12.1991, Female

E-Form

Select form

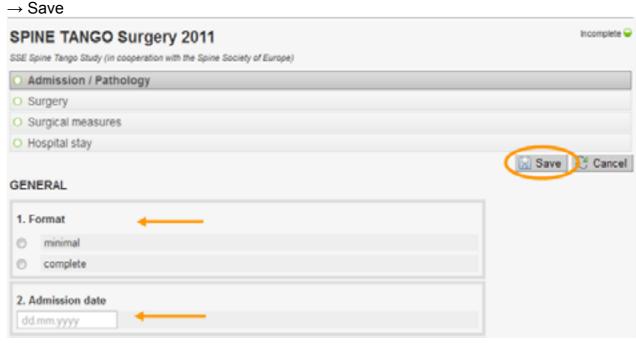
Please select.

→ select operated/ treated segments/ area

Level of procedure	Please select	•
	Please select upper cervical mid lower cervical cervicothoracic cervico-thoraco-lumbar thoracic thoraco-lumbar thoraco-lumbo-sacral lumbar lumbar lumbo-sacral sacral coccyx	

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Enter the data at all the shown subforms and save each single one !!! If you choose "minimal" in the first question, only the minimum of needed questions will appear. In "complete", you will have to answer all questions.



Spine Tango Form used for example

Only when all requested questions are answered the data will be saved and the there will be filled, green circle which means: completed and saved.



You can leave the form anytime to find your saved data again when you come back. When you make changes and don't save them, you will lose them!

If you make changes to an already completed, but not yet submitted form, the subform will be marked brown. You won't be able to submit the form now, you first have to either save or reset the subform where you changed something. This is to ensure that you don't lose any changes.

Admission / Pathology	
Surgery	
Implants	
 Surgical measures 	
 Hospital stay 	
	☐ Save

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 \rightarrow Submit



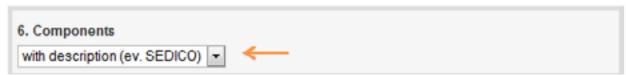
Spine Tango Form used for example

Implant tracking / Component

For implant tracking or manual implant description, question 14 (Implant Characteristics) at the bottom of the Subform Surgery needs to be answered with "yes". Then, select:

→ Save

Memdoc Manua



An extra subform Components is triggered that way and will appear:



To identify the implants you can either scan the implant-codes with SEDICO/ GHX, search the electronic supplier catalogues or enter the implant information manually. First, select:

→ Add implant

This window will appear:

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Implant tracking with Sedico

SEDICO/ GHX: The implant barcodes can be scanned directly after surgery. To match with the right patient, four criteria have to be consistent:

- Medical Record Number (MRN)
- Surgery date has to match the scan date
- Location chosen during scanning and location indicated for the e-form (e.g. "lumbo-sacral)
- Clinic: your scanner is linked to your Spine Tango clinic account with a code during installation. This code does not have to be entered again for implant tracking.

If these four criteria match, AND the scanner is operated in ordering/tracking or solely tracking mode, the implants will be inserted into the "Components" subform automatically.

Manual implant data input

You can use your personal Implant Notebook and choose the right implants. (To create your own Implant Notebook, click on 'Edit Implant Notebook' (circled)).

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Supplier	Please select.	_
Catalogue language	Please select. Implant Notebook	
Article number	Advanced Medical Technologies AG	
Article description	B. Braun Medical Biomet	Search Reset
Manually add in		
Scan Implant	DePuy-France Heraeus Medical Johnson & Johnson	
Search results	Link Implants Mathys Medacta Medtronic Schweiz	
	Smith & Nephew	Confinition

an just select:

→ Search

Implant management

and the whole notebook will appear. To choose an implant, click:

If desired, the Lot-number can be manually added for each component before adding it.

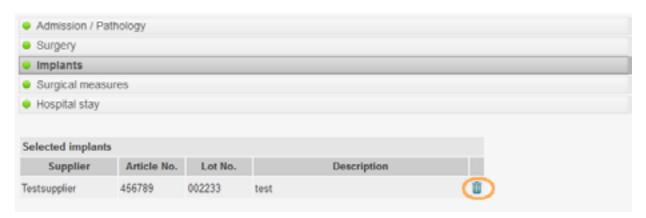
nplant mana	gement				
Implant	search				
Supplier	•	Implant	Notebook	•	(iii) Edit Implant Notebook
Article number	ĺ	1		─	
Article descrip	tion	123458	789	C Search	
		1859110	007		
Manually	add implant				
Scan Imp	olant				
Search r	esults				
There are 2	hits		Show 5	sults per page	<< 1 v > >>
Supplier	Article num	<u>ber</u> ▲	Description	Lot number	
TEST	123456789		test implant	12346	(*)
DePuy-Spine	185911007		Cervikale Bandscheibe DISCOVER Klein x 7mn		+

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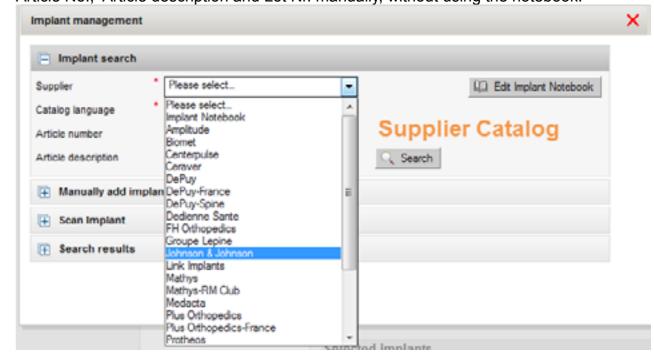
After you have chosen all Implants, close the window and your list of selected implants will appear. To delete an implant, select:

 \rightarrow Delete

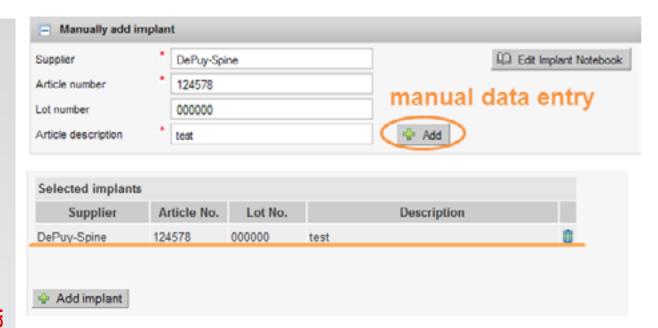
×



You can also search the Supplier Catalogues for other Components or enter Supplier, Article No., Article description and Lot Nr. manually, without using the notebook.



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Edit Implant Notebook

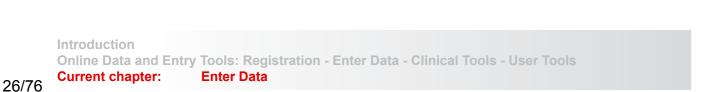
You can insert your own Components by searching implants and add them. Choose minimum the supplier and the catalogue language and then click:

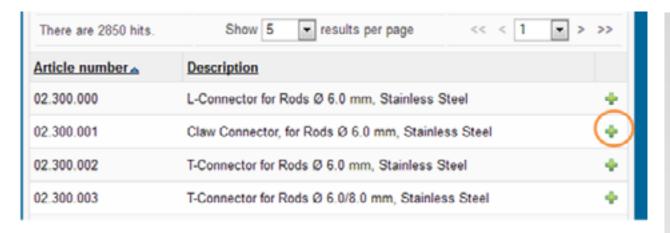
→ Search

Edit Implant No	tebook		
		X Close	Implant Notebook
No data found			
Implant search			
Supplier	* DePuy	- ←	
Catalog language	* english		7
Article number Article description		Q Search € Re	set

Beyond "Search results" you find all implants that match your search results. To add them to the notebook, select:







You can as well add components manually. Insert the supplier, the article number and the description and click on:

→ Add to notebook

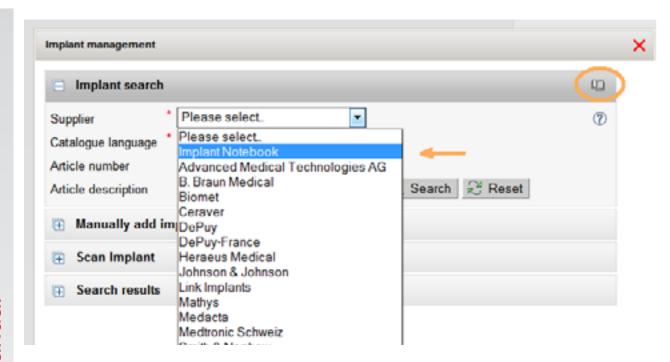


The next time you open your Implant Notebook all the inserted Components are shown.



Then you can easily link them to your patient by searching the Implant Notebook and selecting the respective Implants:

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Submission

When all subforms except Additional are saved and all the circles appear green and filled, the e-form can be submitted. Select:

→ Submit



Spine Tango Form used for example

After submission you cannot change or delete your data anymore without personally contacting the data center.

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Clinical Tools

Download data

This tool provides you to retrieve data from the server. You will be able to download your personal data as well data created by other users within the module, or across multiple modules, depending on the strength of your user's profile.

Click on:

→ Download data



The download data page is comprised by two panels: the available downloads pannel, which lists the set of downloads that you have requested and which have completed successfully; and a download interface pannel, presenting the user all the download options for which his user's profile is configured.

Depending on your profile configuration the panel Download Interface can be as compact as the image illustrates. In this case, you will not be able to configure any of the personal data of patients, users, clinics or departments to be exported.

Step 1:

Choose a form to export.

Step 2:

Choose the scope of the download. Your options below clinic are:

- All my cases
- Cases I created
- Cases I submitted
- (- Cases I operated / I assisted) -> only when the chosen form has the "Surgeon /Staff" question.
- "All cases"-options (Every case registered in Module, Clinic, Department). Your options may differ, depending on your profile function. Please check the profile you are currently logged into, in case you have various.

Step 3: Choose the form state that is relevant for the export.

Form	SPINE TANGO: Surgery 2011 (V1)	•	
Cases	All my cases in MEMdocTest		
Form option	Download only submitted forms	•	
Download Type	Anonymous		
Information to e	xport		
	custom headers		
Surgery 2000			
	3		
Surgery 2000	3		
Surgery 2000 Expand all	\$ thology		

Spine Tango Form used for example

Step 4:

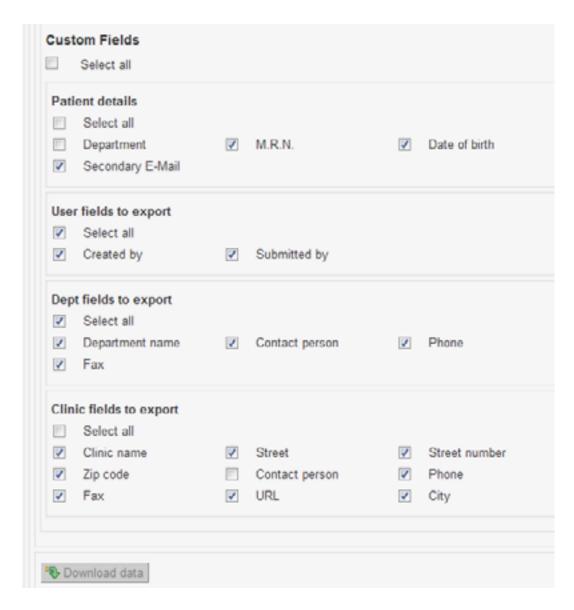
Choose the desired download type. Your options are (again depending on your profile allowance):

- Anonymous data (contains no details regarding the patient)
- Pseudo anonymous data (contains hashed values such as MRN, clinic name, department name)
- Personalized data:

Contains identifiable information about a patient, clinic or department or doctor that you wish to export.

Choose "export with custom headers" in case your study included custom headers (concerning the excel-files).

Specify the exact personal data below in "Custom Fields": you can extract information about the patients, the users who operated in the forms, the departments and the various clinics.



Step 5:

Select the relevant questions / subforms (can be expanded by clicking) to be exported in your file. If you want only few data, reduce the outcome to the questions you like, e.g if you are only interested in Admission / Pathology, Decompression and Fusion:

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Surgery 2006	
Expand all	
Admission / Pathology	
Surgery	
Surgical measures	
✓ Decompression	Specify decompression
Specify other decompression	V Fusion
Specify fusion	Specify other fusion
Fusion material	Specify other fusion material
Stabilization rigid	Specify stabilization rigid
Specify other stabilization rigid	Stabilization motion preserving
Specify stabilization motion preserving	Specify other stabilization motion preserving
Percutaneous measures	Specify percutaneous measures
Specify other percutaneous measures	Other surgical measures
Specify other surgical measures	Surgical notes
Discharge	

Step 6:

Click the "Download Data" button.

Wait for a few minutes for the data to become available. This process can take a while, depending on the number of exports that user's have requested. Also, each module only asks from the central server for data every minute. The export process is a complex process involving large volumes of data for a considerable number of consumers world wide.

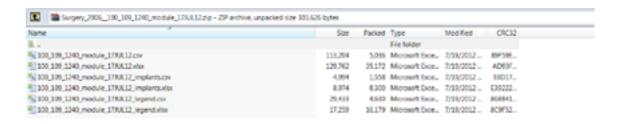
As soon as your data is available to be downloaded, it shall appear on the top of the Download Data page.

By clicking either on the name of the file, or on the download icon, a prompt of saving the zip archive shall appear.

The zip archive downloaded should always contain at least two excel files. The comma separated files are encoded using UTF8.

The main data file contains both the clinical data/form answers and the custom field data the user chose to export. The legend file comprises a description of the meaning of question headers of the main export file. Additionally, a third file containing implants will also exist if any of the form data exported was linked to implants data.

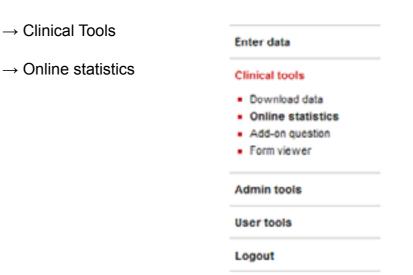
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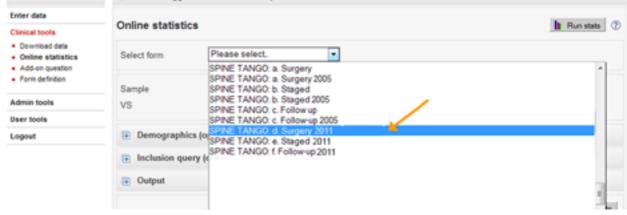
Online statistics

Spine Tango gives you the possibility to create some descriptive online statistics with your data and also to compare your data against the anonymized data pool (benchmarking).

You activate this tool via:



Please choose the form you want to query.



Spine Tango Form used for example

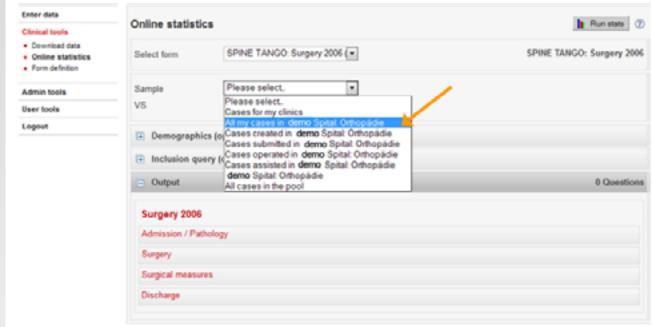
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Selection of patient samples

You have different possibilities to view and compare patient samples: Select a sample first:



You have the same possibilities as in "Download data". Now decide the cases you want for a comparison.

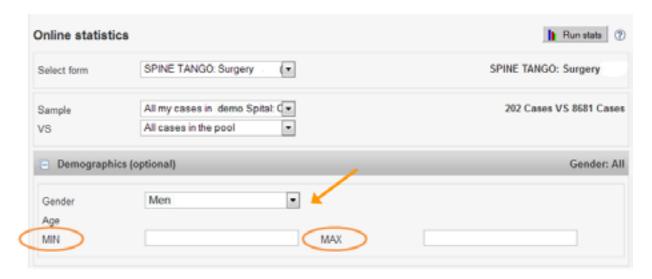
You can also leave it empty if you don't want to compare different data.



Enter data	Online statistics			Run stats ⑦
Connical tools Download data Online statistics Form definition	Select form	SPINE TANGO: Surge	ry (x	SPINE TANGO: Surgery
Admin tools	Sample	All my cases in	Spitat C.	202 Cases VS 8681 Cases
User tools	VS	Please select. Cases for my clinics		1
Logout	 Demographic 	All my cases in demo Spital: Orthopadie Demographics (o Cases created in demo Spital: Orthopadie Cases submitted in demo Spital: Orthopadie		Gender: All
	Gender Age MN	Cases operated in dor Cases assisted in den domo Spitat. Orthopid AT cases in the pool	no Spital: Orthopadie	Here you can see the number of cases your choice would generate
	■ Inclusion quer	y (optional)		
	Output			6 Questions
	Surgery Admission / Paths	dow		
	ElAdmission date		☑ Main pathology	
	Specify other m		▼Type of degeneration	
		ain patrology openerative disease	(c) Type of deformity	

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In "Demographics" you can create subsamples of patients by applying certain filter criteria like age or gender. It's optional, you may also ignore it.

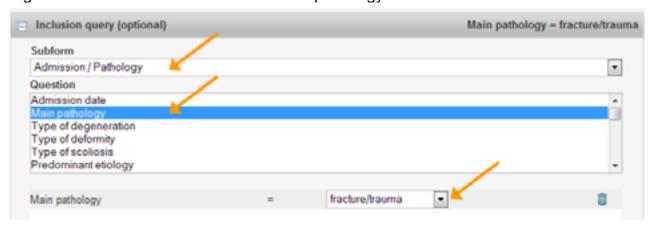


Inclusion query

A second possibility to filter the data is the "Inclusion query":

This is a tool to combine answer-possibilities to generate a well defined patient group.

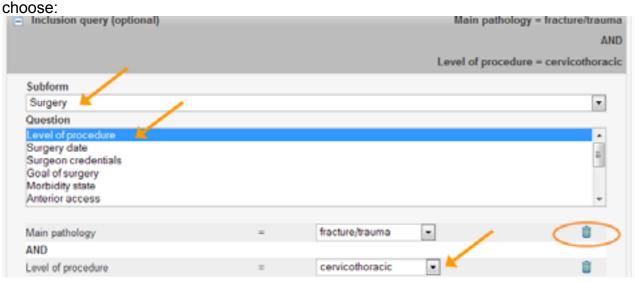
First choose the subform which the criteria includes you want to determine. Choose the question and corresponding question you want to analyse. e.g. Patients with fracture/ trauma as main pathology



For choosing more than one inclusion criteria you can combine several criteria. If you want to have more than one answer possibility of one question. e.g. you want to have the patients with fracture/trauma OR pathological fracture:



You can also choose critera from different subforms and questions: e.g. patients with fracture AND trauma only cervicothoracic:



If you want to delete an inclusion, click on the recycle bin.

Output parameter

Beyond output please choose all options you wish to analize. Scroll down and select no more than 3-5 outputs at once to reduce calculation times. You can choose options from all subforms.

Surgery Admission / Pathology Format Admission date Main pathology Specify other main pathology Type of degeneration Specify other degenerative disease Type of deformity Specify other type of deformity Type of scoliosis Predominant etiology Type of (pathological) fracture/trauma Specify other predominant etiology Specify other type of fracture/trauma Dens fracture type C3-L5/S1 AO fracture type C3-L5/S1 AO fracture group C3-L5/S1 AO fracture subgroup Pathological fracture due to Specify other reason Fracture age Type of spondylolisthesis Crade of spondylolisthesis Type of inflammation Specify other type of inflammation Infection specification Specify other type of infection Affected structure(s) Specify other type of affected structure Type of tumor Specify type of tumor □ Localization
 □ Specify other localization Type of repeat surgery Specify other type of repeat surgery Comments regarding main pathology Most severely affected segment/vertebral body Most severely affected Extent of lesion (segments/vertebral bodies) Additional pathology Specify other additional pathology Mumber of previous spine surperies Previous surgery/ies at same level Previous surgery/ies at same hospital Previous treatments for main pathology (max. 2) E BMI Current smoker

Spine Tango Form used for example

At last, please choose the type of your statistics.

"Descriptive" means this analysis is without p-values, "Scientific" gives you an analysis with p-values for gender, age, continuos variables and binary variables.



Statistical analysis of Surgery forms

As explained, first you have to select a sample and thereafter you may want to apply filter criteria for this sample.

For example:

We want to look at the distribution of type of degeneration, decompression and fusion in our group of patients with degenerative disease in the complete data pool.

We also want to know about the surgical complications.

- Viewing all cases in the pool
- No filtering with respect to gender, age, or surgery date, but applying Main Pathology : degenerative disease as filter criterion.

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ample	All cases in the pool	* 4	_	7785 Case
s	Please select.			
Demograp	phics (optional)			Gender: A
Gender	All			
Age				
MN Inclusion	mery fortional)	MAX	Main patholog	v = degenerative diseas
	query (optional)	MAX	Main patholog	y = degenerative diseas
Inclusion of Subform	query (optional)	MAX	Main patholog	ry = degenerative diseas
Inclusion of Subform		MAX	Main patholog	ry = degenerative diseas
Subform Admission Question Admission of	/ Pathology date	MAX	Main patholog	
Subform Admission Question Admission of	/ Pathology	MAX	Main patholog	
Subform Admission Question Admission of Type of deg	/ Pathology date 097/ peneration	MAX	Main patholog	
Subform Admission Question Admission of	/ Pathology date Sgy speneration comity liosis	MAX	Main patholog	

Scroll down and select no more than 3-5 outputs, but select at least one question! For our example choose the output parameters: type of degeneration, decompression, fusion, surgical complications

Output		3 Questions
Surgery		
Admission / Pathology		
Format	Admission date	
Main pathology	Specify other main pathology	
▼Type of degeneration ←	Specify other degenerative disease	
☐Type of deformity	Specify other type of deformity	
Type of scoliosis	Predominant etiology	
Specify other predominant etiology	Type of (pathological) fracture/trauma	
Specify other type of fracture/trauma	Dens fracture type	
C3-L5/S1 AO fracture type	C3-L5/S1 AO fracture group	
C3-L5/S1 AO fracture subgroup	Pathological fracture due to	

	Surgical measures	
	☑ Decompression ←	Specify decompression
	Specify other decompression	▼Fusion promoting measures ← —
	Specify fusion	Specify other fusion
	Fusion material	Specify other fusion material
	Stabilization rigid	Specify stabilization rigid
	Specify other stabilization rigid	Stabilization motion preserving
	Specify stabilization motion preserving	Specify other stabilization motion preserving
	Percutaneous measures	Specify percutaneous measures
	Specify other percutaneous measures	Other surgical measures
	Specify other surgical measures	Extent of surgery - indicate as
	from	 to
	Intraop, surgical complications	Specify other intraop surgical complications
	Surgical measures during index surgery	Specify other surgical measure
	Intraop general complications	Specify other intraop general complications
	Hospital stay	
	Postop surgical complications before discharge	 Specify postop surgical complications before discharge
	Postop general complications before discharge	Specify postop general complications before discharge
	Re-intervention after index surgery	Specify re-intervention
	Hospital stay	Status of surgical complications
	Therapeutic goals upon discharge	FU foreseen
	Discharge Date	
I	Now, click on:	
	→ Run Stats	
	(1)	Due state
		Run stats

Depending on the size of the patient sample chosen and the number of parameters selected it might take up to half a minute until a SAS output window will open, which shows your statistics as tables and graphs. The graphs are pictures and can be used in e.g. Power Point presentations with a right mouse click. The tables must be marked with the left mouse button, copied, and then inserted into the slides.

The graphs of the parameters are always shown in percent. The frequencies are listed in the tables.

The statistics always show the Gender and Age distribution of your group: Spine Tango Form used for example

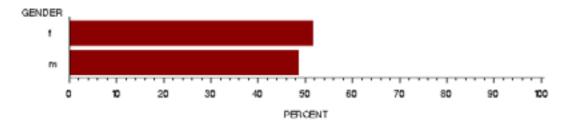
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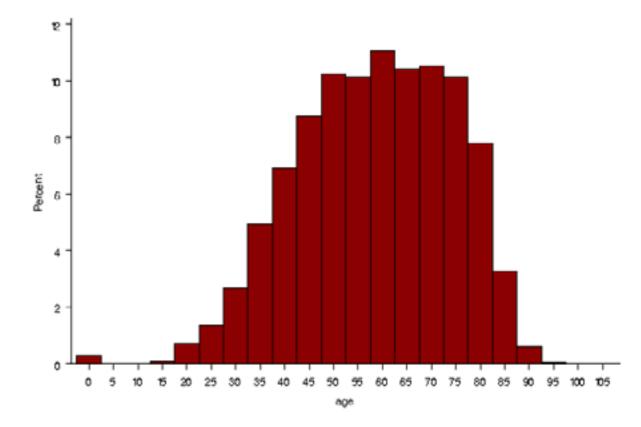
Gender Distribution

GENDER	Frequency Count	Percent of Total Frequency
f	3466	51.52
m	3261	40.40
	6727	100.0



Age Distribution

Analysis Variable : age						
N	Minimum	Median	Maximum	Mean	Std Dev	
6727	0.00	59.00	107.00	58.39	15.65	



According to your selection of outcomes, in this example:

→ Distribution of type of degeneration

Distribution of Type of degeneration

LABELTEXT	Frequency Count	Percent of Total Frequency
spinal stenosis	3339	24.26
disc hemiation	3166	23.01
disc degeneration	2575	18.71
spondylarthrosis	1931	14.03
spondylosis	1088	7.91
black disc	769	5.50
adjacent segment degeneration	542	3.94
other	351	2.55
	13761	100.0

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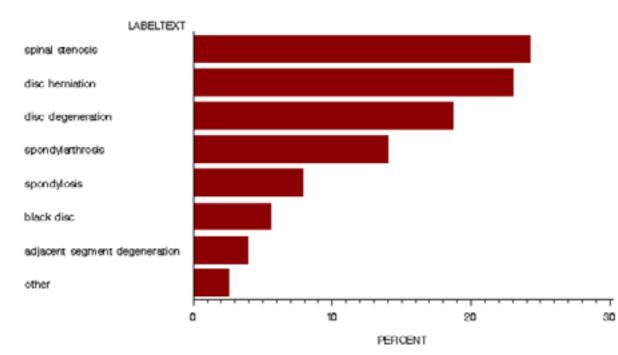
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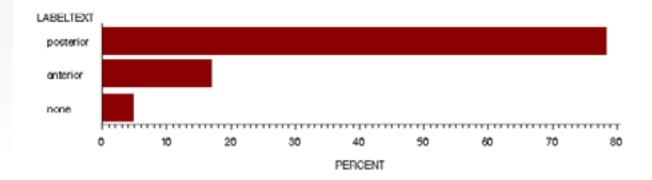
→ Distribution of decompression

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Distribution of Decompression

LABELTEXT	Frequency Count	Percent of Total Frequency
posterior	5443	78.32
anterior	1179	10.90
none	328	4.72
	6950	100.0

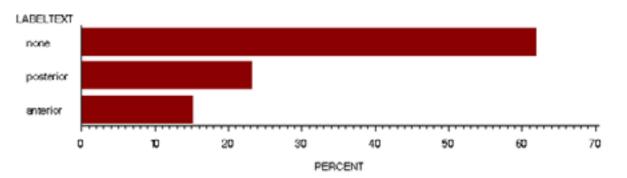


→ Distribution of fusion

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Distribution of Fusion

LABELTEXT	Frequency Count	Percent of Total Frequency
none	4358	61.78
posterior	1630	23.11
anterior	1068	15.11
	7054	100.0



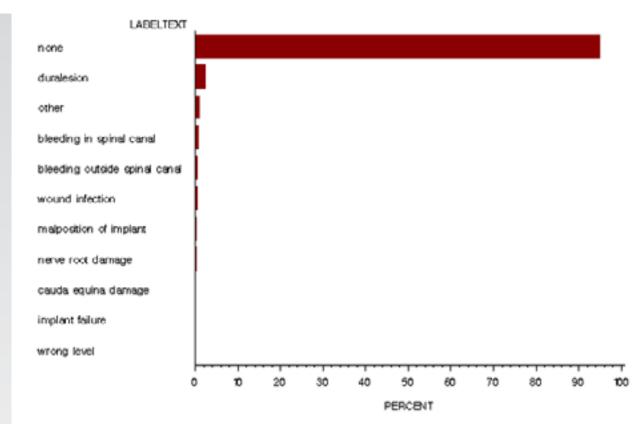
→ and distribution of surgical complications is displayed as output.

Distribution of Surgical complications

LABELTEXT	Frequency Count	Percent of Total Frequency
none	6291	94.83
duralesion	158	2.35
other	59	0.89
bleeding in spinal canal	40	0.60
bleeding outside spinal canal	26	0.39
wound infection	24	0.38
malposition of implant	18	0.24
nerve root damage	15	0.23
cauda equina damage	3	0.05
implant failure	2	0.03
wrong level	2	0.03
	6634	100.0

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Statiscal analysis of followup forms

In the same manner statistical analysis from the followup forms can be performed, Except for that you need to choose the Followup form in selection of forms!

The selection of the patient sample as well as the inclusion criteria can be chosen like shown before.

The output parameter can be choosen from the followup form.

The chosen parameters from the followup form are shown according to the FU Intervall.

Comparative statistical analysis (benchmarking)

In this online statistical function you can also perform a comparative statistical analysis e.g compare your data with the data of the complete pool.

Apply the same procedure as for the statistical analysis before.

When selecting a sample e.g. click on: "My data" for comparison VS: "All cases".

Online statistics Run stats SPINE TANGO: Surgery SPINE TANGO: Surgery Select form 201 Cases VS 8680 Cases Sample All my cases in demo Spital VS Then again you can select the required output criteria. In this example we chose: Main pathology: Online statistics NASS: Surgery (V1) Form All my cases in Spine Demo Clinic: Spinal Surgery 202 Cases VS 8681 Cases Sample All cases in the pool VS and Morbidity state: Surgery Level of main pathology Surgery date Surgeon Assistant Therapeutic goals Specify other surgery goal Components Anterior access Specify other anterior access Posterior access

Surgeon credentials

Specify other technology

Prophylaxis

▼ Morbidity state

Operation time

We want a descriptive analysis:

Descriptive

Scientific

Now select:

Technology

Blood loss

Blood transfusion

→ Run stats

Specify other posterior access

Specify other prophylaxis

Specify other surgeon credentials



In this comparison your data is shown in red, the pool data in grey:

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→ distribution of gender

Again, the demographic data (age and gender) are automatically shown for the groups.

	Ge	ender Distributio	п		
SAM	PLE GENDE	IR Frequency Count	Percent of Total Frequency	ny .	
	1 1	114	56.7	2	
	1 m	87	43.2	18	
	2 f	4090	54.0	13	
	2 m	3990	45.9	7	
Number of Subjects in the Stratum	er Distribution Chi-Square	OF for		sher's Exact est P-value (2-Tail)	

The second table shows results from the Chi-Square and Fisher's Exact test. The test proves if the distribution of gender in the two samples is random (p-value > 0.05) or if there is a significant difference between the samples (p-value < 0.05). The usual rule of thumb for deciding whether the chi-squared approximation is good enough is that the chisquared test is not suitable when the expected values in any of the cells of a contingency table are below 5, or below 10 when there is only one degree of freedom (this rule is now known to be overly conservative). In such small samples the results of Fisher's Exact Test should be used.

For further information, visit:

http://math.hws.edu/javamath/ryan/ChiSquare.html

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Percent of Total Frequency → distribution of age Age Distribution Analysis Variable : age

SAA						Maximum		
	1	201	201	10.00	61.00	90.00	58.67	18.36
	2	8680	8680	0.00	59.00	107.00	67.80	17.17

		Age Distribution	Testing for Sign	ificance	
Analysis Variable	Two-sample Willoaxon Statistic	P-value, Wilcoxon Test (Two-sided)	Kruskal-Wallis Statistic	Degrees of Freedom, Kruskal-Wallis Test	P-value, Kruskal-Wallis Test
age	935338	0.23472	1,41204	1	0.23472

The Wilcoxon Test is a non-parametric test for assessing whether two independent samples of observations have equally large values. The Kruskal-Wallis Test is a non-parametric method for testing equality of population medians among groups.

The two tests are quite similar and therefore they have similar p-values. If the p-values are >0.05 the distribution is natural, else there is a significant difference.

For further information, visit:

SAMPLE GENDER

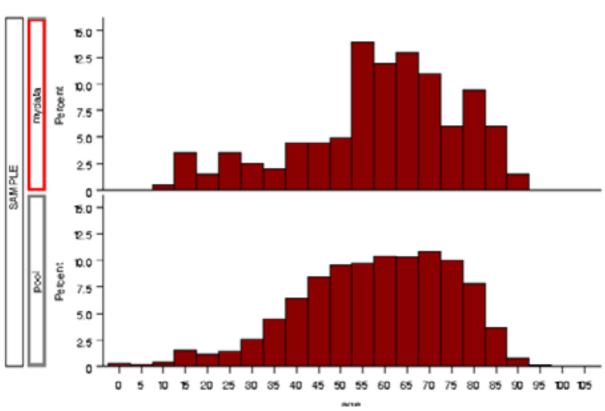
http://en.wikipedia.org/wiki/Mann-Whitney U

http://en.wikipedia.org/wiki/Kruskal%E2%80%93Wallis one-way analysis of variance

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 \rightarrow distribution of Main Pathology

SAMPLE LABELTEXT Frequency Count Percent of Total Frequency 14.43 9.95 9.95 7.98 4,48 0.50 76.29 5.20 5.15 4.18 3.55 2 fracture/trauma 2.29 127 1.45 0.98 0.56 0.33

Distribution of Main pathology

Distribution of Main pathology - Testing for Significance

it	Number of Subjects the Stratum	Chi-Square	DF for Chi-Square	P-value for Chi-Square
	8881	94.5208	9	2.0082E-16

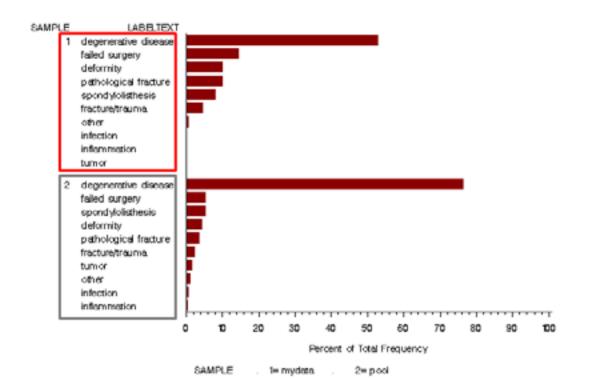
The Chi-square Test here shows a p-value of 2.01*10^-16, which is far below 0.05 and, hence, significant. The low p-value means that the distribution is not explainable only by chance. In the example the distributions of main pathology are significantly different in the two samples.

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→ distribution of Morbidity State

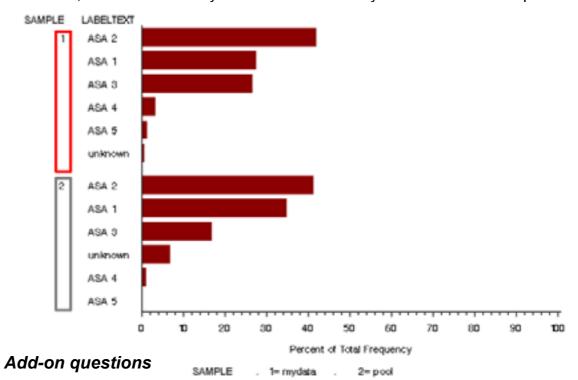
Distribution of Morbidity state

SAMP	Ε	LABELTEXT	Frequency Count	
	1	ASA 2	84	41.79
	1	ASA1	66	27.36
	1	ASA 3	53	26.37
	1	ASA 4	6	2.99
	1	A8A 5	2	1.00
	1	unknown	1	0.60
	2	ASA2	3516	41.04
	2	ASA 1	2970	34.68
	2	ASA 3	1438	16.76
	2	unknown	571	0.00
	2	ASA4	74	0.00
	2	ASA 5	1	0.01

Distribution of Morbidity state - Testing for Significance

Number of Subjects in the Stratum	Chi-Square	DF for Chi-Square	P-value for Chi-Square
8769	90.3870	5	5.5722E-18

Here we get the same "Testing for Significance" as in "Main Pathology". The result is similar too, the P-value is very small. The unnaturally accumulation is in option "ASA 2".

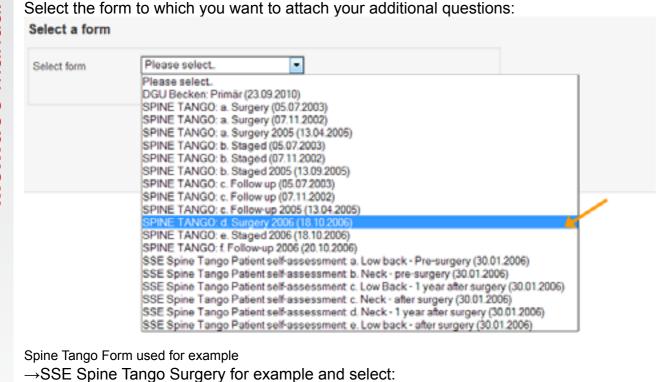


This function is only available for clinical administrators.

In this section you can create your own subform for customized online data entry in addition to an existing form. That means that the questions/ the additional subform is related to one form (eg. The surgery form or the followup form). The generated additional subform is available for all registered members of your department.

Click on Add-on question

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Admin tools

User tools

Logout

Add-on guestion

If you have not created a subform yet, create a new one \rightarrow OK

Select a form

Select form

Next

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SPINE TANGO: Surgery 2006 (*



If there is already an existing subform for additional questions you have different possibilities:

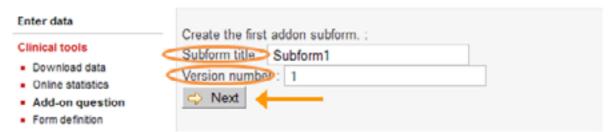
- a: Create a new subform
- b: Add new question(s) to an existing subform
- c: Change an activated subform (only one subform can be active at a given time)



a. New subform

Enter a Subform title and a Version number and select:

 \rightarrow Next



→ Question-Generator - step1

There are three different question types you can choose:

- 1.: text question: user enters a text answer.
- 2.: single choice question: user selects one of several possible answers.
- 3.: multiple choice question: user may mark one or more of several possible answers.

 \rightarrow Next

Enter data

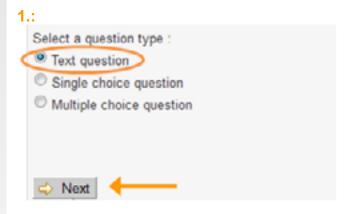
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Download data

 Online statistics Add-on question Form definition

Choose the question type you want to create and select:

 \rightarrow Next



→ Question-Generator – step 2

Enter your question text and optionally a default answer



To go on, select:

→ Next

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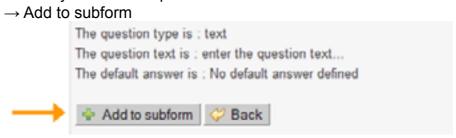
By selecting

 \rightarrow Back

you can always go a step back.



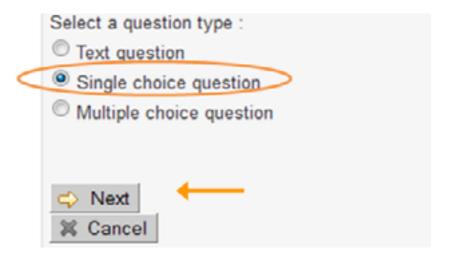
Control your entered question and select:



Then you repeat the "Question-Generator –step 1" to add further questions Do this by selecting a question type and select:

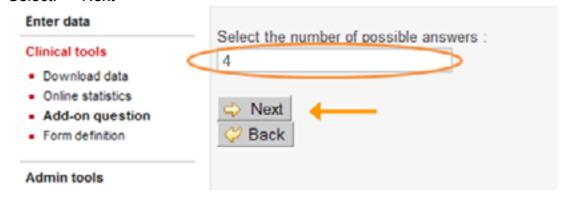
→ Next

2.:



Select the number of the possible answers for your question. The number should be between 1 and 30.

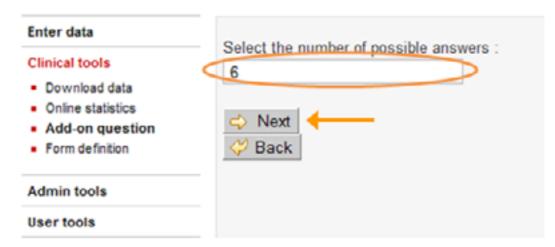
Select: → Next



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→ Question-Generator – step 3
Enter your question and answers and select: → Next
Enter the question text: Rate your pain after the operation
Enter the answers :
much better
slightly better
same
worse
◇ Next ◇ Back
Control your entered question and the answers and select: → Add to subform
The question type is : single The question text is : Rate your pain after the operation compared to preoperative The possible answers are :
much better
slightly better
same
worse
Add to subform 💝 Back
Then you end up again at the Question-Generator –step 1
3.:
Select a question type :
Text question
Single choice question
Multiple choice question
Novt

Select the numbers of possible answers for your question. The number should be between 1 and 30.



Enter your question and answer-possibilites and select:

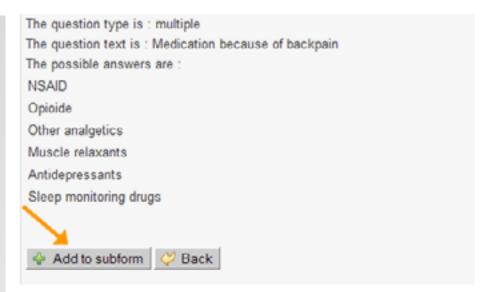
 \rightarrow Next

	Opioide Other analgetics	Enter the question text : Enter the answers :	Medication because of backpain
Other analgetics Muscle relaxants Antidepressants	Other analgetics Muscle relaxants Antidepressants	NSAID	
Muscle relaxants Antidepressants	Muscle relaxants Antidepressants	Opioide	
Antidepressants	Antidepressants	Other analgetics	
		Muscle relaxants	
Sleep monitoring drugs	Sleep monitoring drugs	Antidepressants	
		Sleep monitoring drug	js .
Next 4		✓ Back	

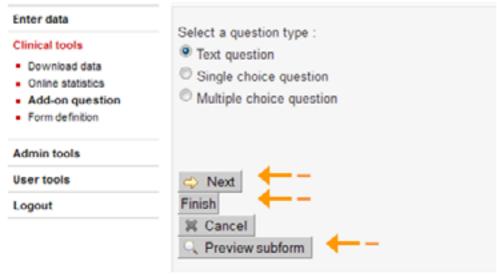
Control the entered question and answer-possibilities and select:

 \rightarrow Add to subform

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Then you end up again at the Question-Generator –step 1 with the following options:



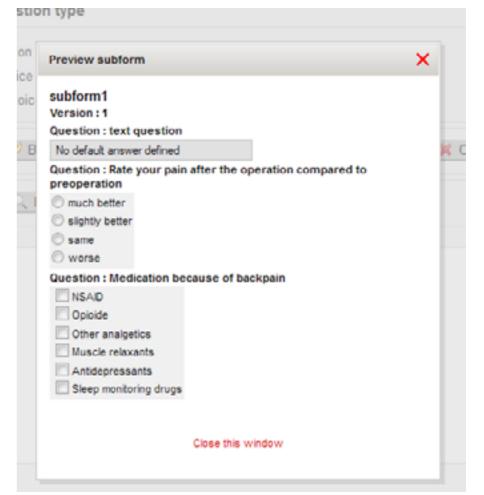
Add further questions by selecting the question type and select:

 \rightarrow Next

View the Subform (list of questions), select:

→ Preview subform

The list with all your created questions will open in an additional window:

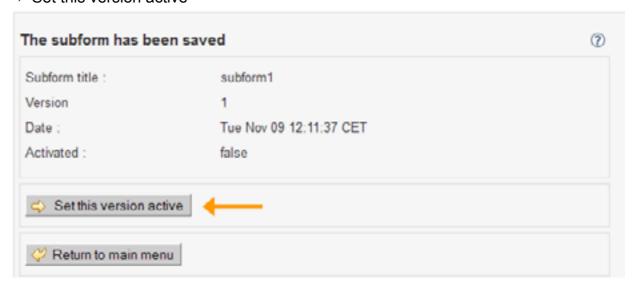


End adding questions and save the subform, select:

 \rightarrow Finish

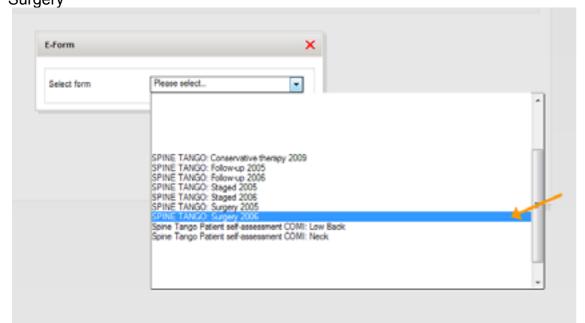
If you want your new subform to be active now, select:

→ Set this version active



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Create an according e-Form for your patient. That means you have to choose the same study form for which you created the additional subform, in our example "SPINE TANGO Surgery"



Spine Tango Form used for example

In "Additional Subforms" you find your activated subform. Here e.g. subform1



Click: \rightarrow Add and your subform will be activated and inserted as separate tab.

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b: Add new question(s) to an existing subform



Select the version and date of the subform you want to add questions to. You have to give this subform a new version number. Then select:

→ Next



You get back to Question-Generator-step 1. Add questions as shown above.

To save the added questions to the new version you have to click on:

→ Finish



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То

set the new subform active, click on:

→ Set this version active

Subform title :	subform1
Version	2.1
Date :	Tue Nov 09 15:33:58 CET
Activated :	false
Set this version ac	tive

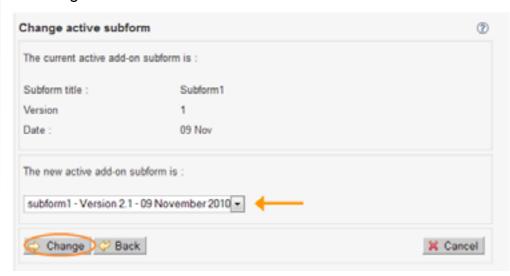
There is no possibility to delete questions or change questions in an existing subform. For this purpose you would need to create a new subform.

c: Change an activated subform



You see the currently activated subform. You can change this to another version, here e.g. Version 1, 9.11. To change, select:

 \rightarrow Change

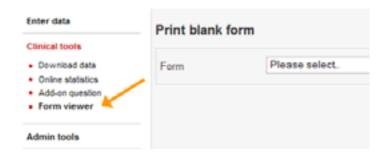


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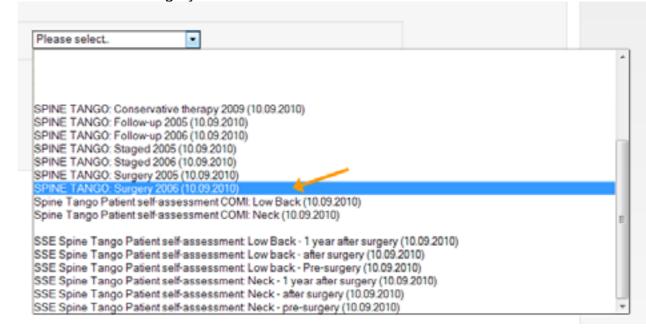
Form viewer

In "Form viewer", you find all the forms in a PDF-document. These documents can NOT be scanned, they do NOT replace the manual paper forms. They may help you to get an overwiev of all questions and possible answers. You can fill them in online and then save or print them out, to discuss, display etc.

→ choose "Form viewer"



With the pull-down menu, choose the form you want to read. In our example, we chose "SPINE TANGO: Surgery".



Spine Tango Form used for example

An Adobe Acrobat Reader file will open in a new window. If you want to save the document, select:



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If you want to print the document, select: \rightarrow Print All fields, that CAN be filled in, are highlited blue: deformity pathological fracture inflammation tumor other Questions, where only one answer is allowed (single choice questions), have circles to tick: Main pathology degenerative disease fracture/trauma spondylolisthesis infection failed surgery

Questions, where several answers are allowed (multiple choice questoins), have squares to tick

oqu	aroo to tron.	
4.	Type of degeneration (1 - 8)	
	black disc	disc degeneration
	✓ disc herniation	spondylosis
	spondylarthrosis	x spinal stenosis
	adjacent segment degeneration	other
Afte	er a multiple choice question, you see i	n brackets, how many answers are allowed:

4.	Fusion (1 - 2)		
	none	anterior	
	posterior		

If a question is optional, it is written behind the question itself. If there is nothing written, a question is always mandatory.

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Specify other decompression (optional)

Follow-up Calendar

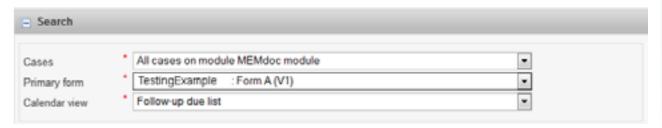
In "Available Downloads" you find already created Excel-files, which can be opened and used. The name is created as follows: Study: Form - Interval, Chosen cases - creation date & creation time.



Spine Tango Form used for example

Below "Search" you can create new follow-up calendars. These can be used by doctors to keep track of their follow-ups for each patient or as well by a module administrator for example, to check if all doctors perform and register their follow-up examinations.

- Please choose the cases you want to include. Your options depend on your profile, as an Admin you can choose between all of your cases or all cases in the clinic/department
- Next, choose the primary form you want to conduct follow-ups on. Only primary forms with defined rules will be shown (rules being defined by your module administrator).
- In "Calendar view", please choose if you want to conduct a "due list" which shows every follow-up from now on or if you wish an "interval view" where you define a time period.



Follow-up due list

To get a due list, you have to define a time period in the future.

Afterwards, please click "Create".

Specify the desired	upcoming fol	low-up period to view	
Follow-ups due in	4	\bigcirc day(s) \circledast week(s) \bigcirc month(s) \bigcirc year(s)	
			Create

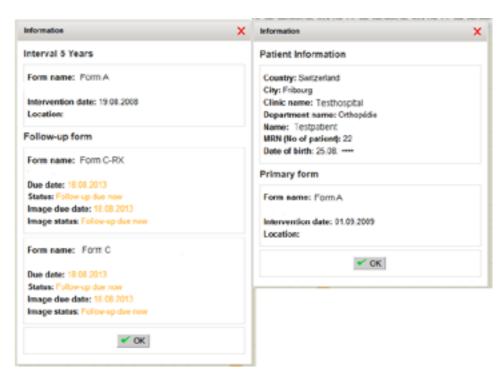
Search results:

Per line, you see one patient and his follow-ups in the future. The calendar will begin in the first month containing a follow-up and end in the last month containing one. On top you will see the color code: orange blocks mean FU due now, grey means FU due in future. You also see the amount of forms found.

The display shows one month. Using the arrows, you can move forwards/backwards in monthly jumps.

Search	resul	ts																													
																									Pri	int	8	Do	wnk	oad	list
Follow-up	due	nov	٧							Foll	ow-	up d	lue i	now	not	req	uire	d			F	ollo	w-ug	du	e in	futu	re				
Affinis Inver Weeks perio		hou	lde	r En	dop	ros	the	sis:	For	m A	(V	1) -	Fol	low-	-up	due	lis	t Fr	om	20.0	08.2	013	To	17.0	9.20	013	(4	į	ш		
																								62	2 Fo	ollo	v-u	p fo	rm(s	i) fo	ound
	ф													ı	Aug	ust	201	3												٦.	4
Patient.	Thu 01	Fri 02		-	Mon 05		07							Wed 14															_		
1234 11.07.2013																															

By clicking on the patient or the shown FU-blocks, you'll see further information about the patient respectively the follow-up form (dates, interval, primary form etc). If there are two blocks together, it means that a forms and an image are required.



You can change between a "Grid-View" (default) or a "List-view". In Grid-View you can sort by patient (ascending or descending), in List-View by patient and Due date.



You can print your data or add it to your download list, where an Excel-Form will be cre-

ated	Print	¹ ♣ Download list	
116.			

Follow up Interval view

Please define a time episode for which you want to display the follow-ups. In case you don't apply a date in "from" or "to", everything from the past respectively from the future will be displayed.

Specify the desired	upcoming follow-up interval to view	,		
From	01.01.2010	То	31.12.2010	
				Create

The data appears listed. Please take a look at the color code.

You'll see all the patients with all their primary forms and corresponding follow ups.

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Search results

Patient

CBH

Follow-up performed Follow-up missed Follow-up due now

Primary form

03.05.2011

At the end, you'll find follow-ups which don't match the timing (Outliers).

amount of time until the file appears in "Available Downloads".

CBH BONE PRESERVING: Case Report Form A (V1) - Follow-up interval view From 01.01.2010 To 31.12.2013

04.05.2011 Testform, Form C

Follow-up form

Testform, Form C

Testform, Form C

Testform, Form C

You can download/print the Interval view as well. When downloading, please wait a short

User Tools

Modify user information

To change anything in your user information, for example your Email, just type in what you want to be changed and then select:

 \rightarrow Send

Print Bownload list

1 Primary form(s) found

14.06.2011 14.06.2011

02.05.2012 02.05.2012

02.05.2013 02.05.2013

Due date

6 Months 30.10.2011 30.10.2011

outside of

intervals

due date

Follow-up due in

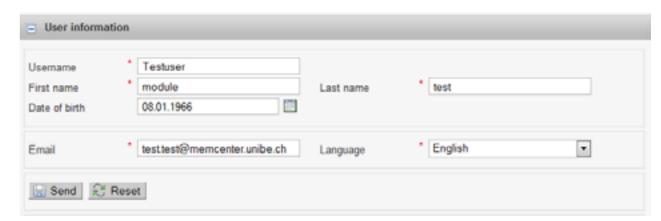
6 Weeks

1 Year

Follow-up due now

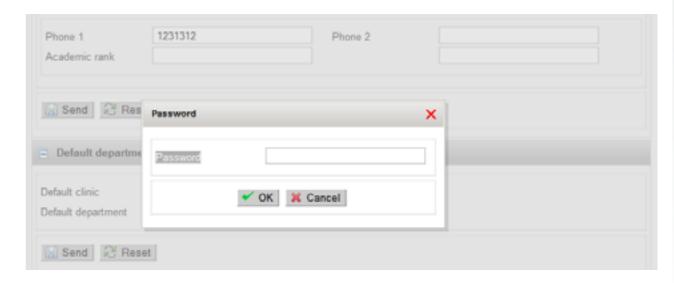
To set back your changes (before saving!), click:

→ Reset



You will have to type your password to confirm your changes. Then select:

 $\to \mathsf{OK}$



Change password

To change your password, select

→ Change password

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Enter and re-enter your new password, it must be at least 8 characters with upper and lower case letters and at least 1 number. Click Send to save.

ange password	
Re-enter new password.	
	☐ Send

Change details

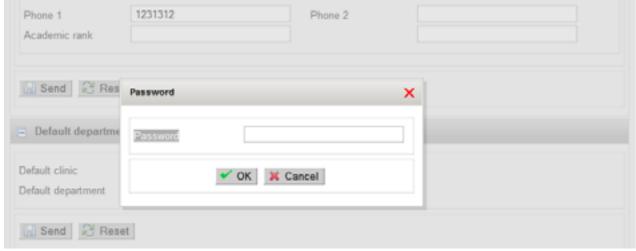
You can add or change the details and further information of your departments beneath "Staff". In the pull-down menus you see all your clinics and all your departments from all your profiles. Choose the one you wish to change and make your changes:

 \rightarrow Send

Clinic Department	* MEMcenter2 * Testing Division	•	
Phone 1 Academic rank	1231312	Phone 2	

You will have to type your password to confirm your changes. Then select:

 \rightarrow OK



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After login into the system you are always in a department. You have the possibility to define your default department here. This may be comfortable when you are registered in various departments and you use one of them more than the others.

It's important to make sure you are in the right department as you will only see the patients registered within.

You will still be able to change between the departments in the header.

Choose your default clinic and its default department, then choose:

Default departm	ent / Default clinic		
efault clinic	MEMcenter2	· —	
efault department	Testing Division	· —	

You will have to type your password to confirm your changes. Then select: → OK

hone 1	1231312	Phone 2		
cademic rank				
Send Res	Password		×	
Default departme	Password			
fault clinic		✓ OK X Cancel		
fault department				

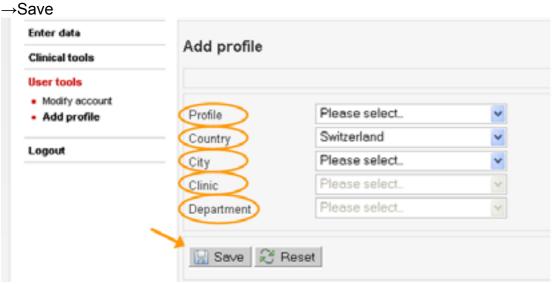
Add Profile

View Profiles:

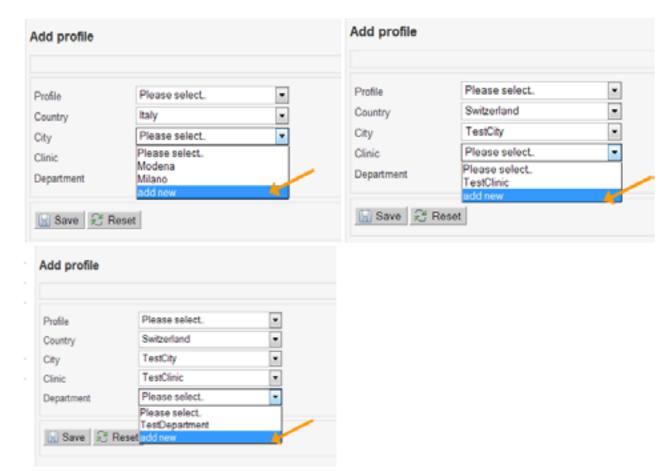
This gives you an overview of all your profiles in all your clinics and departments. A ratio button shows wether the profile is active or not. You can not change anything, but get a list of all your profiles.

Profiles	33 View profiles		
Implant Clinic: C	Ortho, Bern CH		
Doctor	raio, beni cir	Activated	 Deactivated
spital: ortho, Ber	m CH		
Data Entry Clerk		Activated	 Deactivated
spitalhof: ortho,	Liestal CH		
Doctor		Activated	Deactivated
ST Test Clinic: S	Spine Department 3, Bern CH		
Department Admi	nistrator	Activated	 Deactivated
ST Test Clinic: S	Spine Department 2, Bern CH		
Department Admi	nistrator	Activated	 Deactivated
Doctor		Activated	 Deactivated
ST Test Clinic: S	Spine Department, Bern CH		
Clinic Administrat	or	Activated	Deactivated
Department Admi	nistrator	Activated	 Deactivated
Doctor		Activated	 Deactivated

If you want to add a profile to your account, e.g when you are clinical administrator but you are a surgeon as well, please fill out the marked fields and select:



If you want to add a City/ Clinic/ Department, select:
→Add



If you add a new City / Clinic, fill out the marked fields (all the other fields are optional!) and select:

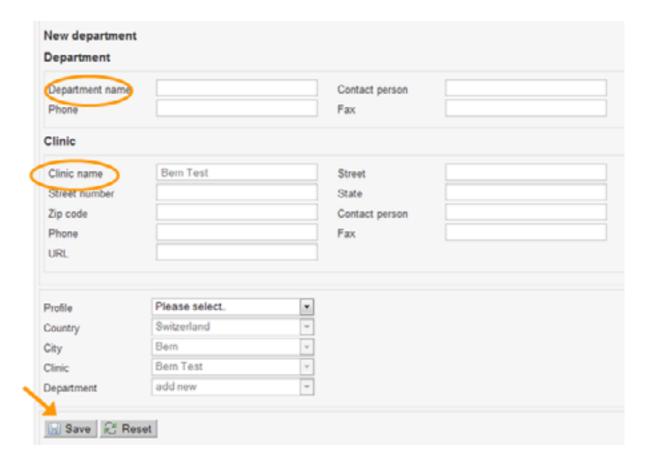
 \rightarrow Save

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New City			
City			
Department			
Department name Phone		Contact person Fax	
Clinie			
Clinic name		Street	
Street number		State	
Zip code		Contact person	
Phone		Fax	
URL			
Profile	Please select.	•	
Country	Switzerland	v	
City	Please select.	v	
Clinic	Please select.	v	
Department	Please select.	~	

If you add a new Department, fill out the marked fields and select:

→ Save Add profile New clinic Department Department nam Contact person Phone Fax Clinic Clinic name Street Street number State Zip code Contact person Phone Fax URL docteur Profile Country Bern City Clinic Please select. 🖫 Save 🤰 Reset



Always when you added something, this window will appear:

lew staff	×
Phone1	
Phone2	
Academic rank	
Title	

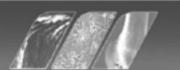
Filling out the fields is optional, you may also leave everything empty and select: \rightarrow OK

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Société Française de Chirurgie Orthopédique et Traumatologique





Schweizerische Ophthalmologische Gesellschaft. Societé Suisse d'Ophthalmologie Societé Svizzera di Offalmologia Swiss Society of Ophthalmology

