



b UNIVERSITÄT BERN

User Manual Swiss Heart Surgery Registry

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1.1. Access

The registry can be accessed here: https://swissheartsurgery.swissrdl.unibe.ch/.

1.2. Supported languages

The application is available in German, French, Italian and English. However, the registry form is available in English only.

DE EN IT FR Language setting (bottom right corner): Please change to the desired language by clicking on it.

A- A A+ Font size setting (top right corner): Clicking on A+/A- allows you to increase/decrease the font size.

1.3. Functions and symbols in the Swiss Heart Surgery Registry

In the Swiss Heart Surgery Registry, you will find different icons with different functions. By a "mouse roll over", positioning the cursor on a symbol, you can read the function of the symbol. In the following, all the icons are briefly explained:

Help		
F5	Update	In case of a problem, click the F5 key on your keyboard. This will cause the page to refresh.
?	Help	Specific help or information can be found for certain items by clicking on the question-mark icon.
Gene	ral	
Ŧ	Open	Open a drop-down list or extended details
Ŷ	Arrow	Back to Search (Back to Patient / back to search function)
On th	e patients list	When searching a patient: Patient O Form
000	List of forms	Viewing, adding and modifying the patient's forms
٥.	Demography	Viewing and modifying the patient's demographic information
B.	E-Form	Adding an electronic form directly
Ū	Delete	Delete the patient (only possible if all forms have been deleted before).
		Attention: Deletion of a patient record is irreversible!
On th	e forms list	When searching a form: O Patient Form
÷	E-Form	Adding an electronic form
0	Edit	Viewing, editing and completing a form
£	Print	Printing a form
U	Delete	Deleting a form (only possible with entering your password)
		Attention: Deletion of a form is irreversible!
Form	status	
Θ	incomplete	Incomplete entry, mandatory information is missing; in order to be submitted, a
		form must first be completed
•	complete	All mandatory information is entered, form can be edited and submitted (locked),
		provided that the components are completely recorded (Check!)
	submitted	All mandatory information is entered, form is locked and no longer editable. Only

All mandatory information is entered, form is locked and no longer editable. Only submitted forms are considered for reports and analyses.

2. **REGISTRATION**

There are two levels of registration in the heart surgery registry: **the user level (= login)** and **the profile level (= permissions)**. During registration, you apply for a new user, who is then assigned one or two profiles depending on the function.



Attention: Due to reasons of data protection, each user needs to create a new user login on their own. During user registration, only one profile can be chosen.

Further profiles will be assigned by SwissRDL in collaboration with the respective clinics. **Any new users will be validated by the support team of SwissRDL**. The participating departments / Department Administrators will receive a form and will be kindly asked to provide SwissRDL with all the necessary information (contact details, required profiles, etc.) for all their collaborators in need of an account. By returning or keeping this list up to date the departments can assist and speed up the registration process.

2.1. Who needs an own user account?

For data protection reasons, every person who enters data in this registry needs a separate user account. In this way, the requirement of person-specific tracing of all activities can be taken into account. **Non-specific 'collective logins' are not permitted**.

The user is responsible for their activity on the Swiss Heart Surgery Registry and is liable for any damage resulting from the loss of user data or sharing of the password. **Your login information is therefore confidential and must not be shared with third parties.**

<u>Activity in several clinics</u>: If you are or have been active in several clinics, please make sure that you have only **1 user account**, which is adapted to your current activity and affiliation in each case. If you change clinics, the login 'moves' with you.

2.2. Profiles in the Swiss Heart Surgery Registry

The level of rights, access to registry tools (e.g., data export or online statistics), and the right to enter and modify patient data is regulated at the level of the profiles. There are two different profile options in the Swiss Heart Surgery Registry, each with different authorizations. If a person performs both functions simultaneously both profiles can be assigned to their user (by the SwissRDL Support Team, in collaboration with the Department Administrator(s)). The list below describes the profiles and their main functions:

- Department Administrator: Download/Export of the entered (raw) data of the entire department; onlinestatistics: comparison of their department with the pool, can search for patients, but cannot create new patients nor new forms.
- Data Entry Person: Data entry, submitting of forms, deletion of unsubmitted forms.

The list below provides an overview of who needs which profile:

Description	Required Profile
I am a surgeon and I do register my surgeries regularly in the registry	→ Data Entry Person profile
I am a surgeon and I do not register my own surgeries in the registry, nor do I need to per- form data export*	ightarrow No user account required
I am a resident physician and record or cor- rect surgeries on behalf of a / several sur- geon(s)	→ Data Entry Person profile
I am not a physician but record or correct surgeries on behalf of a / several surgeon(s)	→ Data Entry Person profile
In my department I am responsible for the registry and need admin rights including the right to export data	→ Department Administrator profile
As quality manager of the clinic, I am respon- sible for internal monitoring	→ Department Administrator profile

k

* Please note: surgeons that do not perform data capture and who do not fulfil a role as Department Administrator do not need to create a login.

(Minimal) requirements for profiles:

Each department needs to register:

- At least 1, maximally 3 Department Administrators
- At least 1 Data Entry Person



Note: The number of **Department Administrator** profiles is limited for each clinic (1-3) and may only be assigned with justification of the corresponding functions.

2.3. Create an account

Registering as a new user, if you do not already have a user account, is done in a few steps. Please Click on "New user" (1) on the login page https://swissheartsurgery.swissrdl.unibe.ch/.

SwissHeartSurgery Module			
Username	Password		a Login
	2	Forgot password	New user 1

Complete your registration by entering the information marked with *:

- Username and password (they are case sensitive)
- First name, last name, date of birth, e-mail, language



Note: The provided e-mail must be a **personal hin-secured address** [HIN secured] (only clinic e-mails, no private e-mails such as ...@bluewin.ch, ...@gmail.com). Collective e-mails (i. e. herzzentrum@klinik.ch) are not permitted either.

• The desired profile (profile, city, clinic, department)



Please note that you can choose only one profile during user registration. The support team of SwissRDL will assign the additional profile upon request. We kindly ask the Department Administrators to return the provided list of registry users. Please add any additional profiles to this list

- For validation, the contents of a security image must be transmitted
- Please take a few minutes to carefully read through the **confidentiality agreement** and then accept it. If you have any questions, please do not hesitate to contact us.

The support team of SwissRDL will process your request and validate your profile.



Please note that SwissRDL can validate only those users for which we received a confirmation by the corresponding department. Departments can assist SwissRDL and speed up the registration process by keeping us updated with their list of collaborators and required profiles!

As soon as the profile has been activated, you will be notified by e-mail. You can then log in with your username and password and start your documentation work. If the account is not activated within two working days, please contact the SwissRDL support team (tel: **+41 31 684 59 66** / e-mail: swissrdl@ispm.unibe.ch).

Please remember to create only one user account for yourself. If you notice that you accidentally have more than one validated user account, please contact SwissRDL to merge them (see contact information above).

2.4. Inactivated user account

If you do not log in to your user account for over six months, your account will become inactive and the message "Your account expired on dd.mm.yyyy" appears. Please contact the SwissRDL support team to reactivate it (by calling +41 31 684 59 66 or writing an e-mail to swissrdl@ispm.unibe.ch). Please do not create a new account if your account has expired.

2.5. Forgot password

If you have forgotten your password, please click on "Forgot password" on the login page to reset it. You will then receive an e-mail with a link. By clicking on this link, you can create a new password.



Note: You must enter your username and NOT your e-mail address after selecting "Forgot password". If you do not remember your username, please contact the SwissRDL support team (tel: **+41 31 684 59 66** / e-mail: swissrdl@ispm.unibe.ch).

3. User validation and management

User validation and user management is performed by SwissRDL in collaboration with the local Department Administrators.

4. PATIENT DATA

The data to be collected is non-anonymized health data, which is considered to be particularly worthy of protection under the Federal Act on Data Protection (FADP/DSG/LPD, of 19 June 1992, SR 235.1) and the Human Research Act (HRA/HFG/LRH, of 30 September 2011, SR 810.30). When processing the data, those people authorized to access the data must take these requirements into account. You only have access to your own data as well as to data for which you have authorization.

4.1. Search patient

Please check in a first step if the patient you want to register already exists in the registry to avoid duplicate registration.

- (3) Click on *Enter data* and then *Search patient* (3) on the navigation bar.
- (4) You can now search a patient based on the medical record number (*MRN= Patient-ID*), last name or *date of birth*. Only enter one entry in the search engine at a time. The more items you use for your search, the higher is the risk of a mistake (during registration and during the search), and as a consequence, the higher the risk of not finding the patient because of this reason. Use the * function as a wildcard for names or patient numbers, for example, to identify patients with double names or patient numbers with preceding zeros. We recommend searching by the date of birth since names can easily be misspelled.
- (5) Select the patient search Patient Form. If several patients match the search criteria, use the *form list* to select the appropriate patient.
- (6) You can also extend your search by clicking on 🗄 *Extended search* to search based e.g. on gender, or first name.

dep1, admin1 2	Logged into:SwissRDL: dep1, Bern Switzerland
Enter data Search patient 	Search 4 5 Patient O Form ?
Clinical tools	M.R.N. Date of birth dd.mm.yyyy
Admin tools	Last name
Logout	् Search 🖉 Reset
	Extended search 6
	E Search result

In contrast to the patient search • Patient • Form, a form search • Patient • Form directly displays all forms or operations that are linked to your search criteria. The search results remain identical, the only difference is the display thereof.

4.2. Extended search – search patient cohort

The extended search can help you if you want to search forms with one or more specific criteria. For example, it is possible to identify all the forms that are incomplete or unsubmitted. Or you may want to elicit all cases from a past year to check their completeness. The search for answers within the forms allows you to search for a specific clinical collective, such as all patients with angina CCS 3 or CCS 4.

(6) Expand the search by clicking on 🗄 to open the extended search and detailed specifications. If you do not specify a criterion in more detail and click on <a>Search directly, all forms or patients which you have the authorization for, will be displayed.

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Extended search	5 <mark>.</mark>		
Gender	⊖ Female ⊖ Male	First name at birth	
Doctor 7	Please select 🗸		
Form state Attached objects	All Incomplete Comp	lete (but not submitted) Sub	mitted 7
Selected questions		All questions	
Form 7 Swiss Heart Surgery Re Subform 8 Admission/ Pre-operativ	gistry: Surgery (V0.6) e examination		✓
Date of admission Angina Dyspnoea Congestive heart failure (Previous MI Time elapsed between la: Type of most recent MI (or	optional) st MI and surgery ptional)		
Angina		= CCS 3 = CCS 4	✓ 10 OR ^m / ₀
			् Search 🖉 Reset
E Search result			

- (7) With each criterion displayed, you can narrow down the search. Select the conditions for the *form*, the *period*, the *doctor* and/or the *form status* according to your requirements. Please note that "Doctor" refers to the person performing data capture in the case of the Swiss Heart Surgery Registry.
- (8) With the search in subform you can specify the selection even further if necessary. You will then search for all forms with specific answer options. First select the *form* (7), then the *subform* (8), and then the corresponding questions will open.
- (9) By double-clicking on the questions, you will see the answer options below, from which you can choose again. If you want to limit your search by more than one criterion, repeat the double-click on the question and another option field will be added. You can also compile the restrictions across different *subforms* (8).
- (10) The result can further be narrowed down by means of the AND/OR condition.

4.3. Create a patient record (only Data Entry Person profiles)



Attention: Each patient to be registered needs to sign a statement of informed consent.

A new patient record may only be created if the patient is not already registered and therefore has not been found via *Search patient*.

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Check: Before entering a new patient, check that the patient has not already been created (see **4.1. Search Patient**). A new patient may only be entered if no patient record has been found.

- (1) To create a new patient record, click on the navigation bar on *Enter data* and then *New patient*.
- (2) Please record the following mandatory demographic information marked with an *:
 - Medical record number (MRN) / Patient number: unique, hospital-internal patient identification number (PID)
 - Date of Birth
 - Gender
 - Last name
 - First name
- (3) Complete the process by saving the patient record

dep1, doc1 🗸	Logged into:SwissRDL: dep1, Bern Switzerland						
Enter data New patient Search patient 	New patient * is required 2						
Logout	M.R.N. Gender	* * ○ Female ○ Male	Date of birth	* dd.mm.yyyy			
	First name at birth	*	Last name	*			
				3 ☐ Save 🛱 Reset			



Important: Please register the patient under his **patient number (PID/MRN)** and not under the **case number (FID)**. If the patient requires more than one surgery-visits, it is possible to add several forms to this patient (see **5 Data entry – forms**)

4.4. Edit a patient record (only Data Entry Person profiles)

In case of subsequent changes of the patient information, search for the patient record (see **4.1. Search patient**) and click on the **demographics** icon **(1)** of the respective record in the **search results**. You can subsequently change / add the respective information and then save the changes **Save**.

<u>M.R.N.</u>	Date of birth	Gender	First name at birth	Last name		1	🔀 Export
ab20211129	01.01.1990	Female	Petra	Muster	Ħ	2	₽.

4.5. Delete a patient record (only Data Entry Person profiles)

A patient can only be deleted if no entries or forms exist for the patient (see 5.5. Delete a form).

If the patient has been entered twice and the operation is recorded in duplicate (check date!), do the following:

- 1) Delete the duplicate forms of the patient record to be deleted
- 2) Only then the patient record can also be deleted.



Important: The deletion of form entries as well as patients cannot be undone!

There are two options for deleting the patient entry:

"Search result" variant: directly in the search results

(1) Click on the recycle bin and confirm the deletion with your password.

Search res	ult				
26 patients foun	ıd		Show 20 v patier	nts	<< < 1-20 v > >>
<u>M.R.N.</u>	Date of birth	Gender	First name at birth	<u>Last name</u> ▼	
Test	31.08.2000	Male	TestFirstname	TestName	🗒 🦢 🖺 🖷 🗴 <mark>1</mark>
ab20201109	01.01.1911	Female	ab	testab	🗒 🦢 🖹 📮

"Demographics" variant: After selection of the patient 🥍 in the patient search.

- (2) Open the demographics
- (3) Check that the list of forms contains 0 form(s).
- (4) Click on the *delete*-icon

Demographics: TestN	lame TestFirstname, M.R.N.: Test	, 31.08.2000, Male <mark>2</mark>			
M.R.N. * Gender	Test O Female Male	Date of birth	* 31.08.2000		
First name at birth	TestFirstname	Last name	* TestName		
Bave ≈ Reset Delete 4					
E Form list: 0 form(s)	3				
		🖶 E-Form	Form @ Send form link Send letter		
No forms available for this	patient				

5.1. Create a new form

There are two ways to create a new form:

- a. In the patient list, which you generate via the search function
- b. E-Form After opening the patient record

5.2. Modify / complete a form

To modify or complete a form that already exists but has not yet been completed, go to the patient record. Click at the corresponding form on \checkmark to edit it. Do not forget to save the changes. Forms that have already been submitted cannot be edited. If editing is necessary, contact the SwissRDL support team (tel: +41 31 684 59 66 / e-mail: swissrdl@ispm.unibe.ch).

See 5.6. Processing states of forms for a description of the various form states.

Admission/ Pre-operative examination Operation 1 Operation - Valve EuroScore II Post-operative course 🖫 Save 🔍 Save incomplete 🛛 🗟 Reset Admission/ Pre-operative examination 2 Operation **Operation - CABG Operation** - Valve **Operation** - Aortic Operation - Other cardiac Operation - Other non-cardiac EuroScore II Post-operative course

After creating a new form, you will be guided through the data entry process.

- (1) Click on the respective gray bar to jump to the corresponding part of the form (i.e., subform).
- (2) The subforms *Operation CABG, Operation Valve, Operation Aortic, Operation Other cardiac*, and *Operation non-cardiac* are automatically activated after you save the *Operation* subform if they are required based on the information you have provided there.

Click on save each subform and move to the next subform. If the data is still incomplete and not all necessary information is available, save the subform incompletely save incomplete. The circles next to the subforms indicate the status of the subforms (see **5.6 Processing states of forms**).



Attention: Any changes to the forms need to be saved. Therefore, we recommend saving forms incompletely Save incomplete immediately at the beginning and regularly during the data capture. Otherwise, you may risk losing the information already entered.

5.4. Submit a form

If all the required information from all the subforms has been filled in completely, you must submit 🖗 Submit the form.

Submitted forms are protected and cannot be reopened and changed or deleted afterwards.

Swiss Heart Surgery Registry: Surgery	Complete 单
Swiss Heart Surgery Registry	2 🔆 Submit
Admission/ Pre-operative examination	
Operation	
Operation - Valve	
EuroScore II	
Post-operative course	
1	🔚 Save 🖳 Save incomplete 🛛 🕄 Reset

- (1) Check: Submission is only possible if all circles are completely filled out in green <a> and the form as a whole is marked as "complete".
- (2) Click on 🖗 Submit; The form is now submitted / locked 🔒.



Important: Only completed and submitted forms are taken into account for the evaluations and (annual) reports. Therefore, check each time that the form is not only "complete" — but is also "submitted" — . We recommend that you occasionally check whether you still have any open forms (see **4.2. Extended search**).

5.5. Delete a form

If you have discovered that a form has been entered in duplicate or if the planned surgery has not taken place, you can delete a form that is already incompletely or completely saved. However, submitted forms cannot be deleted by the user (see **5.6. Processing states of forms**).

To delete a form, search for the respective patient (see **4.1. Patient search**). In the form list of the patient, click on to delete the form in question (**1**). You will be asked to provide your password.

✓ Back to search ⑦							
E Demographics: Muster Petra, M.R.N.: ab20211208, 01.01.1990, Female							
Form list: 1 form(s)							
Please select V	▲ E-Form 🖨 OMR Form 🥝 Send form link 🖂 Send letter						
	🕂 🚽 e 🖂						
1 Swiss Heart Surgery Registry Surgery	\[\begin{aligned} &						



Attention: Forms that have already been submitted cannot be deleted by the user themselves. Please contact the SwissRDL support team (by calling +41 31 684 59 66 or writing an e-mail to swissrdl@ispm.unibe.ch) if a form needs to be unlocked.

5.6. Processing states of forms

State of subform	State of form	Description
0		Subform does not contain any answers.
0		Subform is filled out partially but not saved. ** The answers will be lost if the subform is closed or left to go back to the case before saving. However, switching between the subforms will leave the answers unchanged.
		Subform is saved but some of the required answers are missing.
		Subform is complete and saved.
		Unsaved change(s) in a previously completely saved subform. ** see above.
		Incomplete, form to be completed.
	0	Complete, form to be submitted.
	8	Complete and submitted, not editable, case is included in the online statistics

There are three different processing states for forms and 5 different states for subforms:



Help with status errors: It may happen that a subform or a form is displayed as "incomplete" and therefore cannot be submitted, even though all the information has been entered. In this case, open the (sub-) form again and then click on the "Save" button. If the problem persists, please contact the SwissRDL support team or send the case notes with a description of the problem to swissrdl@ispm.unibe.ch.

The data export can be helpful when checking for completeness, i.e. when comparing internally whether all forms of a certain period have been entered. This function is allowed for users with a **Department Administrator** profile. They are allowed to export the (raw) data for all the entries of the entire department. Please note that users are only granted access to data from within their department. **Please note that you are not allowed to share data with unauthorized persons**.

Reviewer, SGHC	Logged into:SGHC Testclinic: Demo, Zürich Schweiz				
Enter data Clinical tools • Download data • Online statistics • Add-on question	Download data Image: Available Downloads 6 Download Interface				
 Form viewer Follow-up calendar Documents 	Form 2 * Please select ~				
My Account Config tools Logout	Cases * Please select ~ Form option 2 * Download only submitted forms ~ Download Type * Anonymous ~				
	Intervention date 3 From To				
	Information to export				
	Bownload data 5				

- (1) Select *Download data* under the menu *Clinical Tools* in the navigation bar.
- (2) Use the drop-down lists to select the required export options (marked with *): *form, cases, form options* and *download type*.
- (3) If you specify a time interval at the date of the procedure, you can further restrict the range of data to be exported.
- (4) Depending on the selection of the export options, further specification options will appear: Select the variables that are relevant for your purpose.

Note: By clicking directly on the form categories (displayed in red) one can select individual variables.

Surgery 4							
Expand all							
Admission/ Pre-operative examination							
✓ Operation 4							
✓Date of surgery	Start time of surgery (cut)						
☑Duration of surgery (from cut to suture = 'skin to skin')	Operation urgency						
Applied procedure(s)	\Box Symptomatic status at time of surgery (optional)						
Cardio-pulmonary bypass (optional)	CPB-time (min)						
□X-clamp performed?	Duration of x-clamp (min)						
□ Surgical access	Other surgical access, please specify						
Operation - CABG							
Operation - Valve							
Operation - Aortic							
Operation - Other cardiac							
Operation - Other non-cardiac							
Z EuroScore II 4							
Post-operative course							
Nownload data 5							

- (5) By pressing Download data you download the data. The data export may take several minutes, depending on the amount of entries.
- (6) Once the process is complete, you can retrieve, open and save the files above under *Available Downloads* 🦫.

For each data export you perform, you will receive a zip-folder containing two different files: a legend-file and a data-file (in form of Excel- and text files).



Attention: Excel files of the data are only included in the export up to a certain size of the database. We recommend using the data-files in the form of the text-files for subsequent analyses, especially when using automated routines.

Please pay attention to the extension of the documents:

Ending _dept: data files; Listing of the form entries with the selected variables (row: 1 recorded form per row, columns: selected variables)

Ending _dept_legend: List of codes used in the data files

7. ONLINE STATISTICS (ONLY ADMINISTRATOR PROFILES)

There is the option of obtaining a statistical overview of your department's cases using the **Online statistics** tool. Users with a **Department Administrator** profile can compare their department with the entire registry's "pool" data. The online statistics tool creates an aggregated evaluation of the data that can be downloaded as a pdf-file. The data always remains anonymous; no direct conclusions can be drawn about confidential patient or surgeon data.

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Reviewer, SGHC	Logged into:SGHC Testclinic: Demo, Zürich Schweiz					
Enter data	Online statistics	0				
Clinical tools Download data Online statistics Add-on question Form viewer Follow-up calendar Documents	Form 2	~				
	Sample VS 3	* Please select v Please select v				
My Account	Show age and gender distribution					
Config tools	Demographics (optional) 4					
Logout	Gender Min. Age	All Max. Age				
	E Filter (optional)					
	Subform	Please select	~			
	🖻 Output 🛛 🗧		0 Questions			
	Surgery Admission/ Pre-operative examination Operation Operation - CABG Operation - Valve Operation - Aortic Operation - Other cardiac Operation - Other non-cardiac EuroScore II Post-operative course					
			6 🛿 Run stats			

- (1) Go to *Clinical tools* in the navigation bar and then click on *Online statistics*.
- (2) Select the required information under *Form* and *Sample* (marked with *).
- (3) If you want to analyze the data with a comparison collective (pool data), select the corresponding comparison data under *VS*. The selection of a comparison collective is optional.
- (4) By means of the *Demographics (optional)* options, you can determine to what extent you would like to further restrict the data used for the online evaluation. These restrictions are optional.
- (5) Under *Output*, select one or more variables that you want to analyze. At least one variable must be selected.
- (6) By clicking on **It** Run stats you will soon see tables and bar charts with the information you have selected. The produced document can be saved as a pdf-file.

8.1. Support for clinics

Support team of SwissRDL (swissrdl@ispm.unibe.ch, +41 31 684 59 66) for:

- Notification of personnel mutations and new contact persons
- Support for user administration
- Support for data entry
- Requests for training

Technical support team (swissrdl_itsupport@ispm.unibe.ch, +41 31 684 31 18) for:

- Technical problems, accessibility of the registry
- Interfaces, Web Services
- Requests of technical nature