



mySmartBlood

CE IVD

INSTRUCTIONS FOR USE



Smart Blood Analytics Swiss SA
Address: Höschgasse 25, CH-8008 ZÜRICH,
Switzerland
Email: info@sba-swiss.com

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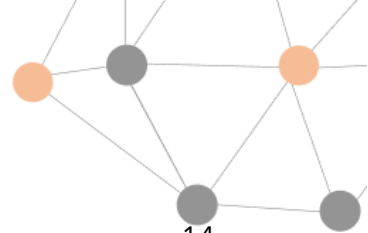


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1 INTRODUCTION

Smart Blood Analytics Swiss SA specializes in providing an artificial intelligence machine learning model that enables users to quickly and accurately gain information about most likely diseases, based solely on their blood test results.

The mySmartBlood artificial intelligence machine learning model is specifically developed for the following fields of internal medicine:

- Toxicology
- Endocrinology
- Gastroenterology
- Cardiology
- Hematology
- Nephrology
- Pulmonology
- Rheumatology

1.1 Purpose

The purpose of this document is to provide information for the users of the mySmartBlood mobile application, including general medical device information, instructions for use, warnings and other data.

1.2 Scope

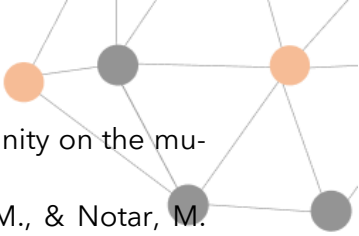
This document covers the mySmartBlood mobile application manufactured by Smart Blood Analytics Swiss SA.

1.3 Audience

This document is intended for users of the mySmartBlood mobile application.

1.4 References

- [1] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- [2] ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.
- [3] EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices.
- [4] ISO 14971:2019 Medical devices – Application of risk management to medical devices.
- [5] ISO 15223-1:2021 Medical devices – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
- [6] EC 62304:2006+AMD 1:2015 Medical device software – Software life cycle process – Amendment 1.
- [7] IEC 62366-1:2015+AMD 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices.
- [8] MEDICAL DEVICE SWISS-CC 812.21 Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

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- [9] Agreement between the Swiss Confederation and the European Community on the mutual recognition of conformity assessments – MRA 0.946.526.81.
- [10] Gunčar, G., Kukar, M., Notar, M., Brvar, M., Černelč, P., Notar, M., & Notar, M. (2018). An application of machine learning to haematological diagnosis. *Scientific reports*, 8(1), 1-12.
- [11] Podnar, S., Kukar, M., Gunčar, G., Notar, M., Gošnjak, N., & Notar, M. (2019). Diagnosing brain tumours by routine blood tests using machine learning. *Scientific reports*, 9(1), 1-7.
- [12] Kukar, M., Gunčar, G., Vovko, T., Podnar, S., Černelč, P., Brvar, M., ... & Notar, M. (2021). COVID-19 diagnosis by routine blood tests using machine learning. *Scientific reports*, 11(1), 1-9.










1.5 Abbreviations

| Acronym | Meaning |
|---------------|---|
| SBAS | Smart Blood Analytics Swiss SA |
| IVD | <i>In vitro</i> diagnostic |
| MBPL | Mandatory Blood Parameters List |
| IFU | Instructions For Use |
| APP | Application |
| ICD-10 | International Classification of Disease 10th Revision |
| UDI | Unique Device Identifier |
| UDI-DI | UDI device identifier |
| UDI-PI | UDI production identifier |

2 SYMBOLS

The different symbols used in this document are intended to warn and inform the user of certain risks and dangers that could occur when using mySmartBlood.

Please read the Instructions For Use carefully before using mySmartBlood.

| SYMBOL | DESCRIPTION |
|---|--|
|  | Basic symbol for danger |
|  | Important |
|  | CE marking of conformity |
|  | <i>In vitro</i> diagnostic medical device |
|  | Date of manufacture |
|  | Manufacturer |
|  | Consult Instructions for use |
|  | Unique Device Identifier |
|  | Authorized representative in the European Community/European Union |

3 GENERAL INFORMATION

Medical Device Name: **mySmartBlood**

Version: **2**

Basic UDI-DI: **7649996089007mySB2F**

3.1 Manufacturer



Smart Blood Analytics Swiss SA
Address: Höschgasse 25, CH-8008 ZÜRICH, Switzerland
Email: info@sba-swiss.com
SRN: CHF-MF-000024251



Authorised Representative:

Smart Blood Analytics d.o.o.
Address: Župančičeva ulica 18, 1000 Ljubljana, Slovenia
Email: info@sba-swiss.com
SRN: SI-AR-000024052

3.1.1 Medical Device Questions and Technical Support

For additional information, technical support or reporting of incidents pertaining to mySmartBlood, please contact us at support@mysmartblood.com.

Competent Authority for Switzerland:
Swissmedic
Address: Hallerstrasse 7, CH-3012 Bern, Switzerland
Phone: +41 58 462 02 11

Competent authority for EU:
Javna agencija RS za zdravila in medicinske pripomočke
Address: Slovenčeva ulica 22, 1000 Ljubljana, Slovenia
Phone: +386 (0)8 2000 500
Email: info@jazmp.si

Notice: Any serious incident that has occurred in relation to the mySmartBlood should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

3.2 Intended Purpose

The mySmartBlood application is an *in vitro* diagnostic medical device, intended to provide information to symptomatic users (lay persons) concerning medical conditions or groups of diseases and the respective physiological or pathological states thereof, using the user's results of *in vitro* blood examination, which has been performed in the external medical laboratory.

The application provides a list of potential groups of diseases. It is used as a mobile application for iOS and Android mobile devices.

It operates by using the SBAS Software machine learning model Internal medicine P54 trained on clinical cases.

3.2.1 Rationale and Further Explanation

Users must enter blood test results, which they obtained independently in external medical laboratory and must include the prescribed mandatory blood parameters, age and biological sex. The Mandatory Blood Parameters List (MBPL) ([Annex I](#)) was obtained experimentally with various parameter-importance analysis techniques and the general accessibility of the blood tests to the public.

The blood test results are entered into the mySmartBlood application, and the machine learning model interpretation is run.

The result of the analysis, presented in mySmartBlood report, shows a maximum of five of the most likely groups of diseases. The International Statistical Classification of Diseases and Related Health Problems (ICD) group codes are used and within each group, specific diseases and the parameters that contributed to the result are stated.



- **mySmartBlood is not a diagnostic medical device and does not present a final diagnosis. However, it provides a list of most likely groups of diseases.**
- **The user is not allowed and should not make any decisions based only on the results obtained by mySmartBlood and are not intended to be prompted or encouraged to draw any therapeutic conclusions, without consulting a physician.**
- **The information provided by mySmartBlood can never replace or overrule any medical advice, diagnosis or treatment.**
- **The final diagnosis shall always be determined by the responsible physician based on all available physical findings, the user's medical history, symptoms and results of other diagnostic tests.**
- **The interpretation provided by mySmartBlood is only an information of a general nature and to guide the user to consult the appropriate physician.**

3.3 Intended User Profiles

The mySmartBlood application is intended to be used by symptomatic adult users (older than 18 years old), both male and non-pregnant female.

3.4 Indications for Use

mySmartBlood is intended to be used for interpreting blood results of adult users (older than 18 years old), both female (non-pregnant) and male, with acute and/or chronic conditions in the following fields of internal medicine:

- Toxicology
- Endocrinology
- Gastroenterology
- Cardiology
- Hematology
- Nephrology
- Pulmonology
- Rheumatology
-

3.5 Contraindications for Use

mySmartBlood is contraindicated for use in:

- users below the age of 18,
- emergency situations in general, e.g.:
 - signs of a heart attack (severe/heavy/crushing chest pain...),
 - signs of a stroke (facial weakness, slurred speech, inability to hold both arms up...),
 - severe breathing problems,
 - any other untoward sign or symptom that may be of urgent nature or necessitate urgent or emergency care,
- Users who are pregnant.

3.6 Special Warnings and Precautions for Use



- **All groups of diseases generated by mySmartBlood can never replace any medical advice, diagnosis or treatment. You shall never disregard a physician's advice or cancel an appointment with a physician because you are relying only on information provided by mySmartBlood.**
- **In case of a medical emergency, a physician or the emergency services shall be contacted immediately.**
- **You assume full risk and responsibility for the use of information obtained from or through mySmartBlood.**
- **mySmartBlood was clinically evaluated on data of Caucasian adult patients. The performance of the mySmartBlood, when used in an unevaluated population, can be lower than specified.**
- **Certain kinds of medication therapy can affect mySmartBlood outputs. When consulting with a physician, please inform them regarding this.**
- **mySmartBlood can only be used if all parameters from the Mandatory Blood Parameter List are available and the input of the blood parameters and values are correct. The Mandatory Blood Parameter List is available in [Annex I](#).**
- **mySmartBlood can only predict the groups of diseases that are available in its database. All the available groups of diseases are listed in [Annex II](#).**
- **You should use mySmartBlood only if you are showing any kind of medical symptoms.**

- **mySmartBlood is not designed for screening purposes.**



Please note that obtaining the blood test results prescribed by the MBPL might be subject to additional costs by your healthcare provider or local laboratory. mySmartBlood interpretation is subject to payment of a one-time fee to the in amount of CHF 29 per individual report in accordance with our Pricing. Note that exact prices can vary depending on your location, currency, exchange rates or Promo code used.



You should carefully read and make sure you understand the Instructions For Use (this document). You should also be able to operate smart mobile devices. The mySmartBlood application may not function properly if not installed on the recommended mobile operating system defined in section 4.1 of the Instructions For Use.

3.7 Operation Principle

mySmartBlood is a mobile application based on the medical device SBAS Software intended for users (lay persons). It provides a user interface that allows users to input their blood test results and use the mySmartBlood model for determining the most likely groups of diseases based solely on the individual's blood test results.

The mySmartBlood model was developed using state-of-the-art supervised machine learning algorithms, leveraging a large, curated database of diagnosed patients from several fields of internal medicine. It uses a complex decision-making approach, which considers available parameters to suggest the most likely diseases. The model can detect even subtle correlated deviations in parameters that are significant for an accurate prediction. For the scientific description of our models see our peer-reviewed publications [10- 12].

The mySmartBlood model is locked and does not further learn or change its behavior after verification and validation. Further model improvements are handled as new releases of the product.

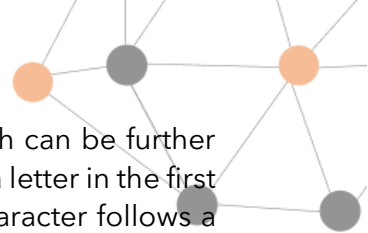
The mySmartBlood report consists of a maximum of five of the most likely groups of diseases. Within each group, the relevant diseases are listed, along with information about which parameters contributed the most towards predicting that specific group of diseases.

3.7.1 ICD-10 Classification

The groups of diseases or blocks predicted by the mySmartBlood are based on ICD-10 classification.

The purpose of the ICD is to permit systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas and at different times. The ICD is used to translate diagnoses of diseases and other health problems from words into an alphanumeric code, which permits easy storage, retrieval and analysis of the data. In practice, the ICD has become the international standard diagnostic classification for all general epidemiological and many health-management purposes. These include analysis of the general health situation of population groups and monitoring of the incidence and prevalence of diseases and other health problems in relation to other variables, such as the characteristics and circumstances of the individuals affected¹.

¹ https://icd.who.int/browse10/Content/statichtml/ICD10Volume2_en_2019.pdf



The basic ICD is a single coded list of three-character categories, each of which can be further divided into up to 10 four-character subcategories. An alphanumeric code uses a letter in the first position and a number in the second, third and fourth positions. The fourth character follows a decimal point. Possible code numbers therefore range from A00.0 to Z99.9.

The ICD classification is firstly divided into 22 chapters (for more details see Annex II). The first character of the ICD code is a letter, and each letter is associated with a particular chapter, except for the letter D, which is used in both Chapter II and Chapter III and the letter H, which is used in both Chapter VII and Chapter VIII. Four chapters (Chapters I, II, XIX and XX) use more than one letter in the first position of their codes. Each chapter contains sufficient three-character categories to cover its content. And these categories are our groups of diseases that are presented as a mySmartBlood result.

Since mySmartBlood predicts conditions in the field of internal medicine (Toxicology, Endocrinology, Gastroenterology, Cardiology, Hematology, Nephrology, Pulmonology, Rheumatology) specific classification chapters are not included, such as: VI Diseases of the nervous system, VII Diseases of the eye and adnexa, VIII Diseases of the ear and mastoid process, XV Pregnancy, childbirth and the puerperium, XVI Certain conditions originating in the perinatal period, XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified, XX External causes of morbidity and mortality, XXI Factors influencing health status and contact with health services, XXII Codes for special purposes.

All available groups of diseases are listed in [Annex II - GROUPS OF DISEASES](#).

3.7.2 Labelling

The label with the UDI marking is presented at the bottom of each generated mySmartBlood report. The UDI is a numerical code, which classifies the manufacturing unit of the device. The UDI-DI is the number of the manufacturer. The UDI-PI includes the date of manufacturing/date of release and software identification.

Additional labelling information is available in the application **Settings** under **Regulatory compliance**.

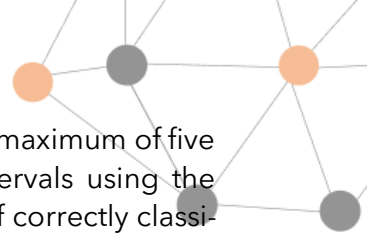
3.7.3 Identification of Life Expectancy

mySmartBlood is valid as long as the intended and specified mobile devices are used with the supported operating system. There are no other restrictions on life expectancy of the software. Only the valid version of the mySmartBlood application is available to the user.

3.8 Performance of the mySmartBlood Application

Performance of the medical device was evaluated on a test set consisting of 34152 cases from UMC Ljubljana, where the majority of the patients are Caucasian race. The patients were diagnosed by physicians with the help of blood test results as well as other diagnostical tools.

The test set was strictly reserved for performance evaluation purposes and has not been used for the development of the mySmartBlood model. The test cases were chosen randomly but stratified, meaning that the prevalence of the diseases within the test set is roughly the same as in the dataset used for the development of mySmartBlood model.

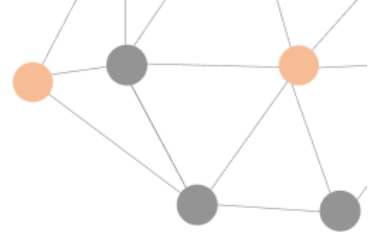


Performance evaluation results are characterized using diagnostic accuracy of a maximum of five of the most likely groups of diseases with the 95% binominal confidence intervals using the Agresti-Coull method. The accuracy is defined as a ratio between the number of correctly classified cases and the number of all cases in a test set. Correctly classified case is defined as a case for which a group of diseases that has been diagnosed by a physician is also present in the mySmartBlood report. In this way the accuracy represents how often the mySmartBlood report would indicate the correct group of diseases.

The accuracy can be formally written in a following way:

$$\text{Accuracy} = \frac{\text{number of correctly classified cases}}{\text{number of cases}}$$

The accuracy of the mySmartBlood medical device = 75 % ± 1 %



4 USER REQUIREMENTS

4.1 Digital Device

mySmartBlood can be used anytime and anywhere as long as it is used on a compatible, functioning mobile device with sufficient battery and with the proper Internet connection. Without the Internet connection you are not able to use mySmartBlood application.

The minimum system requirements for running the mySmartBlood mobile device application is either of:

- iOS operating system version iOS 13 or later
- Android operating system version Android 8 or later.

When an update of the mobile application is available, you will be notified via an in-app pop up. You must update the application in order to continue using it. It is recommended that you set your smartphone to update the app automatically, so that you always have the latest version. With each new release of mySmartBlood, the previous release becomes obsolete, and its records retention period begins.

You can update the mySmartBlood application in the App Store or on Google Play.



If mySmartBlood is not updated to the latest applicable version, you will not be able to use the mySmartBlood application.



SBAS performs proactive mySmartBlood IVD medical device monitoring. If you cannot find the application in the App Store or on Google Play, it has been preventively removed.

4.2 Data

To properly use mySmartBlood and get the report you will have to enter some of your personal information/data, such as name, email address, country of residence, date of birth (age), biological sex and 52 blood parameters that are measured at a local medical laboratory. We care about your privacy. All data you share is confidential. For more information, please refer to our Privacy Policy.

4.3 Requirements for Blood Testing

The blood tests, provided as an input to mySmartBlood, shall be measured by a medical laboratory, according to the regulatory requirements applicable for such laboratory. All mandatory blood parameters shall be measured ideally at the same time or a maximum of ten days apart.

5 HOW TO USE MYSMARTBLOOD

To use the mySmartBlood application as intended please follow the steps below:

1. Carefully read the Instructions For Use (this document).
2. Download the Mandatory Blood Parameters List.
3. Measure all the blood parameters from the Mandatory Blood Parameters List at your local medical laboratory/hospital/physician.
4. Enter and submit blood test results in the mySmartBlood application.
5. Make the payment for the mySmartBlood report.
6. Receive your mySmartBlood report including the list of most likely groups of diseases and explanations of parameters contributing to the results.
7. Consult with your physician.

5.1 Download the mySmartBlood Application

Download and install the mySmartBlood application from the App Store or Google Play. A suitable Internet connection is required to download mySmartBlood. Once the download is completed and the application is successfully installed, you can open the app.

5.2 Setting up Your Personal Account

When you open the mySmartBlood application for the first time, you will be presented with a walk-through as can be seen in Figure 1. Follow the steps to familiarize yourself with the application flow or skip to the registration form.

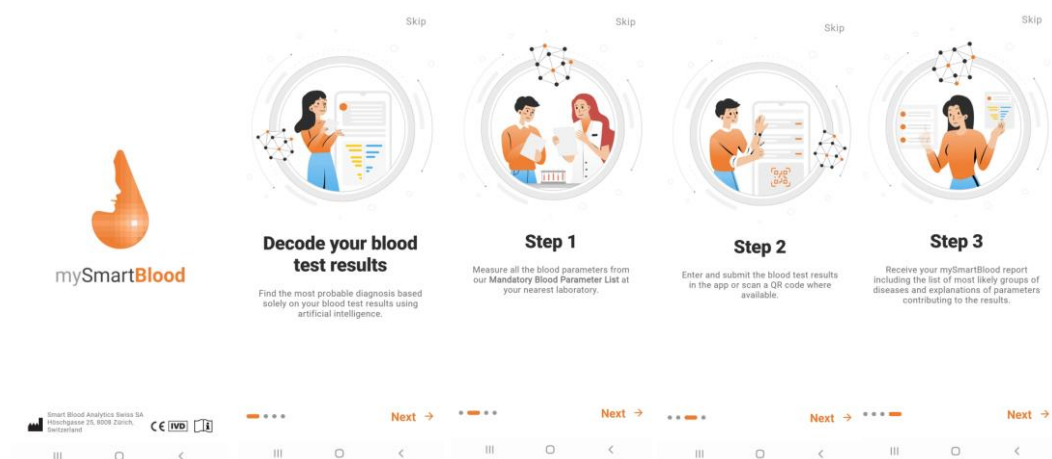


Figure 1: Walk-through for first-time users.

Sign into the app with your Apple, or Google account or with your email and create a new account. A confirmation email will be sent to the email provided and you can only proceed with using the app after the account has been confirmed (Figure 2). To successfully create your personal account, you must also enter your date of birth and biological sex. If necessary, you can always later change your account information in **Settings**. A password-reset option is also available if needed for users signing into app with email (not with Google or Apple account).

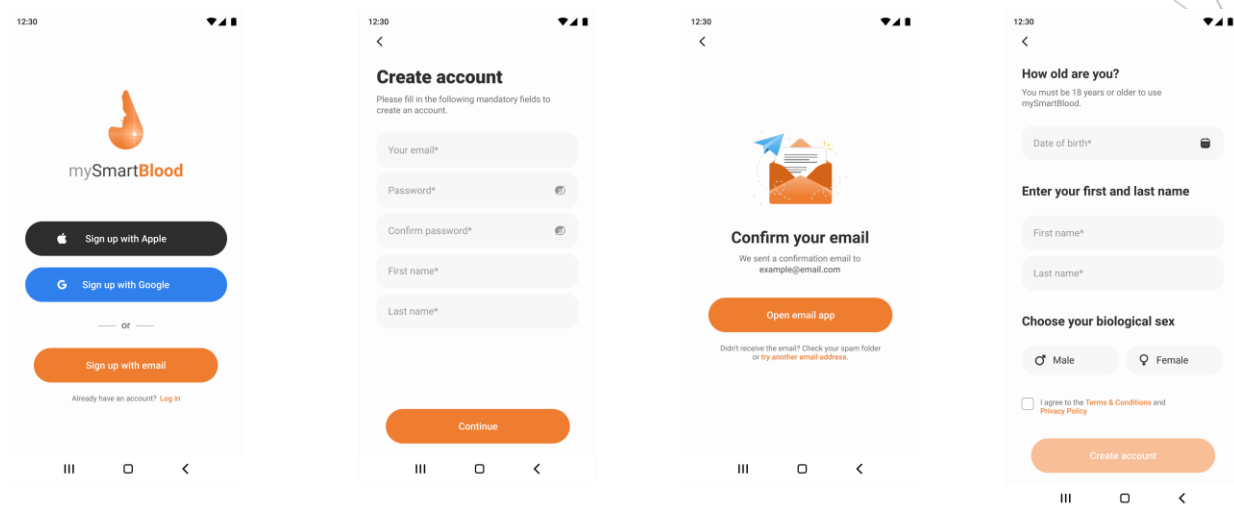


Figure 2: Steps to creating your personal account.



The mySmartBlood application is not intended for users under 18 years old and pregnant women.

5.3 Terms & Conditions, Privacy Policy

Upon the first login with the newly created account, you should read and agree to the “Terms & Conditions” and “Privacy Policy” before proceeding with the use of the mySmartBlood (Figure 2). If we update the “Terms & Conditions” and “Privacy Policy” will be updated, we will ask you to read and agree with them again.



After creating your personal account and before proceeding with use of mySmartBlood you will have to agree that you have been informed of and that you have read and understood the Instructions For Use and Disclaimer – Important information.

5.4 mySmartBlood Home Screen

The Home screen (Figure 3) is the main screen of the application from where you start entering your blood test results. From the Home screen you can access all previously generated mySmartBlood reports, your partially completed blood tests, the Mandatory Blood Parameters List and Instructions For Use.

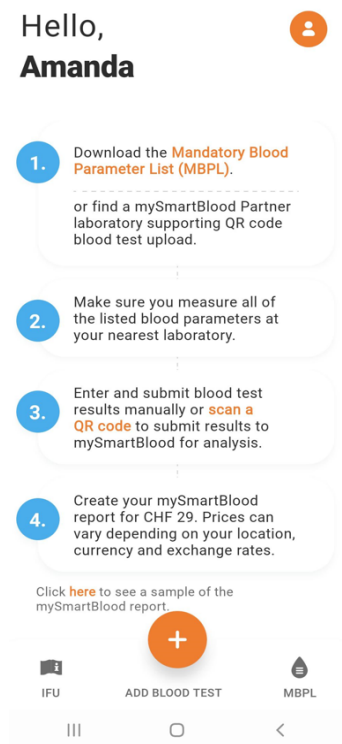


Figure 3a: Home screen - when no blood tests are entered and/or reports generated

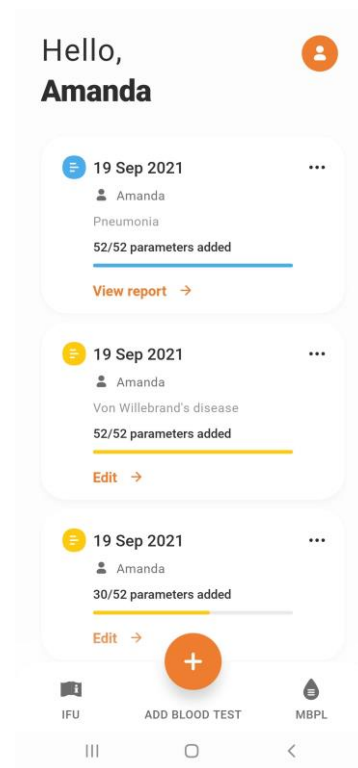


Figure 3b: Home screen - when blood tests are entered and/or reports generated

5.4.1 mySmartBlood Settings

To access **Settings**, you can tap the orange icon on the top right of the Home screen. Settings contains the following information:

- **Personal Information:** You can update your personal information after you have set up your account.
- **Change Password:** You can change your password anytime you want. However, this feature is only available to users that sign into app with their email (not with a Google or Apple account).
- **Language:** You can change language of the mySmartBlood application.
- **Pricing & Report sample:** You can see the price for generating a mySmartBlood report and see a sample of a mySmartblood report.
- **Mandatory Blood Parameter List:** You can view and share which blood parameters are mandatory to measure.
- **mySmartBlood Partner Laboratories:** Here you can view the list of medical laboratories which support QR code blood test upload. The name and the address of the laboratories are listed.
- **Help Desk & Feedback:** You can view how to contact the mySmartBlood help center and how to communicate your feedback to us.
- **Instructions For Use:** You can refer to the Instructions For Use (this document) whenever you need to.
- **Disclaimer:** This is the Disclaimer that you accepted prior to your first use of the mySmartBlood application.

- **Terms & Conditions:** These are the Terms & Conditions that you accepted prior to your first use of the mySmartBlood application.
- **Privacy Policy:** This is the Privacy Policy that you accepted prior to your first use of the mySmartBlood application.
- **Notification preferences:** You can disable push notifications.
- **Regulatory Compliance:** This lists our certificates and view how we comply with the applicable regulatory requirements.
- **Delete Account:** You can delete your account and all your personal data at any time.
- **Log Out:** You can log out from the application.

5.4.2 Logging In and Out

To log in to mySmartBlood, enter your registered username and password or use your Google or Apple account.

To log out from the application, go to **Settings** and select **Log out**. The application will automatically log you out after 1 month.

5.4.3 Delete mySmartBlood Account

Your account - and all your personal data - can always be deleted. Please contact our support group at support@mysmartblood.com to delete your personal mySmartBlood account.

5.5 Add New Blood Test

Once you login, you are taken to the home screen of mySmartBlood (Figure 3). Tap **Add Blood Test** and the How would you like to enter your blood parameters? screen is displayed (Figure 4). You can either enter the blood parameters manually or scan a QR code to upload blood parameters.

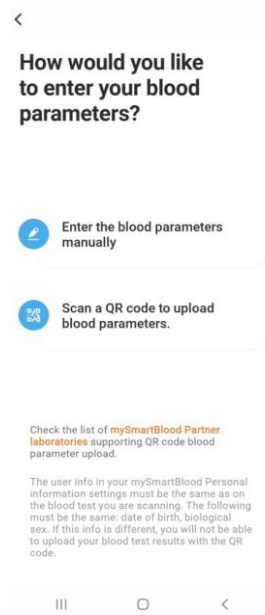


Figure 4: Two options of entering your blood parameters.

5.5.1 Enter the blood parameters manually

Tap **Enter the blood parameters manually** and follow the instructions (Figure 5). You have to enter all of the 52 parameters from the Mandatory Blood Parameters List that were obtained from the local medical laboratory and select their units manually. Please pay particular attention that the entered values are correct.

Figure 5: Manually adding a new blood test.



The measured blood parameters shall be in SI (International System of Units) or CONV (Conventional) units. If not, please perform the appropriate conversion.

If you are interrupted while entering the blood parameters, the measurements will be automatically stored in the mySmartBlood application, and you can continue later. You can also correct or delete the entered parameter values. Once the report is generated this is no longer possible.



If the entered blood parameter value deviates too much from the Informative reference range mySmartBlood will ask you to additionally confirm the entered value.



The final mySmartBlood report can be generated only if all blood parameters from the Mandatory Blood Parameters List are entered.

After successfully submitting all 52 blood parameters, tap **Create report** to submit the results for analysis.

5.5.2 Scan QR code to upload blood parameters

Tap **Scan a QR code to upload blood parameters** and follow the instructions (Figure 6). The QR code is available on your blood test report that was obtained independently in one of the mySmartBlood Partner Laboratories. The list of all mySmartBlood Partner Laboratories that support QR code blood parameter upload is available under Settings.

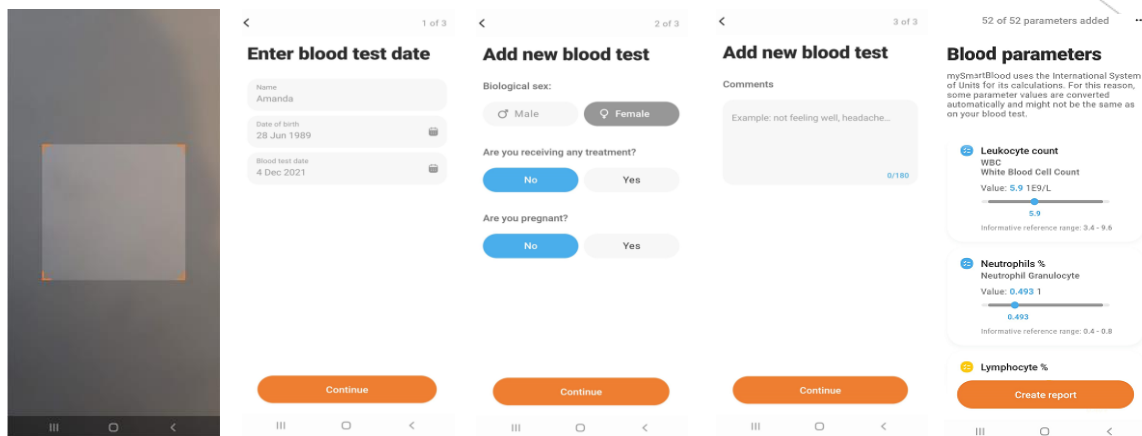


Figure 6: Upload blood parameters with QR code.



The user information in the mySmartBlood Personal information settings must be the same as on the blood test you are scanning. Specifically, the date of birth and biological sex must be the same. If this information is different, you will not be able to upload the blood test using the QR code (Figure 7).

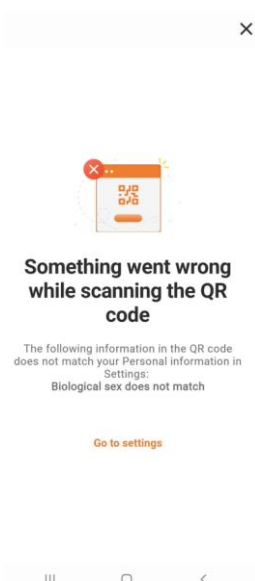


Figure 7: Something went wrong while scanning QR code.

Once the blood parameters are uploaded you are not able to manually change values or units of blood parameters.



mySmartBlood uses the International System of Units for its calculation. For this reason, some parameter values are converted automatically and might not be the same as on your blood test.

After you have successfully uploaded blood parameters by scanning a QR code, tap **Create report** to submit the results for analysis.

Each blood parameter can have several synonyms (e.g. Creatine Kinase = CK = Phosphocreatine kinase = Creatine phosphokinase = CPK). Alternate names are available in the Mandatory Blood Parameters List ([Annex I](#)).

For each blood parameter the Informative reference range is shown. Informative reference ranges for blood tests are sets of values used by health professional to interpret a set of medical test results from blood samples. Informative reference ranges of medical laboratory tests are frequently established using distribution-based (e.g. normal or log normal) 95% confidence intervals of healthy subjects' laboratory test results. The reference ranges play an important role in clinical practice in screening for diseases, assessing disease progression and treatment response².



Please note that different medical laboratories can have different Informative reference ranges and that reference ranges are highly dependent on age and biological sex.

If your entered blood parameter is out of bounds of the Informative reference range, it will be marked in yellow, and if it is within range, will be marked in blue.



All mandatory blood parameters shall be measured ideally at the same time or a maximum of ten days apart.

5.6 mySmartBlood Report

Once payment is successful, you will receive your mySmartBlood report (Figure 8). The report includes a maximum of five of the most likely groups of diseases, the most relevant diseases within each predicted group of diseases, the parameter contributions for each group of diseases and the field of medicine for each group of diseases. The report also includes your submitted blood parameters and your personal information.

² Source: Lim E, Miyamura J, Chen JJ. Racial/Ethnic-Specific Reference Intervals for Common Laboratory Tests: A Comparison among Asians, Blacks, Hispanics, and White. *Hawaii J Med Public Health*. 2015 Sep;74(9):302-10. PMID: 26468426; PMCID: PMC4578165.

Figure 8a:

On the first page of the report (Figure 8a), you see the list of the maximum of five of the most likely groups of diseases that mySmartBlood predicts based on your blood test results. The likelihood is also represented graphically with the segmented circle.



Please note: these are not percentages, however, it represents the number of people with similar blood test results that were diagnosed with one of the diseases from this group.

All available groups of diseases are listed in Annex II - GROUPS OF DISEASES.

If you tap **Show details**, mySmartBlood gives you more information (Figure 8b).

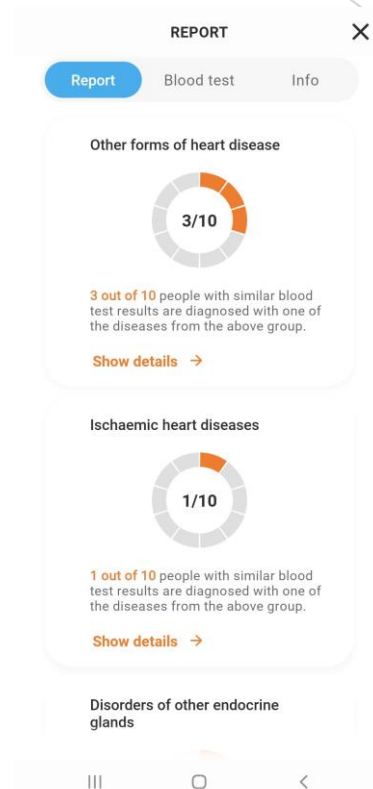


Figure 8a: mySmartBlood report showing the list of the most likely groups of diseases.

Figure 8b:

Within each group of diseases specific relevant diseases with ICD codes are indicated (Figure 8b).

The parameter contribution explains which parameters contributed the most to this mySmartBlood decision. The parameters in blue are those that are most in favour of the decision, while those in yellow are most opposed to this decision.

For a better understanding, the group of diseases is also classified in terms of the applicable field of medicine. This is meant to help you select the right physicians.

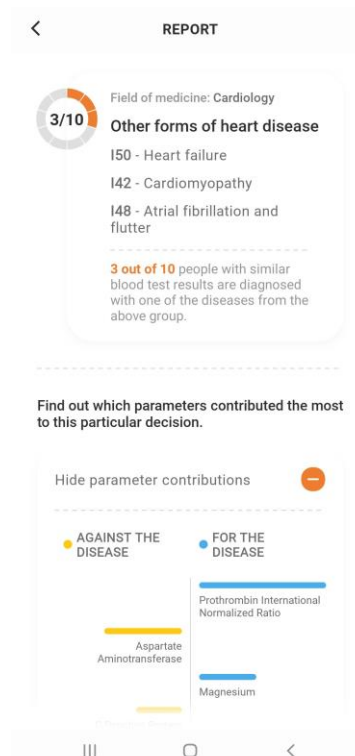


Figure 8b: mySmartBlood report showing detailed information within each group of diseases.

Figure 8c:

The submitted blood parameters are also shown on the report (Figure 8c). You can always review them. However, once the report is generated you cannot change them.

If you notice a mistake, please go back to the Home screen (Figure 3), duplicate the manually entered blood test and then you will be able to edit the blood parameters. If you have a QR code please scan it again to upload blood parameters.

Please note that you will have to pay to generate new report with corrected blood parameters, so please confirm that you have entered the correct values.

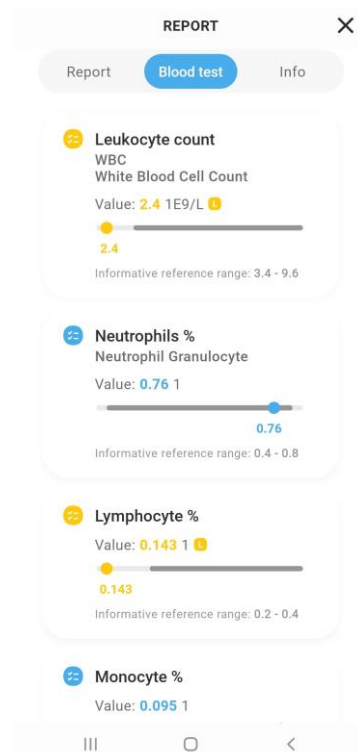


Figure 8c: Submitted Blood parameters in mySmartBlood report.

Figure 8d:

On the report you can also review your entered personal information, such as (Figure 8d):

- Name
- Birth Date
- Blood Test Date
- Biological sex
- Receiving treatment
- Pregnant
- Additional information

The screenshot displays the 'REPORT' screen with tabs for 'Report', 'Blood test', and 'Info'. The 'Info' tab is active. It shows the following personal information:

- Name: Amanda
- Birth year: 15. Jan 1989
- Blood test date: 11. apr 2021
- Biological sex: Female
- Receiving treatment: No
- Pregnant: No
- Additional information: -

Figure 8d: Personal information shown on mySmartBlood report

If you tap the **Share** button you will generate and share the mySmartBlood report as a PDF file (Figure 9).

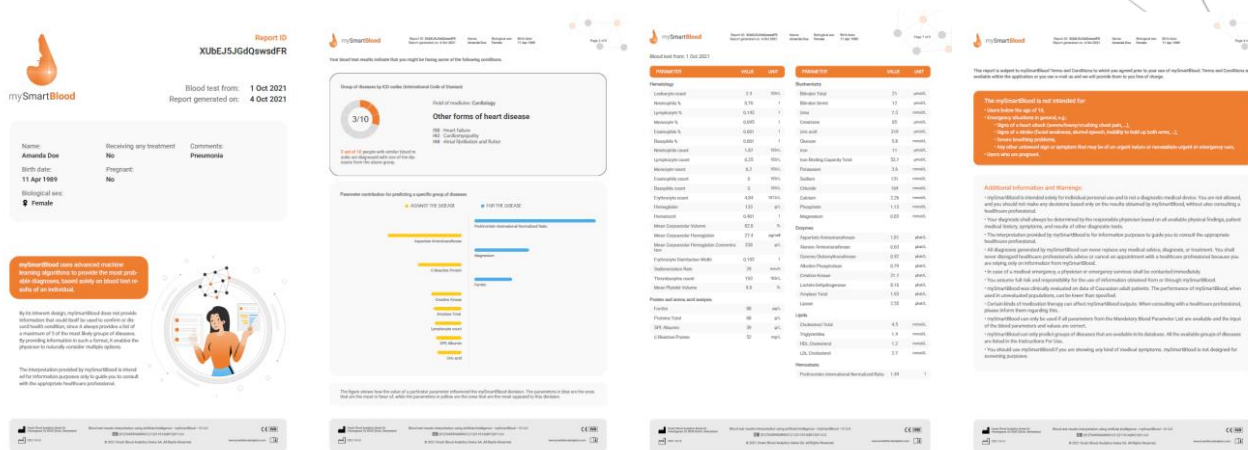


Figure 9: Final pdf mySmartBlood report.

- **The mySmartBlood interpretation is not a final diagnosis and should not replace and/or overrule professional medical advice.**
- **A complete diagnosis cannot be made based on the mySmartBlood report alone.**
- **Please consult your physician before making any medical decision.**
- **Although the mySmartBlood can be an invaluable tool to enhance the diagnostic process, there is a substantial risk that in some situations mySmartBlood could fail to provide useful information to the user and their physician to identify the right diagnoses.**



5.7 Delete the mySmartBlood Application

You can always delete the mySmartBlood application through the settings of your mobile device.

- iOS device: Tap and hold the mySmartBlood application icon until it jiggles. Tap the "X" in the upper-left corner of the app, then tap "Delete" in the dialog box that appears.
- Android device: Open your device's Settings app. Go to Apps & notifications. Tap on the mySmartBlood application, then select 'Uninstall'.

6 CYBERSECURITY

We, at Smart Blood Analytics Swiss SA, maintain a high security and data privacy level in our mySmartBlood application. The application is monitored for security events and data breaches. If a security event or data breach should occur, the issue will be contained and resolved with urgency according to our established processes and you as a user will receive the information you need regarding your continued safe and secure use of the application. A continuous backup system is used to make sure all data is secure. Upon written request, we can provide you with a list of people in our team that may have access to your Personal Data. These people have entered into confidentiality agreements prior to having been granted access to your Personal Data.

It is strongly recommended that you choose a strong password to protect your account from unauthorized use and to make sure that your smartphone is up to level with the right security features. While not recommended, if you should choose to share your login with somebody, you do so at your own risk. Keep in mind that you can always revoke access by changing the password to your account and contacting support in order to close existing sessions.

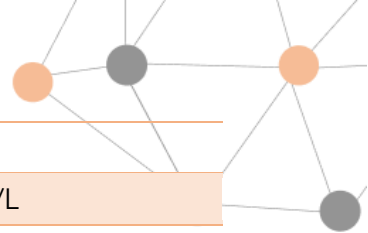
mySmartBlood does its utmost to guarantee your data safety. It is very important for you as a user to keep in mind the following recommendations:

- do not share your credentials,
- use a secured Internet connection,
- only use compatible devices,
- do not use rooted or jailbroken devices,
- do not use emulators.

7 ANNEX I - MANDATORY BLOOD PARAMETERS LIST

The mySmartBlood can only be used if all 52 blood test parameters from the following Mandatory blood parameter list are available:

| Blood parameters | Units (SI) | Units (CONV) |
|---|-------------|--------------|
| Leukocyte count; WBC; White Blood Cell Count | 1E9/L | 1E3/ μ L |
| Neutrophils %; Neutrophil Granulocyte | 1 | % |
| Lymphocyte % | 1 | % |
| Monocyte % | 1 | % |
| Eosinophils %; Eosinophils/100 leukocytes in Blood; Eosinophil Granulocyte | 1 | % |
| Basophils %; Basophils/100 leukocytes in Blood; Basophil Granulocyte | 1 | % |
| Neutrophils count; Neutrophil Granulocyte | 1E9/L | 1E3/ μ L |
| Lymphocyte count | 1E9/L | 1E3/ μ L |
| Monocyte count | 1E9/L | 1E3/ μ L |
| Eosinophils count; Eosinophil Granulocyte | 1E9/L | 1E3/ μ L |
| Basophils count; Basophil Granulocyte | 1E9/L | 1E3/ μ L |
| Erythrocyte count; RBC; Red Blood Cells | 1E12/L | 1E6/ μ L |
| Hemoglobin; Hb; Hgb | g/L | g/dL |
| Hematocrit; Hct | 1 | % |
| Mean Corpuscular Volume; MCV | fL | fL |
| Mean Corpuscular Hemoglobin; MCH | pg/cell | pg/cell |
| Mean Corpuscular Hemoglobin Concentration; MCHC | g/L | g/dL |
| Erythrocyte Distribution Width; RDW; Red Cell Distribution Width | 1 | % |
| Sedimentation Rate; SR; Erythrocyte sedimentation rate; ESR | mm/h | mm/h |
| Thrombocytes count; Platelet count | 1E9/L | 1E3/ μ L |
| Mean Platelet Volume; MPV | fL | fL |
| Aspartate Aminotransferase; AST; GOT; Aspartate transaminase; Glutamic oxaloacetic transaminase | μ kat/L | U/L |
| Alanine Aminotransferase; ALT; GPT; Glutamic-pyruvic transferase; Alanine transaminase | μ kat/L | U/L |
| Gamma-Glutamyltransferase; GGT | μ kat/L | U/L |
| Alkaline Phosphatase; AP; ALP | μ kat/L | U/L |
| Creatine Kinase; CK; Phosphocreatine kinase; Creatine phosphokinase; CPK | μ kat/L | U/L |
| Lactate Dehydrogenase; LD; LDH | μ kat/L | U/L |
| Amylase Total; Alpha amylase; | μ kat/L | U/L |

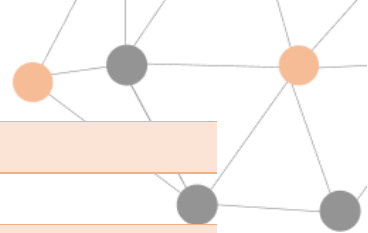


| | | |
|---|--------|--------|
| Lipase | μkat/L | U/L |
| Bilirubin Total | μmol/L | mg/dL |
| Bilirubin Direct | μmol/L | mg/dL |
| Urea | mmol/L | mg/dL |
| Creatinine | μmol/L | mg/dL |
| Uric acid | μmol/L | mg/dL |
| Glucose | mmol/L | mg/dL |
| Iron; Fe | μmol/L | μg/dL |
| Iron-Binding Capacity Total | μmol/L | μg/dL |
| Potassium; K; Potassium in serum | mmol/L | mEq/L |
| Sodium; Na; Sodium in serum | mmol/L | mEq/L |
| Chloride; Cl | mmol/L | mEq/L |
| Calcium; Ca | mmol/L | mg/dL |
| Phosphate; Inorganic Phosphorus; PO ₄ ; Phosphorus | mmol/L | mg/dL |
| Magnesium; Mg | mmol/L | mg/dL |
| Cholesterol Total | mmol/L | mg/dL |
| Triglycerides | mmol/L | mg/dL |
| HDL Cholesterol | mmol/L | mg/dL |
| LDL Cholesterol | mmol/L | mg/dL |
| Ferritin | μg/L | ng/mL |
| Proteins Total | g/L | g/dL |
| SPE Albumin | g/L | g/dL |
| C-Reactive Protein; CRP | mg/L | mg/dL |
| Prothrombin International Normalized Ratio; INR | 1E9/L | 1E3/μL |

8 ANNEX II - GROUPS OF DISEASES

mySmartBlood can only predict the groups of diseases that are available in its database. All the available groups of diseases are listed in below table:

| ICD | GROUPS OF DISEASES |
|------------|--|
| I | Certain infectious and parasitic diseases |
| A00-A09 | Intestinal infectious diseases |
| A15-A19 | Tuberculosis |
| A50-A64 | Infections with a predominantly sexual mode of transmission |
| B15-B19 | Viral hepatitis |
| B35-B49 | Mycoses |
| B50-B64 | Protozoal diseases |
| B65-B83 | Helminthiases |
| B90-B94 | Sequelae of infectious and parasitic diseases |
| II | Neoplasms |
| C15-C26 | Malignant neoplasms of digestive organs |
| C30-C39 | Malignant neoplasms of respiratory and intrathoracic organs |
| C45-C49 | Malignant neoplasms of mesothelial and soft tissue |
| C60-C63 | Malignant neoplasms of male genital organs |
| C64-C68 | Malignant neoplasms of urinary tract |
| C73-C75 | Malignant neoplasms of thyroid and other endocrine glands |
| C76-C80 | Malignant neoplasms of ill-defined, secondary and unspecified sites |
| C81-C96 | Malignant neoplasms of lymphoid, haematopoietic and related tissue |
| D10-D36 | Benign neoplasms |
| D37-D48 | Neoplasms of uncertain or unknown behaviour |
| III | Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism |
| D50-D53 | Nutritional anaemias |
| D55-D59 | Haemolytic anaemias |
| D60-D64 | Aplastic and other anaemias |
| D65-D69 | Coagulation defects, purpura and other haemorrhagic conditions |
| D70-D77 | Other diseases of blood and blood-forming organs |
| D80-D89 | Certain disorders involving the immune mechanism |
| IV | Endocrine, nutritional and metabolic diseases |
| E00-E07 | Disorders of thyroid gland |
| E09-E14 | Impaired glucose regulation and diabetes mellitus |
| E15-E16 | Other disorders of glucose regulation and pancreatic internal secretion |



| | |
|---------|-------------------------------------|
| E20-E35 | Disorders of other endocrine glands |
|---------|-------------------------------------|

| | |
|---------|--------------|
| E40-E46 | Malnutrition |
|---------|--------------|

| | |
|---------|--------------------------------|
| E50-E64 | Other nutritional deficiencies |
|---------|--------------------------------|

| | |
|---------|-------------------------------------|
| E65-E68 | Obesity and other hyperalimentation |
|---------|-------------------------------------|

| | |
|---------|---------------------|
| E70-E89 | Metabolic disorders |
|---------|---------------------|

| | |
|----------|---|
| V | Mental and behavioural disorders |
|----------|---|

| | |
|---------|--|
| F60-F69 | Disorders of adult personality and behaviour |
|---------|--|

| | |
|-----------|---|
| IX | Diseases of the circulatory system |
|-----------|---|

| | |
|---------|-----------------------|
| I00-I02 | Acute rheumatic fever |
|---------|-----------------------|

| | |
|---------|----------------------------------|
| I05-I09 | Chronic rheumatic heart diseases |
|---------|----------------------------------|

| | |
|---------|-----------------------|
| I10-I15 | Hypertensive diseases |
|---------|-----------------------|

| | |
|---------|--------------------------|
| I20-I25 | Ischaemic heart diseases |
|---------|--------------------------|

| | |
|---------|---|
| I26-I28 | Pulmonary heart disease and diseases of pulmonary circulation |
|---------|---|

| | |
|---------|------------------------------|
| I30-I52 | Other forms of heart disease |
|---------|------------------------------|

| | |
|---------|--------------------------|
| I60-I69 | Cerebrovascular diseases |
|---------|--------------------------|

| | |
|---------|--|
| I70-I79 | Diseases of arteries, arterioles and capillaries |
|---------|--|

| | |
|---------|--|
| I80-I89 | Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified |
|---------|--|

| | |
|---------|---|
| I95-I99 | Other and unspecified disorders of the circulatory system |
|---------|---|

| | |
|----------|---|
| X | Diseases of the respiratory system |
|----------|---|

| | |
|---------|------------------------------------|
| J00-J06 | Acute upper respiratory infections |
|---------|------------------------------------|

| | |
|---------|-------------------------|
| J09-J18 | Influenza and pneumonia |
|---------|-------------------------|

| | |
|---------|--|
| J20-J22 | Other acute lower respiratory infections |
|---------|--|

| | |
|---------|---|
| J30-J39 | Other diseases of upper respiratory tract |
|---------|---|

| | |
|---------|------------------------------------|
| J40-J47 | Chronic lower respiratory diseases |
|---------|------------------------------------|

| | |
|---------|--------------------------------------|
| J60-J70 | Lung diseases due to external agents |
|---------|--------------------------------------|

| | |
|---------|---|
| J80-J84 | Other respiratory diseases principally affecting the interstitium |
|---------|---|

| | |
|---------|--|
| J85-J86 | Suppurative and necrotic conditions of lower respiratory tract |
|---------|--|

| | |
|---------|--------------------------|
| J90-J94 | Other diseases of pleura |
|---------|--------------------------|

| | |
|---------|--|
| J95-J99 | Other diseases of the respiratory system |
|---------|--|

| | |
|-----------|---|
| XI | Diseases of the digestive system |
|-----------|---|

| | |
|---------|---|
| K00-K14 | Diseases of oral cavity, salivary glands and jaws |
|---------|---|

| | |
|---------|--|
| K20-K31 | Diseases of oesophagus, stomach and duodenum |
|---------|--|

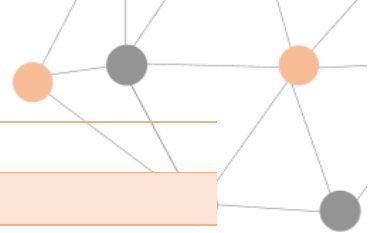
| | |
|---------|----------------------|
| K35-K38 | Diseases of appendix |
|---------|----------------------|

| | |
|---------|--------|
| K40-K46 | Hernia |
|---------|--------|

| | |
|---------|------------------------------------|
| K50-K52 | Noninfective enteritis and colitis |
|---------|------------------------------------|

| | |
|---------|------------------------------|
| K55-K63 | Other diseases of intestines |
|---------|------------------------------|

| | |
|---------|------------------------|
| K65-K67 | Diseases of peritoneum |
|---------|------------------------|



| | |
|-------------|---|
| K70-K77 | Diseases of liver |
| K80-K87 | Disorders of gallbladder, biliary tract and pancreas |
| K90-K93 | Other diseases of the digestive system |
| XII | Diseases of the skin and subcutaneous tissue |
| L80-L99 | Other disorders of the skin and subcutaneous tissue |
| XIII | Diseases of the musculoskeletal system and connective tissue |
| M00-M03 | Infectious arthropathies |
| M05-M14 | Inflammatory polyarthropathies |
| M15-M19 | Arthrosis |
| M20-M25 | Other joint disorders |
| M30-M36 | Systemic connective tissue disorders |
| M40-M43 | Deforming dorsopathies |
| M45-M49 | Spondylopathies |
| M50-M54 | Other dorsopathies |
| M60-M63 | Disorders of muscles |
| M65-M68 | Disorders of synovium and tendon |
| M70-M79 | Other soft tissue disorders |
| M80-M85 | Disorders of bone density and structure |
| M86-M90 | Other osteopathies |
| M91-M94 | Chondropathies |
| XIV | Diseases of the genitourinary system |
| N00-N08 | Glomerular diseases |
| N10-N16 | Renal tubulo-interstitial diseases |
| N17-N19 | Kidney failure |
| N20-N23 | Urolithiasis |
| N25-N29 | Other disorders of kidney and ureter |
| N30-N39 | Other diseases of urinary system |
| N40-N51 | Diseases of male genital organs |
| N60-N64 | Disorders of breast |
| N80-N98 | Noninflammatory disorders of female genital tract |
| XVII | Congenital malformations, deformations and chromosomal abnormalities |
| Q60-Q64 | Congenital malformations of the urinary system |
| XIX | Injury, poisoning and certain other consequences of external causes |
| T36-T50 | Poisoning by drugs, medicaments and biological substances |
| T51-T65 | Toxic effects of substances chiefly nonmedicinal as to source |