

Product: ZAF 552

Zafena workstation

User manual



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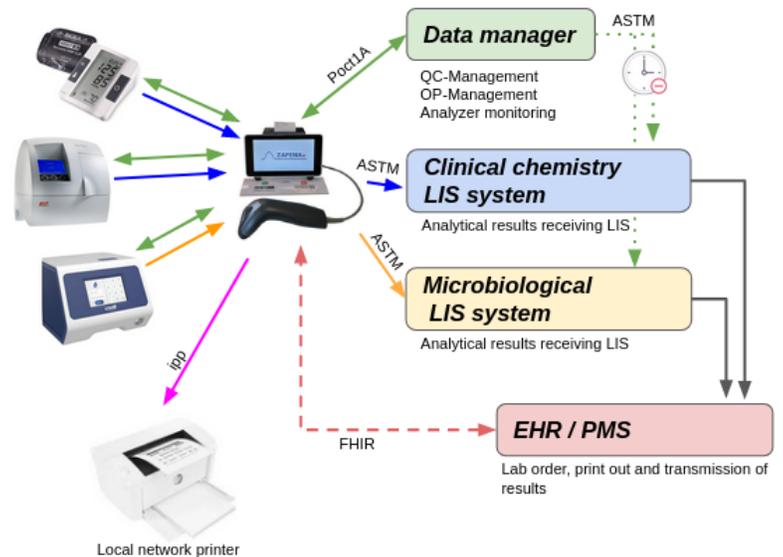
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Information

General connection point

The workstation from Zafena functions as a general connection point for analysis equipment, connected to one or more receiving systems, according to established communication protocols for healthcare. Each workstation from Zafena becomes a point where analytical equipment can be connected and download its measurement results, which are then forwarded to suitable and pre-configured receiving systems. All connected gauges and instruments work separately and can be used simultaneously through the workstation.



Modular instrument

For analysis equipment that does not meet the market's increased demands for IT functionality, the workstation from Zafena becomes an addition to the equipment, which gives the equipment all the most modern functionality it needs to meet today's and future IT and communication requirements.

For more modern analysis equipment that only handles one protocol for communication, the workstation acts as a translator to other protocols that fit better in the receiving IT environment. Each connected meter is marked with an identifying barcode that identifies the meter type and meter individual. We are talking about a modular instrument that contains parts/modules:



1. **Analysmodul**
Everything from a thermometer to a multi-parameter hematology instrument. Each connected analysis module is labeled with an identifying barcode.
2. **IT module**
The workstation provides extended IT functionality.
3. **Barcode scanner**
Connected to the workstation to provide a better workflow when entering patient data and scanning analysis modules.

Any analytical equipment and Medtech that digitally provides results via USB, Ethernet, Wifi, Bluetooth or Serial can function as an analysis module. The workstation receives information about which analysis module, type and/or individual, and which data support is desired, by reading a barcode attached to the analysis module. The workstation provides information on which supplementary information (patient ID, sample type, operator ID, etc.) is needed. After the operator has approved the analysis, the result is automatically packaged together with supplemented information and sent via network to one or more receiving systems within healthcare. The workstation locally logs all information received and sent as well as information about the status of the transmission.

Location

The laboratory

The workflow is one of the important parts of a laboratory. Like a well-oiled clockwork, samples flow in and analysis results flow out of the business. The value of digitizing these analysis results is described by Equalis (Swedish

EQA; <https://www.equalis.se/en/>): *"Eliminate misspellings and secure analysis results"*

Typically occurring; CRP, INR, ESR, Hb, glucose, urine dipstick, HbA1C, Hematology



The doctor's office

When it is the personal contact with the patient that is at the center of the visit, the doctor is relieved by digitizing the measurement results directly into the EHR/LIS. Instead of devoting appointment time to writing down or memorizing analysis results, doctors and patients can devote appointment time to essentials to a greater extent.

Typically occurring analytes; blood pressure, height, weight, temperature, pulse, oxygenation, spirometry.....



The ambulance

In this environment, time is of the essence. Digitizing emergency analysis results in real time and communicating these with the hospital's specialists can improve ambulatory emergency care.

Typically occurring analytes; blood pressure, temperature, CRP, D-dimer, pulse, oxygenation, ECG



Installation

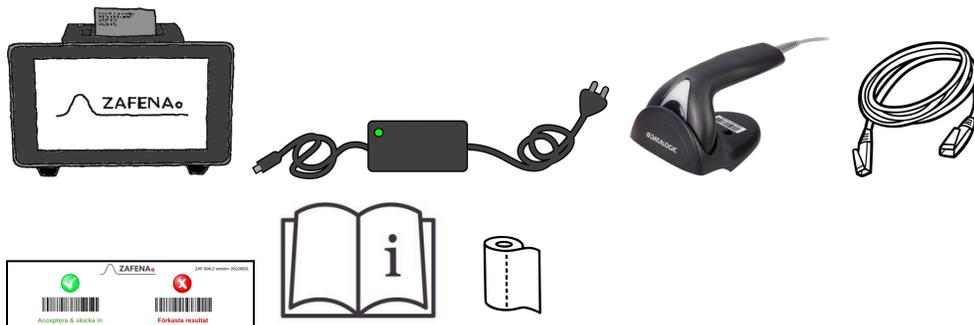
Verify

- That there is **space** for the installation of the workstation.
For installation on a table: 25 x 25 centimeters.
For installation on the wall: 20 x 12 centimeters.
- That there is one **220V electrical outlet** near the installation site. Max 2 meters from the workstation
- That there is access to **network** via RJ45 connection in the wall with cable and/or wireless connection via wifi. It is of course possible to procure a longer network cable yourself for larger ones flexibility.
If all network sockets are occupied, a network switch can be purchased to increase the number of network sockets.

Unpack

The product packaging includes the following parts:

1. Zafena Workstation [ZAF 502]
2. Power cord and power adapter [ZAF 130-12]
3. Barcode Scanner [ZAF 504]
4. Wall holder for barcode scanner [ZAF 504-1]
5. Network cable [ZAF 509]
6. Approve / Reject barcodes
7. Instruction (Link to user manual)
8. A roll of printer paper



Install

Standalone

The workstation works without being connected to the internet or to any receiver of digital measurement results. After the measurement, a receipt is printed with patient information, date and time and analysis results. The workstation's internal memory saves the last 30,000 measurements and then serves as a log of measurements for the small clinic, the mobile team or the doctor's office.

- A.** Place the workstation near the equipment to be digitized and logged.
- B.** Plug the power cord into a 220V power outlet and the other end into the power adapter, then the power adapter cable into the workstation's electrical outlet.
- C.** Connect the barcode reader to one of the workstation's four USB ports.
- D.** Connect gauges, sensors and instruments according to separate specific instructions.

Networked

In order to use the workstation's full potential, it should be connected to a network which in turn has a connection to the Internet. Connect, and it can also:

- Send the system log to Zafena for support. *(Only at the request of the operator)*
- Update online. *(Only at the request of the operator)*
- Setting the clock and date. *(Automagic)*
- Receive and print work orders. *(Depending on the receiving system)*
- Forward pdf printouts to local printers. *(ipp bridge for cloud-based systems)*
- General connection point for digitization of analysis results.

- A.** Place the workstation near the equipment to be digitized and connected.
- B.** Plug the power cord into an electrical outlet and the other end into the power adapter, then the power adapter cable into the workstation power outlet.
- C.** Connect the barcode reader to one of the workstation's four USB ports.



- D.** Connect gauges, sensors and instruments according to separate specific instructions. *(contact Zafena for instrument-specific instructions)*

- E. Connect the network cable to the workstation's network port and the other end to an active network socket with a connection to the Internet.

Connection

There are closed and open networks. Open networks allow anyone who can connect to connect, as well as have free access to the Internet. Locked networks restrict connection via MAC address, as well as have strict rules for accessing the Internet. Generally for networks are:

- **DHCP**
The workstation sends its unique MAC address to the network's DHCP server which then, if communication is allowed, informs the workstation which IP address, netmask, DNS server, Gateway and Host name should be used.
- **DNS**
The DNS server translates IP address to network name or vice versa.
The name or IP address of the LIS/HIS server is needed for the workstation to be able to find the server on the network. The DNS server acts as the network's telephone directory.
- **NTP**
The workstation synchronizes its internal clock to any "Network TimeProtocol" -server, "time server".
- **Analysis data**
The workstation sends packaged information with analysis results and supplementary information to the LIS/HIS/DM server with communication according to standardized protocols such as "ASTM LIS02-A2", "POCT1A", "HL7", "xml" or "FHIR". the workstation is informed whether the transfer was successful or not. If not, the workstation allows retries of transmission.
- **Ipp**
The workstation can function as print bridge for cloud-based systems, which can send printouts as pdf to the workstation which are then printed to local printers via the ipp protocol.
- **Receiving system**
By "receiving system", is meant all the systems that can receive analysis results. For example; Laboratory Information System - LIS, Data Manager - DM, Hospital Information System - HIS, Electronic Health Record - EHR and more.
The workstation communicates with several receiving systems at the same time, over different communication protocols if required, and the choice of receiving system can be controlled by which analysis is performed.

Configure recipients

A receiving system is configured in the workstation, which communication protocol to use, as well as network address and network port.

- **ASTM**

The ASTM-LIS2A protocol is primarily used for communication locally, directly to a Laboratory Information System, within the healthcare provider's network.

The following information is needed for this communication:

- ASTM protocol: `[CFG-EDI=ASTM]`
- IP address of server: `[CFG-server-ip=xxx.xxx.xxx.xxx]`
- Network port to server: `[CFG-server-port=xxxx]`

Sample data according to ASTM-LIS2A can be found under the section "Communication protocol"

- **Poct1A**

The Poct1A protocol is often used when two-way communication is required between the receiving system and the connected meters. Two-way communication is needed when communicating with Data managers who administer the healthcare provider's instrument park, that checks are carried out according to routine and that the operators have the right training for the various analyses.

The following information is needed for this communication:

- Protocol Poct1A: `[CFG-EDI=poct1a]`
- IP address of server: `[CFG-server-ip=xxx.xxx.xxx.xxx]`
- Network port to server: `[CFG-server-port=xxxx]`

Example data according to Poct1A can be found under the section "Communication protocol"

- **MAN**

The FHIR protocol is mainly used to communicate with more modern systems, such as cloud-based systems. In these cases, the traffic that goes over the Internet is encrypted.

To set up this communication, you follow the instructions from the various cloud-based systems. Contact Zafena for questions about this form of communication.

Typically, some barcodes are generated by the system, which are then scanned by the workstation's barcode reader, which automatically configures and connects the workstation.

Example data according to FHIR can be found under the section "Communication protocol"

Connecting meters

All analytical equipment can be connected, from small single-parameter sensors to advanced wet chemical multi-parameter analytical instruments.

Current list of integrated meters:

https://www.zafena.se/en/product/zafena-552-poc-workstation/#tab-additional_information

It is required that each connected meter be marked with an instrument tag, in the form of a barcode, which identifies the instrument type and communication protocol, but can also contain the instrument individual.

Contact Zafena or your nearest dealer for instructions, instrument tag and cable package to digitize your instruments.

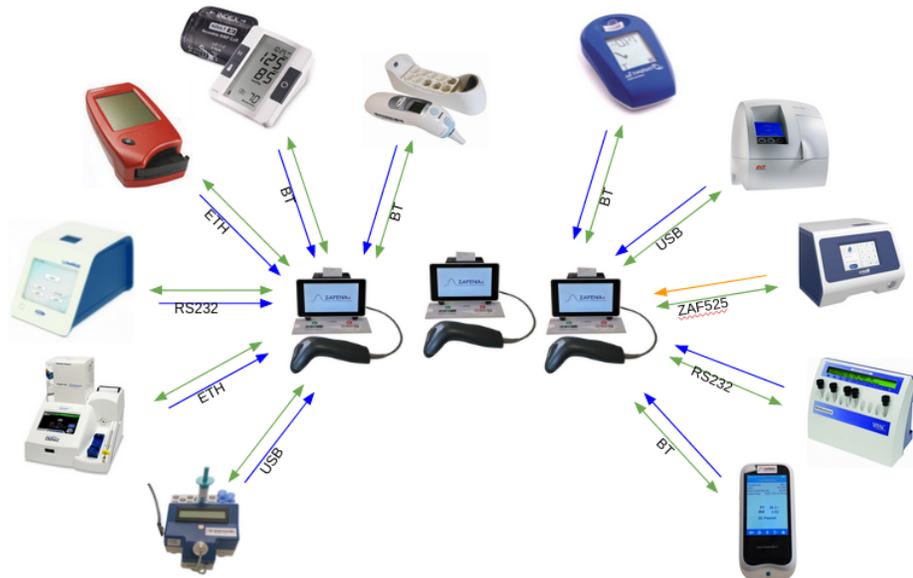
Example:

1. Plug the meter into one of the USB ports on any workstation.



2. Attach the instrument tag to the connected meter.
3. Configure the meter for communication according to instructions.

A gauge with an instrument tag can be plugged into any workstation, and used directly, without complicated configuration. This gives the meters flexible mobility between different workstations and can follow the needs of the caregiver.



Functions

Workstation parts

On/Off-knapp

Limits: Of
 Steady light: On
 Blinks: Startup / Shutdown



Power adapter

12-19V, 3.33A

Power cable

2,5 meter

Memory card

Micro-SD, 16Gb

USB

4 port (USB2.0)

Network sport

RJ45/Gigabit (802.3ac)

Network cable

1,5 meter

Wifi

802.11a/b/g/n/ac

Blue tooth

And

Printer

Thermo 58mm x 37mm

Screen

7" Touch-display

External screen

HDMI

Barcode scanner

USB (Datalogic Touch65)

Sound

Internal speaker

Location

Table / Wall

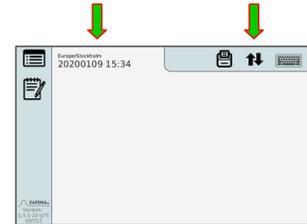


Work flow

Method

1. Verify

First check that the workstation is connected to the network and that it displays the correct date and time. The network icon at the top right of the workstation screen should be black and not show any warning symbols. The date and time are displayed slightly askew at the top left of the screen.



2. Scan meter

Use the barcode scanner connected to the workstation to scan the instrument tag (barcode) on the desired analysis instrument. The bar code on the instrument activates the correct view in the workstation which is getting ready to receive result data from the meter.



3. Scan LID/PID

Please use the barcode reader to add the LID or PID. It is also possible to use the digital keyboard. The analysis to be performed needs to be linked to a patient. This takes place either via a de-identifying laboratory ID, LID, in the form of a serial number or a patient ID, PID, in the form of a social security number or temporary social security number.

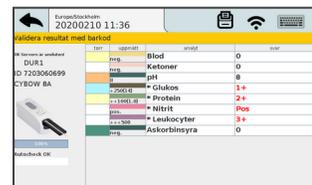


OBS! The workstation does not receive analysis responses if the PID/LID is missing in the analysis view on the workstation!



4. Analysis

Perform analysis on the selected instrument according to manufacturer's instructions.



5. Approve

When the analysis is complete, the results are displayed on the workstation screen. The reasonableness of the values is then checked. After the operator is satisfied, the analysis is approved by scanning "Accept & Submit". When the operator is not satisfied with the results, "Reject results" is scanned, after which a new analysis can be started.



Daily operations

Maintenance

Starting up

Start the workstation in the morning by pressing the large blue/green ON/OFF button on the right side of the workstation. The button will start flashing while the workstation is booting up. When the workstation's screen shows the date and time, as well as a black network icon, with no warning signals, it is ready for use. The ON/OFF button lights up steadily.



Starting the workstation takes about a minute.

Turn off

Turn off the workstation at the end of the work day by pressing and releasing the blue/green ON/OFF button. When switching off, the button flashes and turns off when switching off is complete.

Shutting down the workstation takes about ten seconds.

Restart

To restart the workstation use command; ZAF RESTART.



Cleaning

Clean the workstation and barcode scanner once a week. Make sure the workstation is turned off during cleaning. It is fine to use disinfectants with alcohol and chlorhexidine. Over the years, the shell may yellow slightly, but this does not affect the function of the workstation.

Paper change

Change the paper roll in the printer by folding back the small lever found on the top of the printer, to the left of where the paper exits. Peel out the empty roll and place the full roll, pull out some paper and close the door.



Accept or reject

It comes with a wrapped card with barcodes to approve or reject a result. Place the "Accept / Reject" sheet on the table in front of the workstation or attach it to the wall next to the workstation. If the sheet is missing, cut out and use the one below.



Accept & Submit

After the analysis is completed and the PID/LID is entered, the result is displayed on the workstation screen. The operator checks that the result is within the expected range, and that the PID/LID is correct.

The operator verifies the result by scanning the barcode “Accept & Submit” [ZAF-ACCEPT] or by opening the keyboard and pressing the “Accept” button or by scanning the same PID/LID again.

terr	uppmätt	analyt	svar
neg.		Blod	0
neg.		Ketoner	0
8		pH	8
+25(1.0)		* Glukos	1+
+100(1.0)		* Protein	2+
pos.		* Nitrit	Pos
u++500		* Leukocyter	3+
neg.		Askorbinsyra	0

Once the operator has accepted, it is sent to the receiving system.

Autoaccept

The function is activated if the care provider wishes to automate the human check and submit the result from the analysis, as soon as it is available.

To enable automatic acceptance, scan below command:
CFG-AUTOACCEPT=on



To enable operator verification of results scan below command:
CFG-AUTOACCEPT=off



It can be tied configurations to a specific connected meter/instrument type by adding the instrument designation to the barcode. Example:
CFG-AUTOACCEPT-XXXX=on
(XXXX represents the instrument tag):



Reject results

If the operator considers the results to be unexpected or strange looking, the analysis should be discarded and a new analysis performed. At any time during the workflow, the operator has the option to cancel and discard the ongoing analysis in the activated view. The operator's view is saved in the history for traceability.

Reject results automatically

The cases when the workstation rejects received results automatically.

- **New analysis result comes from the same meter.**
If a result from gauge A is seen on the workstation and a new analysis is run on gauge A, the old result will be discarded to make room for the new one.
This avoids the risk of patient information being linked to the wrong result.
- **There is a missing LID or PID in the view.**
If there is no Laboratory ID or Patient ID in the view of the meter on the workstation when the analysis result is delivered from the meter, the result will be rejected.
This avoids the risk of patient information being linked to the wrong result.
- **Old results.**
If a result remains untouched in view on the workstation for more than 15 minutes, the result is discarded. This avoids the risk of patient information being linked to the wrong result.

configuration

Network

The Zafena workstation can connect to all networks, both wired and wireless. There are several ways to configure the network settings. The most common is for the workstation to ask the network's DHCP server for the settings it needs. The customer's local IT department may need the workstation's MAC address to register the device or authorize the device to communicate over the network.

Wire bound

Wired network connection configures itself automatically when the network cable is connected between the network port in the workstation and an active network outlet in the wall.

The network's DHCP server distributes all the necessary information to the workstation, which is needed to communicate on the connected network.

Identification number (IP), The size of the connected network (Subnet), and the way out to the internet (Gateway).



CFG-wifi=off

A working connection to the network shows an icon consisting of two opposite black arrows.

Enable wired network by command; CFG wifi=off.

Wireless

For wireless communication, the network name (SSID) and password (PSK) need to be configured in the workstation. A working connection to the wireless network shows a black “fan” icon.



Activate wireless network via below commands:

CFG-wifi-ssid=*the network name*

CFG-wifi-psk=*network password*

CFG-wifi=on



Manually:

Scan the barcode 'CFG-wifi-ssid=', then activate the built-in keyboard and enter the network name, then press 'ENTER'.

Scan the barcode 'CFG-wifi-psk=', then activate the built-in keyboard and enter the password, then press 'ENTER'.

Note!

The network name and password must be entered correctly for the connection to work.

Automatic:

Print the entire command as a CODE128 barcode. It is fine to use free online services, such as <https://barcode.tec-it.com/en> to produce barcodes.

By using a barcode for configuration, typos are avoided.

Example: CFG-wifi-ssid=network

Example: CFG-wifi-psk=password

Contact Zafena if you need help producing configuring barcodes that suit your particular installation.



Language

There are several languages available in the Zafena workstation.
These are activated with commands as below:

English: CFG-lang=en_EN



Swedish: CFG-lang=sv



Norwegian: CFG-lang=no_NO



Finnish: CFG-lang=fi_FI



German: CFG-lang=de_DE



Korean: CFG-lang=kr_kr



Datum & Time

The workstation's internal clock is maintained by a supercapacitor instead of a traditional battery, when the workstation is turned off. The supercapacitor maintains the time of the internal clock for about a month, which is more than necessary when transporting or relocating. Zafena checks and sets the date and time in connection with delivery, in addition the workstation is configured to contact an official time server (NTP server) when it is connected to the network, in order to always keep the correct date and time. It is possible to configure your own choice of time server through the command below:

CFG-timeserver=

Scan the barcode 'CFG-timeserver=', then activate the built-in keyboard and enter the server IP or server name, then press 'ENTER'.



Print the server name as a CODE128 barcode. It is fine to use free online services, such as <https://barcode.tec-it.com/en> to produce barcodes.



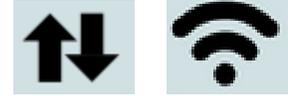
By using a barcode for configuration, typos are avoided.

The default time server is 'pool.ntp.org'

Network control

It is easy to check if network communication is established, and if there is contact with the information system (LIS/HIS).

Check the network icon at the top right of the view. When it is black, communication is established with the receiving system.



To check which network tasks have been assigned to the workstation, press the system log icon where you can see the tasks at the bottom of the log.



Example:

```
LDI_LOG_MESSAGE 20210107 15:57 Europe/Stockholm
MAC: C6:BA:EC:B2:5B:2D 38:D5:47:78:6B:41
IP: 192.168.250.1192.168.1.32
DNS: nameserver 127.0.0.53
```

MAC-address

Each network card has its own unique MAC address, which the IT administrator may need to know in order to allow communication through the network.

You can find the device's MAC address by:

- Look at the label attached under the workstation. (ethernet only)
- Tap the System Log icon to viewlog file.

LID or PID

Some workstations are set up to accept patient ID, PID. This then applies to ordinary Swedish social security numbers and temporary social security numbers with a letter between the date and the last four check digits. These workstations do not accept LID as identification patients.

Switch between Patient ID or Laboratory ID, using these barcodes:



Contact Zafena to design barcodes with settings that suit your needs.



Software update

Zafena's software and the operating system in the Workstation may need to be updated when new functions are desired and/or if security updates are required. This can be done in either of two ways:

Remote update

This requires the device to have access to the internet via the network the device is connected to.



Scan barcode “ZAF-UPDATE” to initiate a remote update via the network. The command switches over the device view to the system log where the download of the latest software version is displayed. The operator can follow the progress by noting the percentage countdown on the screen. The update takes approximately 5 minutes from start until the workstation is ready for new analyses.

All settings are saved using this method.

Changing the memory card

Option 1: A new Micro SD card with updated software, configured and sent by mail from Zafena.

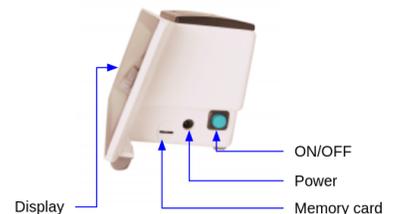


Option 2: Zafena provides a link to download the latest software to a PC. The workstation's micro-SD card is mounted in the PC. The downloaded software is transferred to the card (contact Zafena for instructions) The Micro-SD card is remounted in the workstation.

1. Note the current software version on any paper. You will find the version number in the lower left corner of the Zafena Workstation display.



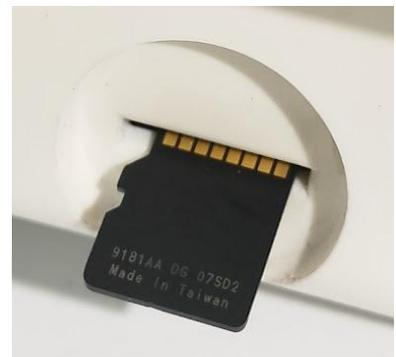
2. Turn off the Zafena Workstation by pressing and releasing the ON/OFF button on the right side of the housing. Shutdown is complete when the button stops flashing.



3. Remove the old memory card by gently grasping the card from the bottom. You can use the new microSD card as a lever under the old card to get it out. There is a small edge on the bottom of the card face that allows you to pull it out. Put the old memory card aside and save it.



4. Install the new memory card in the same slot as the old one, with its golden contacts facing up. Insert it in a slightly upward position. The card must be hooked into a holder and lowered completely into the card slot.



5. Start the workstation by pressing and releasing the ON/OFF button. It will start flashing and after a while the light will stay solid.

6. Check the software version number and compare it to the version number you wrote down.

With this method, all premises are cleared HISTORIC and all local settings. Re-configure the device by scanning server, port and communication protocol barcodes.

Troubleshooting

Gradually

1. **Submit the system log to Zafena.**
As soon as possible, after the perceived error, the system log should be sent to Zafena to get the necessary guidance and help faster.
2. **Describe the problem.**
Write another email info@zafena.se and give a brief description of the problem. Add phone number, name and location. The email to info@ goes to everyone at Zafena, so that the case can be picked up and dealt with quickly.
3. **Instructions from Zafena.**
Personnel from Zafena will contact you by phone or return email with instructions on how to fix the problem.

Symbols and messages

Symbols



1. **Analysis history**
All analyzes run via the workstation are saved here.



2. **Navigation buttons**
“Up” and “Down” button to navigate the history.



3. **Print**
In the welcome view, the icon indicates that 'automatic printing' is activated. The icon appears under the History as an option to print selected results.



4. **Ipp**
'Internet printing protocol', print bridge for cloud services, is enabled.



5. **Systemlogg**
The system log records most of what happens on the workstation and is often very helpful in troubleshooting.



6. **Keyboard**

The digital keyboard can be used to enter information and commands. There are also buttons for "Accept", "Reject" and "Print".



7. **Screensaver**

Tap this icon, and a screen saver will start. To return, tap the screen.



8. **Network icon wired**

The icon indicates that the workstation is connected with a network cable to the network and that the workstation has received all the information to operate on the network. The same icon with light gray arrows and red warning triangle means that the network is not connected.



9. **Network icon wirelessly connected**

The icon indicates that the workstation is connected wirelessly to the network and that the workstation has received all the information to operate on the network. The same icon with light gray waves and red warning triangle means that the network is not connected.



10. **Network problem**

The icon indicates that there is no contact with the receiving system and/or the network.



11. **Temperature warning**

When the icon appears, it is indicated that the temperature of the main processor exceeded 80°C. If this happens temporarily during startup, there is nothing to worry about. If the icon is continuously visible for more than two minutes, it may cause the processor to freeze. Updates in the user interface may be slower to lower the temperature.



12. **Temperature warning**

When the icon appears, it is indicated that the temperature of the main processor exceeded 85°C. If this happens temporarily during startup, there is nothing to worry about. If the icon is continuously visible for more than two minutes, it may cause the processor to freeze. Updates in the user interface may be slower to lower the temperature.



13. **Power warning**

When the icon appears, it indicates that there are current dips below 4.6V. If this happens temporarily during startup, there is nothing to worry about. The system may run slower to avoid that the main processor experiencing power loss. If the icon appears continuously, contact Zafena.

Messages

1. **“Connect the meter via USB cable and start the instrument.”**
The meter scanned is not connected to the workstation or is not started.
2. **“The server is not connected!”**
The workstation has no contact with receiving systems.
3. **“The server is connected!”**
The workstation has contact with the receiving system.
4. **“Please enter the LID or control number”**
The laboratory ID needs to be entered to connect the analysis to a sampling/patient. Analysis results from an instrument will be rejected if the LID is not entered before the results arrive at the workstation. This minimizes test results being sent to the wrong patient due to operator error.
5. **“Perform the measurement”**
The workstation has all the information it needs and is just waiting for the analysis results.

Send system log

This function requires that the workstation has access to the Internet.

At possibly trouble, Zafena is always helped by reading the system log from the device to understand the problem and give guidance on how we most smoothly and easily fix it.

The system log is sent to Zafena by scanning the barcode “ZAF-TRANSFER-LOG”. The system log records all events in the device, which is very helpful in troubleshooting.

This function requires that the workstation has access to the Internet.



The "ZAF-TRANSFER-LOG" function can be used by the operator to give Zafena access to output data from new meters, which the caregiver wishes to be connected to the Workstation. The purpose of the function is to enable the integration of new analytical equipment, without either transporting the equipment to Zafena's facilities or requiring Zafena's personnel to visit the location where the equipment is to be installed.

Views

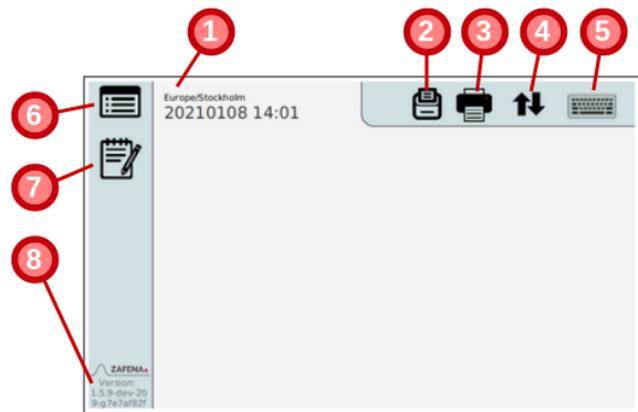
Users are exposed to different views of the workstation:

Welcome view

The view presented after starting the workstation.

In this view, you can access the history and system log, as well as an overview of the gauges/sensors that are connected and activated by scanning the instrument tag. Here you also see if printer functions are activated, as well as the version number, date, time and keyboard.

1. Date, Time and Time Zone
2. Automatic printing enabled
3. Ipp print bridge enabled
4. Network status
5. Keyboard
6. HISTORIC
7. Systemlogg
8. Version number



Systemlogg

Press the icon to read the log file. The system's reactions and events detected by the system are listed here.



HISTORIC

The history of performed analyzes on each individual Workstation can be accessed by pressing the history icon. The history lists results and transfers for all analyzes performed with analysis modules connected to the Workstation.



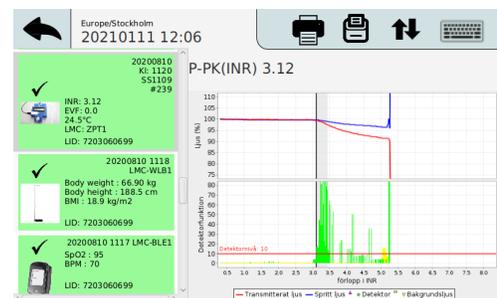
The list of analysis results is mainly for traceability and troubleshooting.

The memory holds roughly 30,000 results.

Color code shows status of transfer to receiving system.

- Delivery was successful (green)
- Failed to deliver (orange)
- The analysis is rejected (grey).

Some meters transfer progression curves overanalysis reactions, these may be depicted in the overview. The same applies to the screen that was displayed when the



analysis result was approved or rejected. Movement in the list takes place either with barcode commands or with the touch function.

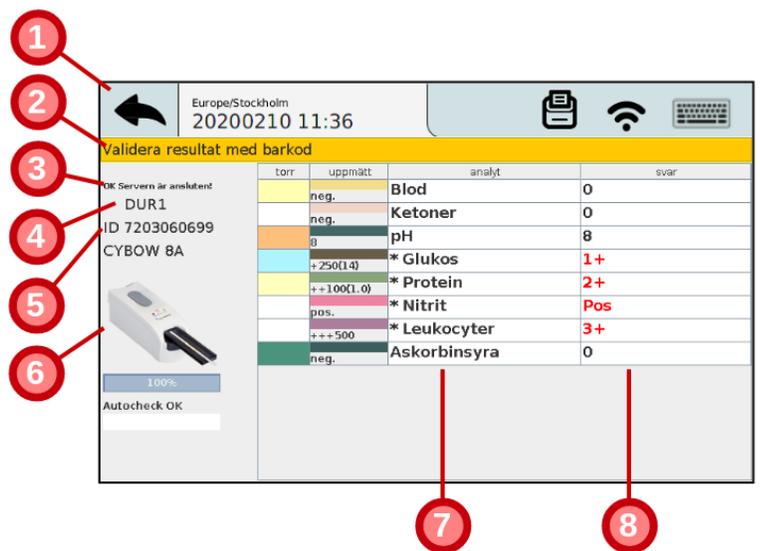
Example: History view, Simple Simon PT with reaction graph and signal strength.

Analys-vy

The view where ongoing analysis is presented. This can be done in different ways based on which meter is used. Some show graphs and others just the results of the analysis.

Example: Analysis view from Simple Simon UA.

1. Back to Home view.
2. Instructions to operator.
3. Server connection information.
4. Instrument tag
5. LID / PID
6. Image of connected meter.
7. List of analyses.
8. Results.



The screenshot shows the analysis view for a Simple Simon UA meter. The interface includes a top status bar with location and time, a yellow header bar with a barcode validation prompt, and a table of analysis results. A sidebar on the left displays server status, instrument ID, and a photo of the meter. A progress bar at the bottom left shows 100% completion.

torr	uppmätt	analyt	svar
neg.		Blod	0
neg.		Ketoner	0
g		pH	8
+250(1.4)		* Glukos	1+
++100(1.0)		* Protein	2+
pos.		* Nitrit	Pos
+++500		* Leukocyter	3+
neg.		Askorbinsyra	0

Printer

Receipt printer

The workstation has a built-in printer for automatic printing of results after analysis.

Enable or disable via command:

CFG-print=on



CFG-print=off



Internet Printing Protocol

'Internet printing protocol' or ipp is a function that enables printing on local network printers without the need for a special driver for the printer. It helps cloud-based record systems reach internal printers on the customer's local network, to send printouts in the form of PDF documents through the workstation. You need to know the IP address of the printer where the prints are going to.

Configure the desired printer through the barcode below:

(Example: IP address 192.168.168.191)



Enable or disable 'ipp' with command:

CFG-ipp=on



CFG-ipp=off



Print barcodes

It is possible to connect a 'Brother barcode printer to the workstation and via a special barcode the possibility to print tests to barcodes (CODE128) is activated.

The barcode printer function is accessed by command:

ZAF-BARCODE



After this function is used, the workstation needs to be restarted to get back to "analysis mode".

Operator control

The need to control who is allowed to perform analysis varies. Therefore, it is possible to set the requirements differently per connected instrument type, as well as different hard requirements per instrument type.

The barcode that sets this up is split into two parts; the first tells which instrument type applies [CFG-ZPT1-OPER=required] (Simple Simon PT). Den andra delen [CFG-ZPT1-OPER=**required**] sets how strict the requirement should be.

Operator registration and control is available at three levels;

- **‘optional’**
This level provides the option to add the operator ID to the analysis result submitted to the central system, but it is not mandatory. This level can be a good option to start with to get staff used to adding their ID to each analysis.
- **‘required’**
This level requires an authorized operator ID to be scanned after each workstation restart.
- **‘reenter’**
This level requires an authorized operator ID to be scanned on each scan.

A list of approved operators per analyte can be entered locally per workstation, but can also be received from a Data manager or LIS that has such a function.

Contact Zafena to design barcodes with settings that suit your needs.

Quality control

Analytical quality control is performed periodically to verify that the equipment is analyzing correctly. To separate QC runs from regular patient analysis in the receiving system, it is common to designate some LIDs (Lab IDs) that are dedicated to specific controls.

The barcode to indicate which LIDs apply to QC is divided into two parts;

[CFG-ZPT1-QC=XXXX]

'ZPT1' stands for which connected meter the setting should apply to and 'XXXX' represents the LID dedicated to QC. It is possible to register more LIDs by separating them with commas (,).

Example:

CFG-ZPT1-QC=123456,234567,345678,456789,567891

Sound

The sound level of the built-in speaker can be set by the barcodes below.

The setting goes from 0, which is completely turned off, to 1, which is the highest volume.



Words & abbreviations

DHCP

Domain Host Control Protocol

This server service informs connected network devices about which network settings the device must make use of. IP address, Netmask and Gateway the device must use.

USB

Universal Serial Bus

Standardized connection for barcode scanners, analytical meters, keyboards, etc.

DNS

Domain Name Server

This server service informs connected network devices about which IP addresses are associated with which network names. You can think of it as the network's telephone directory. (Ex. www.test.se = 23.14.10.11)

NTP

Network Time Protocol

This server service informs connected network devices of the correct time.

LIS / LIMS

Laboratory Information System / Laboratory Information Management System

This is a receiving system for laboratory results, which then sends the results into the patient's record.

HIS

Hospital Information System

This describes the entire hospital's information system, where all the system's services are included.

LID

Laboratory-ID

Instead of, for example, social security number or name, the patient is identified via an LID. The LID is a generated serial number that is linked to the patient when the analyzes are ordered.

PID

Patient-ID

This can be a social security number or a temporary social security number.

EHR

Electronic Health Record

Describes the patient's digital patient record.

MAC-address

Media Access Control-address

Unique identification number when communicating over the network.

Example: EB:27:AA:45:C3:F2

IP address

Internet Protocol address

An address that is linked to the network device unique MAC address. A borrowed one Identification ID to communicate through the network.

Example: 192.168.1.98

Risk assessment

Hardware

IVDD

Zafena's Workstation [ZAF 552] is classified as an "accessory" to a "general in vitro diagnostic medical device" under *Directive 98/79/EC* (in vitro diagnostic medical devices) i enlighet with the directive and the Swedish Medicines Agency's regulation *LVFS 2001:7*.

IVDR

Through MDCG 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR*, the Workstation is classified as an accessory.

The hardware in the ZAF-552 is safe to use under conditions that normally prevail where IVD products are used.

Risk management

The assembled hardware is EMC-tested by accredited laboratory. EMC tests reveal potential risks caused by the hardware.

- **Emission risk**

The hardware, as an accessory, interferes with connected IVD equipment.

Risk management:

The hardware is EMC-tested by an accredited laboratory before a new version of the hardware is put into use. Requirements to pass the tests for Conducted disturbance and Radiated disturbance

EN 60601-1-2:2014

EN 55011:2009 + A1:201 Class B

- **Immunity risk**

The hardware is interfered with by other electrical equipment and therefore stops working.

Risk management:

The hardware is EMC-tested by an accredited laboratory before new versions of the hardware are put into use. Requirements to pass immunity tests according to

EN 60601-1-2:2014

Test criteria

for acceptable loss of functionality when testing immunity

Zafena's minimum requirements are:

- B** EN 61000-4-2: Electronic discharge (ESD) immunity test
Comment: Strong ESD can cause disturbances in the ground plane which can cause electronics restart. It is acceptable about the software restarts and returns to normal state without operator intervention.
- B** EN 61000-4-3: Radiated RF electromagnetic field immunity test
Comment: Because cable traffic can be disrupted by the test then it is acceptable for functionality to go down while the disruption is in progress but cable traffic shall be restored after the disturbance has ceased without operator intervention.
- A** EN 61000-4-4: Electrical fast transient/burst immunity test
- A** EN 61000-4-5: Surge immunity test
- A** EN 61000-4-6: Induced radio frequency field immunity test
- A** EN 61000-4-8: Power frequency magnetic field immunity test
- B C C C** EN 61000-4-11: Voltage dips and short interruptions immunity test
Comment: The product must pass normal test criteria. If power disappears completely, it is acceptable for the product to return to functionality execution after operator intervention.

ZAF-552 is an accessory to IVD analysis equipment, as well as IVDR analysis equipment and is thus, by definition, without the ability to generate analysis results. That in itself is a strong safeguard against ZAF-552 giving rise to garbled analysis results. Further such protection comes from the above described EMC resistance which inhibits the occurrence of both transient and permanent loss of functionality.

Software

Software, ZAF-505-2, is used with ZAF-552. The software has been designed and tested to minimize risks when handling readings from IVD analysis equipment.

Identified risks when handling measurement values from IVD analysis equipment:

- Analysis results flagged as possibly incorrect (error) must not be forwarded to the healthcare information system.
Risk management: The software automatically goes through a checklist before analysis

results are forwarded.

- Analysis results flagged as possibly incorrect are not displayed to the operator, except if required to investigate the origin and cause of the error.
Risk management:
The software hides, from the operator, any suspected incorrect analysis results.
- Results from IVD analyses must not be able to be connected with incorrect LID-, person-, or referral number.
Risk management:
Only one analysis at a time is shown to the operator even if several analyses are running in parallel. Entered LID, person, or referral number associated only with the displayed, active analysis.
- Answer confusion between closely related analyses in time.
Risk management:
The software uses isolated storage spaces for each individual result from the IVD analysis equipment.
- Data about the analysis needs to be collected.
Risk management: Analysis responses are not displayed until all required data about the analysis has been collected.
- Lost functionality in future versions.
Risk management: Zafena creates, continuously, new automatic tests that are performed regularly during development work and during quality testing of updated software to ensure the functionality of the software.
- Alternative platform and operating system.
Risk management: Zafena creates "master cards" where both operating system and software are packaged as a unit. In this way, the software cannot come into contact with alternative versions of operating systems or other platforms. When copies are created by the software, the entire memory card is duplicated where both the software and the Operating System are included with verification that the copy is identical to the master card.

Follow-up

To enable follow-up, Zafena undertakes to:

- create version numbers used when purchasing hardware parts.
- create, when compiling, version numbers of software.
- archive source code for the software so that the version can be derived on at least 2 computers.

Complete history of changes to the software is stored in a way that enables rollback to the previous version. Archived software is located on Zafena's local server and requires personal login.

Regulatory claim

GDPR

Personal data

Zafena does not wish, and has no interest in, receiving data containing personal data from third parties. Zafena objects to the receipt of information that affected by GDRP or PUL.

Management

In the event that personnel at Zafena discover that a sender has sent potentially sensitive information to Zafena, which is subject to GDRP or PUL, the following will take place.

- The sender is contacted to choose destruction or return in consultation.
- Return. Zafena returns the information to the sender and deletes any traces of the information under Zafena's direction.
- Destruction. Zafena deletes all traces of the information under Zafena's direction.

IVDD

Zafena's workstation (ZAF-552) is classified as an "accessory" (accessory) to a "general In vitro diagnostic medical device" under Directive 98/79/EC (in vitro diagnostic medical devices) in accordance with the directive and the Swedish Medicines Agency's regulation LVFS 2001:7 .

A fundamental difference between an "accessory" and an IVD product is that the accessory can only process and convey, not generate, diagnostic information.

In regulatory terms, an accessory must be considered an IVD product and CE marked as such. However, no registration with the Swedish Medicines Agency is required for an accessory. The workstation (ZAF-552) is EMC tested, quality assured, risk assessed and CE marked. Deviations must be followed up as prescribed for "accessories" to IVD products. The software included in the workstation (ZAF-505-2) is also considered an accessory. Many medical devices must have accessories in order to be used as intended. Stand-alone software that is an accessory to a medical device is not in itself a medical device, but must still meet the requirements set for such a product.

Zafena risk assesses possible errors that the ZAF-505-2 software can cause, quality-assures the software regularly with automatic tests, CE marks the software and follows up on the deviations reported when the software is used as an "accessory" to an IVD product.

The product is EMC-tested to ensure compliance with the necessary requirements.

Report: *EMC TEST REPORT 17108* issued by KEMET test laboratory, accredited by SWEDAC.

The product receives the CE mark after approved assembly, testing and quality control according to written instructions.

Each product's MAC address, as well as QC protocols are documented before shipment to the customer to enable traceability and deviation follow-up.

IVDR

Pursuant to MDCG 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR*, the Workstation, ZAF 552, is classified as an accessory to one or more IVD units.

The task of the workstation is to collect analysis data, repackage and send it on.

The workstation does not create or modify analysis results.

The workstation can convert between different result units.

The workstation can calculate and present ratios between different analysis results.

“Software must have a medical purpose on its own to be qualified as a medical device software (MDSW). It should be noted that the intended purpose as described by the manufacturer of the software is relevant for the qualification and classification of any device.”

“It is important to clarify that not all software used within healthcare is qualified as a medical device. For example, “Simple search”, which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software (e.g. library functions).”

Communication protocol

The workstation can simultaneously use several standardized protocols to communicate analysis results to EHR/LIS/middleware, with different communication requirements. Below follows a brief description of the mainly used protocols.

ASTM-LIS2

ASTM, as it is called, is a simple and stable standard for communication of analysis results in healthcare. Formatting of the laboratory response data set is as follows

NCCLS LIS2-A2 Vol. 24 no. 33 a revision of ASTM E1394-97.

Messages are packaged in an ASTM frame with a modulo 256 checksum, documented in the low-level handshake for ASTM according to NCCLS LIS1-A Vol. 23 no. 7 Previously

ASTM E1381-02.

The workstation sends structured data via ASTM-LIS2, according to the example below from an INR analysis:

Header

```
|\^&|||ZAF101^SS291^I485M^J113X|||||P|LIS2-A2|20100217162100
```

|\^&| = The characters used as delimiters during the transfer.

For simplicity, we only use **|\^&|**.

ZAF101 = Type of meter.

SS291 = Mätarindivs.

I485M = LOT number.

J113X = LOT version, software for communication.

P = Production. For simplicity, we will only enter P in this field.

LIS2-A2 = Which communication standard is used.

20100217162100 = Date and time when this transfer is performed formatted according to YYYYMMDDTMMSS

Patient

```
|1||||NKP272M0dVB||||||||||||||||||||||||||||||||
```

1 = Transfer one patient per connection so this number will always be 1.

NKP272M0dVB = Laboratory ID, LID

Order

```
|1|NKP272M0dVB||3289-6^^^|R|||||X||||BLDC^|||||||SS291^1234|F||||
```

1 = Transfer one order per connection so this number will always be 1.

NKP272M0dVB = Laboratory ID, LID

3289-6 = LOINC analysis code 3289-6 for PT/INR

R = Priority. Only R will be entered in this field.

[tom] = Date and time when the analysis was requested. The workstation does not handle query calls, so this is left empty.

X = Action code X = specimen or test already in process. This will always be X. **BLDC** = "Specimen descriptor". Description of test type. The LIS2-A2 standard lacks a complete list of test types. Example: BLDC - capillary bloodfrom finger.

SS291 = Mätarindivs.

1234 = Identification number assigned by the care provider.

F = Final. Only F will be entered in this field.

Results

|1|3289-6^^^|1.19|INR||N||F|||20070803170300|SS291^1234

1 = Only one result is transferred per connection so this number will always be 1.

3289-6 = LOINC analysis code 3289-6 for PT/INR

1.19 = Analysis results with . as a decimal point.

INR = Unit for the result.

N = Normal. Analysis flags for the measurement.

F = Final. Only F is used in this field.

20070803170300 = Date and time network analysis was performed formatted according to YYYYMMDDTTMMSS

SS291 = Mätarindivs.

1234 = Identification number assigned by the care provider.

Terminator

|1|N

1 = Transmit only one terminator message per connection so this number will always be 1.

N = Normal termination. Only N is entered in this field.

Example 2:

LIS02-A2 "ASTM" from VitaPCR connected through Zafena POC-Workstator:

H|^&||CVP1 SARS-CoV-2

test^20K06051^AL07B^V62X|||||60:45:CB:72:EB:DE||P|LIS2-A2|20210209105643

P|1||||VC2102325||||||||||||||||||||

O|1|VC2102325||94500-6^^^SARS-CoV-2|R||||X||||NSECR^|||||||20K06051^CVP1-20K06051|F
| |||

R|1|94500-6^^^SARS-CoV-2|NEGATIVE|||N||F|||20210201154400|20K06051^CVP1-20K06051

O|2|VC2102325||94310-0^^^Universal

SARS-Like|R||||X||||NSECR^|||||||20K06051^CVP1-20K06051|F||||

R|1|94310-0^^^Universal

SARS-Like|NEGATIVE|||N||F|||20210201154400|20K06051^CVP1-20K06051

O|3|VC2102325||94745-7^^^SARS-CoV-2

Ct|R||||X||||NSECR^|||||||20K06051^CVP1-20K06051|F ||||

R|1|94745-7^^^SARS-CoV-2 Ct|0||N||F|||20210201154400|20K06051^CVP1-20K06051

```

O|4|VC2102325||94313-4^^^SARS-like
Ct|R||||X||||NSECRA|||||||20K06051^CVP1-20K06051|F||||
R|1|94313-4^^^SARS-like Ct|0||N||F||||20210201154400|20K06051^CVP1-20K06051
O|5|VC2102325||90101-7^^^SAC Internal
Control|R||||X||||NSECRA|||||||20K06051^CVP1-20K06051|F||||
R|1|90101-7^^^SAC Internal Control|1||N||F||||20210201154400|20K06051^CVP1-20K06051
O|6|VC2102325||81326-1^^^SAC Ct|R||||X||||NSECRA|||||||20K06051^CVP1-20K06051|F||||
R|1|81326-1^^^SAC Ct|25||N||F||||20210201154400|20K06051^CVP1-20K06051
L|1|N

```

Poct1A

Clinical and Laboratory Standards Institute document POCT01-A2, Point-of-Care Connectivity; Approved Standard — Second Edition was developed for those who manufacture diagnostic devices for healthcare professionals, as well as hardware and software used to connect the devices to various information systems in healthcare facilities.

Example:

HbA1C results from EKF Quo-Test, via the Workstation to the receiving system.

```

<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<NOTE.R01>
  <HDR>
    <HDR.control_id V="1015"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2019-06-26T16:25:35+0200"/>
  </HDR>
  <SVC>
    <SVC.observation_dttm V="2017-05-05T11:32:00+0200"/>
  <PT>
    <PT.patient_id V="First POCT1A"/>
  <OBS>
    <OBS.observation_id V="50563-6" SN="LN"/>
    <OBS.value V="131" U="umol/L"/>
    <OBS.interpretation_cd V="N"/>
  </OBS>
</PT>
<OPR>
  <OPR.operator_id V="AUTO"/>
</OPR>
<SPC>
  <SPC.type_cd V=""/>
</SPC>
</SVC>
</OBS.R01>

```

FIHR

The FHIR standard enables so-called profiling of resources. This means that the information in a resource in the form of attributes and elements can be limited or expanded to fit the national and/or specific needs that exist, beyond what the FHIR standard stipulates. A profile is used by the actor to interpret the information in a response, or to create a call with the correct attribute set and format.

Example:

Results from ear thermometer, via the Workstation to the receiving system.

```
{
  "resourceType": "Bundle",
  "entry": [
    {
      "resource": {
        "resourceType": "Observation",
        "Contained": [
          {
            "resourceType": "Practitioner",
            "id": "1"
          },
          {
            "resourceType": "Specimen",
            "id": "2",
            "identifier": [
              {
                "value": "84256"
              }
            ],
            "type": {
              "coding": [
                {
                  "system": "http://hl7.org/fhir/v2/0487",
                  "code": "EAR"
                }
              ]
            }
          },
          {
            "resourceType": "Device",
            "id": "3"
          }
        ],
        "Identifier": [
          {
            "value": "84256"
          }
        ],
        "Status": "final",
        "code": {
          "coding": [
            {
              "system": "http://loinc.org",
              "code": "76011-6",
              "display": "Ear temperature"
            }
          ]
        },
        "issued": "2020-02-26T14:16:00.000+01:00",
        "performer": [
          {
            "reference": "#1"
          }
        ],
        "valueQuantity": {
          "value": 36.5,
          "unit": "Cel"
        },
        "specimen": {
          "reference": "#2"
        },
        "device": {
          "reference": "#3"
        }
      }
    }
  ]
}
```