

User guide

ZAFENA-552

POC-Workstation



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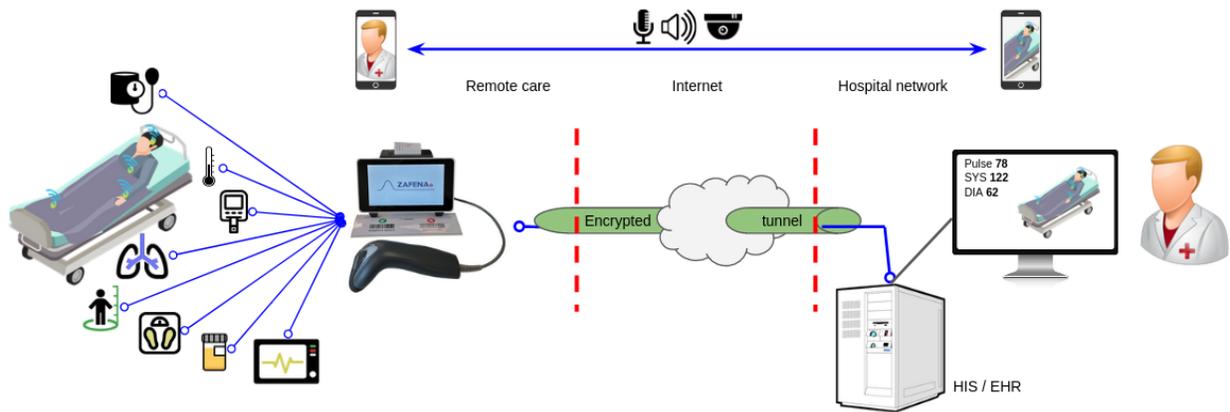
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Modular POC Instrument

Zafenas Poc-Workstation forms modern, patient-centered (POC) instruments together with analytical IVD equipment that is analytically, but not IT-wise, complete. Formed POC instruments meet all healthcare requirements for data processing, documentation and data communication, and can be updated to also meet future requirements for IT support.

Zafena POC-Workstation and analysis module together form a modular instrument. It is a patented creation consisting of:

- 1) IT module (POC-Workstation),
- 2) analysis module,
- 3) barcode reader connected to POC-Workstation, and
- 4) barcode label (instrument tag) attached to the analysis module.



When the label (tag) is read with the bar code reader, the desired IT support is activated (selected) from many possible IT supports stored in POC-Workstation memory, at the same time information about the analysis module's unique identity can be transferred to POC-Workstation. After the desired IT support has been activated, the operator is instructed, step by step, by POC-Workstation, on how the analysis is to be performed. Depending on which IT support is desired, different IT support for a particular analysis module can be obtained.

Required / necessary supplementary information, such as the identity of the sample, the identity of the patient and the identity of the operator, is supplied with the bar code reader, or if desired with a connected keyboard or POC-Workstation touch function.

A modular POC instrument offers obvious practical and economic advantages over a conventional, monolithic, POC instrument. The technical life of analytical modules can be significantly extended, which greatly reduces the training needs of operators. In addition, a POC Workstation can provide IT support for multiple analytics modules, and IT support can be easily updated. In several ways, costs are reduced.



Any analytical equipment such as digital (USB, Wifi, Bluetooth or serial) can deliver analysis results, for example to a printer, can act as an analytical module. Information about which analysis module, type and / or individual, and which data support is desired, POC-Workstation receives by reading a bar code attached to the analysis module. POC-Workstation informs about what 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 supplementary information and sent via network to one or more information systems (LIS / HIS) within healthcare. POC-Workstation locally documents all information received and sent as well as information about the status of the transmission.

Zafena POC-Workstation can be connected to a network and can then interact with a number of network services.

A typical healthcare network may include network services and information systems as shown above. Zafena's POC-Workstation can then interact with the network and information systems (LIS / HIS of various kinds) in the following way:

- Zafena POC-Workstation sends its unique MAC address to the network's DHCP server which then, if communication is allowed, informs POC-Workstation about which IP address, Subnet mask, DNS server, Gateway and Host name to use.
- The DNS server translates the IP address into a network name or vice versa. The name or IP address of the LIS / HIS server is required for the POC-Workstation to be able to find the server on the network. The DNS server acts as the network directory of the network.

- Zafena POC-Workstation can synchronize its internal clock with any "time server" (NTP server).
- Zafena POC-Workstation sends packaged information with analysis results and supplementary information to LIS / LIMS server with secure bidirectional communication according to standardized protocols such as "ASTM LIS02-A2", "POCT1A", "HL7", "xml" or "FHIR". POC-Workstation is informed whether the transfer was successful or not. If not, POC-Workstation allows retransmission attempts.
- Zafena POC-Workstation can connect and in parallel handle up to three wired analysis equipment, as well as several of these via Bluetooth and / or wifi.

Statutory and regulatory requirements for Zafena POC-Workstation

Zafenas POC-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) 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.

An accessory must be considered as an IVD product from a regulatory point of view and be CE-marked as such. However, no registration with the Medical Products Agency is required for an accessory. Zafena POC-Workstation (ZAF-552) must be EMC tested, quality assured, risk assessed and CE marked. Deviations must be followed up as prescribed for "accessories" for IVD product.

The software (ZAF-505-2 located on the camera memory inserted in the ZAF-552) also counts as 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 nevertheless meet the requirements placed on such a product. Zafena must risk assess possible errors that the ZAF-505-2 software may cause, ensure the quality of the software regularly with automatic tests, CE mark the software and follow up the deviations that are reported when the software is used as an "accessory" to an IVD product.

Zafena has had EMC test the product to ensure the necessary compliance. Report is given in document *EMC TEST REPORT 17108* issued by KEMET, a test laboratory accredited by SWEDAC.

Zafena CE marks the product after approved installation and testing in accordance with written instructions.

Zafena documents the product's MAC address before shipment to the customer to enable traceability and deviation follow-up.



Method



1. Scan
analysis equipment
which to use

2. Scan
Patient ID or
Sampling ID

3. Perform analysis
according to the manufacturer
instructions

4. The result is transferred over
EHR / LIS / Middleware

1. Use the barcode reader connected to the POC-Workstation to scan the instrument tag (barcode) on the desired analytical instrument. The barcode on the instrument activates the correct view in the POC-Workstation which is getting ready to receive result data from the meter.
2. To link the analysis to the correct patient and sampling opportunity, the operator scans the barcode generated by the order from EHR. You can also enter the data with the built-in touch keyboard.
3. Perform analysis on the selected instrument. If the operator enters the patient ID in the analysis equipment, the information is followed to the POC-Workstation and further into the EHR / LIS.
4. The results from the analysis are paired with the order via Patient ID / Sampling ID and presented in EHR / LIS.

Example from "Quick guide Simple Simon PT Plus" below:

Select analysis module and sample type Use the Plus screen barcode reader and scan the barcode on the top of the analysis module (a). Note that the Plus screen view changes (b). Follow the instructions on the top of the screen and start the meter by pressing its button (c).

Select the sample type by scanning the corresponding barcode (d). Selection of sample type only needs to be performed if the sample type differs from the previous analysis.

ZAF-CAP – Capillary sample
Whole blood, without additives. (within 3 min.)

ZAF-VEN - Venous sample
Tube with blue cork. Citrate blood. (within 48 hours)

ZAF-PLASMA - Plasma sample (Citrate Plasma)
Centrifuged citrate blood. Also applies to analysis of controls. (within 24 hours)

Perform analysis Lift off the metal cover on the sample holder. Follow the instructions on the screen. Place and attach a reaction tube to the meter's sample holder (1) and remove the blue stopper (2). Follow the instructions and add 10uL of sample by filling the pipette and wiping off excess sample (3). Insert the pipette into the reagent, while emptying the sample into the reagent (4). Mix the sample and reagent by pumping the pipette until instructed to "remove the pipette and attach the cap" (5). The detection takes place automatically. Shortly afterwards, the operator is instructed to remove the cup to see the result (6). Turn the reaction tube upside down to visually confirm that coagulation has taken place. (7)

Approve analysis Use the barcode scanner for additional information, such as Patient ID and Operator ID (8). Approve the result by scanning the barcode "Approve & submit" or reject the analysis by scanning "Reject" (9).

Risk assessment

Hardware

Zafenas Plus-Screen (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) in accordance with the directive and the Swedish Medicines Agency's regulation LVFS 2001: 7

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

Risk management: The hardware is EMC-tested by an accredited laboratory. Risks of errors caused by the hardware are identified during this EMC testing.

- Emission risk is that the hardware as an accessory interferes with connected IVD equipment. Risk management: The hardware must be EMC-tested by an accredited laboratory before a new version of the hardware is used and must then pass the tests for Conducted disturbance and Radiated disturbance
EN 60601-1-2: 2014

EN 55011: 2009 + A1: 201 Class B

- Immunity risk is that the hardware is disturbed by other electrical equipment and therefore stops working. Risk management: The hardware must be EMC tested by an accredited laboratory before new versions of the hardware are used and must then pass immunity tests according to EN 60601-1-2: 2014

Test criteria for acceptable loss of functionality in immunity testing

Zafenas Minimum requirements are:

- B EN 61000-4 -2: Electronic discharge (ESD) immunity test
Comment: Severe ESD can cause disturbance in the ground plane which can cause electronics to restart. It is acceptable if the software restarts and returns to normal without the operator's intervention.
- B EN 61000-4-3: Radiated RF electromagnetic field immunity test
Comment: Since cable traffic, for example, USB can be disturbed by the test, it is acceptable that functionality decreases while the disturbance is going on, but the cable traffic must be restored after the disturbance has stopped 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
- BCCC EN 61000-4-11: Voltage dips and short interruptions immunity test
Comment: The product must pass the normal test criterion.
If power disappears completely, it is acceptable for the product to return to functional design after operator intervention.

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

Risk assessment software

The ZAF-505-2 software used in conjunction with the ZAF-552 must be designed and tested to minimize risks when handling measurement values from an IVD analysis equipment.

Identified risks when handling measured values from IVD analysis equipment:

- Analysis responses marked by the analysis equipment as possibly incorrect (error) must not be able to be forwarded to the healthcare information system.
Risk management: The software should automatically go through a checklist before analyzing responses

- Analysis answers marked as incorrect as possible are not displayed to the operator, unless this is 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 analyzes must not be linked to incorrect LID, personal or referral numbers.
Risk management: Only one analysis view at a time is displayed to the operator, even if several analyzes are in parallel. Entered LID, personal or referral number is only associated with the displayed, active analysis view.

- Confusion of answers between timely analyzes.
Risk management: The software uses isolated storage spaces for each individual result from the IVD analysis equipment.

- Prevent the operator from believing that everything is ready even though more information about the analysis needs to be collected.
Risk management: Analysis answers are not displayed in the analysis view until all mandatory information about the analysis has been collected.

- Implemented functionality may be lost in future versions of the program.
Risk management: Zafena creates automatic tests that are performed regularly during the development work and during quality testing of updated software to ensure the software's functionality.

- Implemented functionality may be lost if the software runs alongside an alternative version of the operating system.
Risk management: Zafena creates "master cards" where both operating system and software are packaged as one unit. The software can thus not come into contact with the alternative version of the operating system. When Zafena creates copies of the software, the entire memory card is duplicated, including both the software and

the operating system, with verification that the copy is identical to the master card.

Follow-up

To enable follow-up, Zafena undertakes to:

- create version numbers that are used when purchasing parts for the hardware.
- create, when compiling, version numbers and lot numbers of software.
- archive the source code of the software so that it is possible to derive the version on at least 2 computers.

Complete history with changes to the software is stored in a way that allows return to the previous version. Archived software is available on the local server at Zafena and requires personal login.

GDPR

Personal Data

Zafena does not wish, and has no interest in, receiving data containing personal data from third parties. Zafena opposes receiving information that is affected by GDPR or PUL.

Destruction

In the event that information subject to GDPR or PUL is sent from a third party to Zafena, one of two incidents will occur.

1. The information is sent back to the sender / third party, with information and reference to this document.
2. All information affected by GDPR or PUL from third parties will be destroyed in consultation with third parties.

Description

Description of POC-Workstation parts.



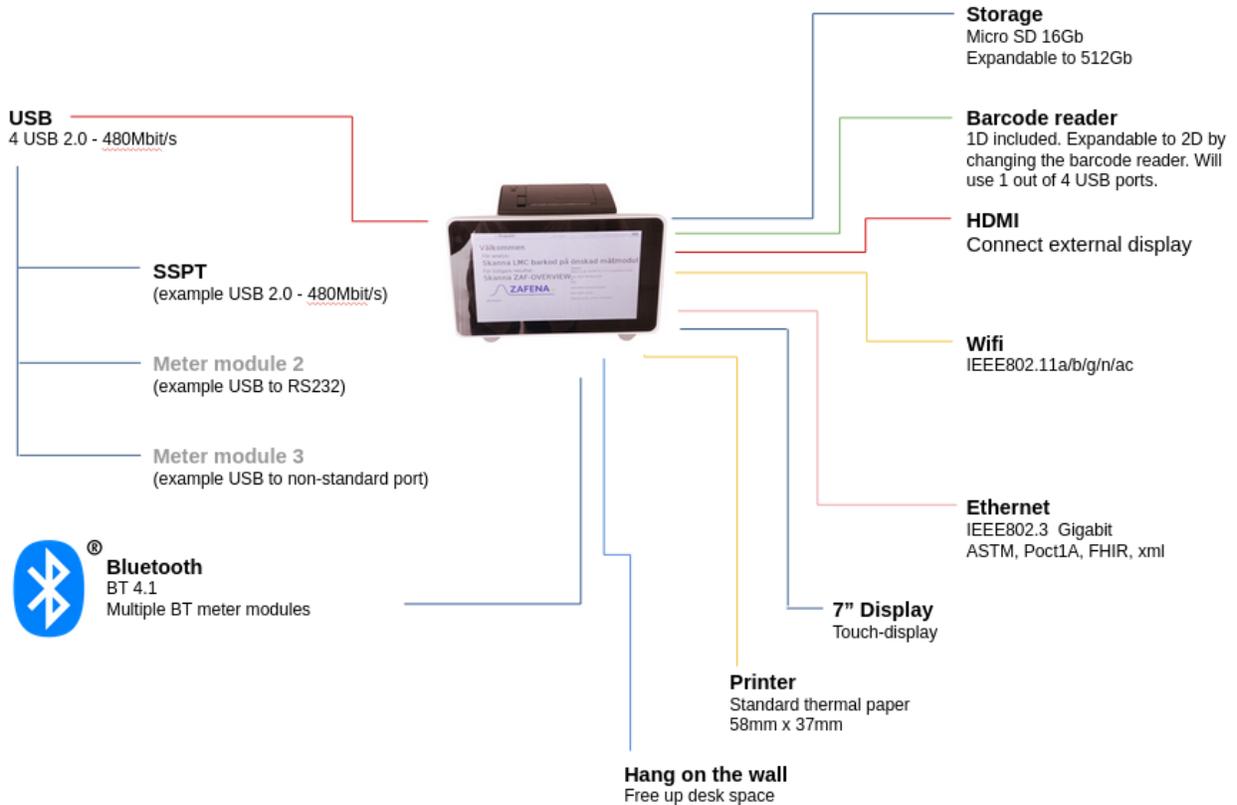
On / Off

Dark: Off
 Fixed light: On
 Flashing: Start-up /

Shut 12-19V / 3.33A
 Memory card Mirco-SD
 whichcontains all software and history



USB 4 ports
 Network port RJ45 / 802.3ac



Installation

Check that

- there is space for installation by POC-Workstation.
For installation on tables: 25 x 25 centimeters.
For wall installation: 20 x 12 centimeters.
- there is a 220V electrical outlet near the installation site. Max 2 meters away.
- there is access to network via RJ45 connection in the wall with cable and / or wireless connection via wifi up to IEEE802.11ac. The included network cable is 1.5 meters.

Unpack and connect

The package includes the following:

- 1st POC-Workstation.
- 1pc 1D Datalogic Touch65 barcode reader ..
- 1pc 1.5 meter network cable.
- 1pc power adapter 12V / 3.33A with 1 meter cable.
- 1 power cable 1.5 meters.
- 1st barcode sheet.

Unpack all parts and remove protective material from the workstation. Place the workstation in a suitable place next to the instruments that require connection.

Connect the power adapter and the power cable to a 220V electrical outlet, and vice versa all the way into the POC-Workstation's power socket. The ON / OFF button will flash when the workstation receives power.

Connect the network cable to an active network socket near the workstation, as well as the other end of the workstation's network port. If wifi is to be used, skip this step and configure wifi when the workstation is running. *See section "Configuring the wireless network"*

Connect the barcode scanner to one of the workstation's four USB ports.

Place the barcode sheet "Accept / Reject" on the table in front of the workstation and / or attach to a wall next to the workstation.

Starting the workstation

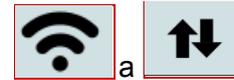
Press the blue / green button next to the power socket on the workstation. The workstation starts and the ON / OFF button flashes during the entire start-up process. At steady light, the workstation is running.



Check that the clock is correct. This indicates that the workstation has established a connection to the internet and via this received the correct time through the NTP protocol. Also check that the network icon does not show a red / yellow triangle that would indicate a communication error.



If the wrong time is displayed or the warning triangle is displayed, there is something wrong with the communication with the internet. Try connecting to another network outlet. Try another network cable. Try connecting via wifi. Test the network socket by connecting laptop to the same and test the internet connection. Contact Zafena.



Configuration

For manual configuration of the receiving system address, the command “CFG-server-ip =” is scanned (below), where after the IP address or network name of the receiving system is entered.



Open the built-in keyboard by pressing the keyboard icon at the top right of the workstation display. Enter the IP address or network name of the receiving server, then press ENTER, EXE or ACCEPT.



Open the built-in keyboard by pressing the keyboard icon at the top right of the workstation display. Enter server port to receiving server and then press ENTER, EXE or ACCEPT.

Languages

There are more languages available in the Zafena POC Workstation. These are activated with barcode commands or memory card replacement. Contact Zafena for support.

Available languages (2021): English, Korean, Swedish, Norwegian, German, Finnish.



Time and time server

Zafena POC-Workstation has an internal clock that is not powered by batteries in the usual sense. Products that contain batteries can cause problems during transport, have an unknown service life and be a problem for the environment. Zafena has therefore developed a battery-free solution, which is based on a supercapacitor, which gives the watch enough power to keep running for more than 30 days. Zafena checks and sets the date and time in connection with delivery, in addition, POC-Workstation is configured to contact an official time server when it is connected to the network, in order to always keep the correct date and time. POC-Workstation can also satisfy the desire to use the customer's own time server.

Example:



Network

Zafena POC-Workstation can connect to any network, both wired and wireless. There are several ways to configure the network settings. The most common is that the POC-Workstation asks the network DHCP server for the settings it needs. The customer's local IT department usually needs the POC Workstation's MAC address, which you will find on the underside of the Workstation, in order to register the device or approve the device communicating via the network.

DHCP Server: All settings required by POC-Workstation are provided by the local network DHCP server.

Wifi: This function is activated via barcodes if you want to use the wireless network instead of the wired one. Wireless function is activated and deactivated via barcodes below:



CFG-wifi=on



CFG-wifi=off

Configure wireless network

To set settings, use command "CFG-" and to set which wireless network / network name the workstation should try to connect to, use command:

"CFG-wifi-ssid =". This is scanned (below) with the barcode reader and immediately after you enter the name of the network with the built-in keyboard.



CFG-wifi-ssid=

Open the built-in keyboard by pressing the keyboard icon at the top right of the workstation display.

Enter your wifi network name and then press ENTER, EXE or ACCEPT.

(It is important that lowercase and uppercase letters are correct)

The password for your wireless network now needs to be set. This is done by scanning the barcode (below) "CFG-wifi-psk =" and immediately after you enter the name of the network with the built-in keyboard.



CFG-wifi-psk=

Open the built-in keyboard by pressing the keyboard icon at the top right of the workstation display. Enter your wifi password and then press ENTER, EXE or ACCEPT.

(It is important that lowercase and uppercase letters are correct)

MAC address

Each network card (wired or wireless) has its own unique MAC address, the IT manager may need to know to allow communication through the network. There are thus different MAC addresses for wired and wireless communication. If wired and wireless communication are used alternately, communication should be opened for both MAC addresses.

You can find the device's MAC address by:

- Look at the label attached under the POC Workstation. (Ethernet only)



- Press  to view the log file. (Both Ethernet and Wifi)

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 icon  top right of the view. When filled, the communication is established with the receiving system. If the link to the network is down, the arrows will appear  over the arrows to alert the user that the network is not available.



To check which network tasks POC-Workstation has been assigned, tap the icon  where you can see the data at the bottom of the log.

```
EDI_LOG_MESSAGE ASTM: client try connect 18080 0
EDI_LOG_MESSAGE 20210107 13:37 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

analysis to go: 670227 ( 87051Mb)
```

Software in ZAF-550 compatibility mode: Zafena POC-Workstation has a Status box on the right of the welcome view that is displayed when the Workstation has been started.

In this box you can read:

- Date & Time Time
- zone (if activated)
- MAC address
- IP address

- Device network name
- Domain Name Server (DNS)
- Contact with Lab / Journal
- system Analyzes that remain until the memory for history (log) is full.

Software

update Zafena's software and operating system in ZAF-552 may need to be updated if new features are required and / or if security updates are required. This can be done in two optional ways:

1. Replacement of Micro SD card.

A new Micro SD card with updated software is sent by mail from Zafena to the customer. The customer's operator switches off the ZAF-552 via the button on the side of the unit. Wait until the button has stopped flashing and is off. Carefully remove the old Micro SD card and insert the new one in the same position. Start the ZAF-552 by pressing the ON / OFF button again and then wait until the Welcome view is displayed together with the correct time and date. The device is now ready for use.

This method clears all local history and all local settings. Re-configure the device by scanning barcodes for server, port and communication protocol.

2. Remote update

Operator scans barcode "ZAF-UPDATE" to initiate a remote update. This requires the device to access the internet through the network to which the device is connected. The command switches over the device view to the system log where downloading the latest software version for ZAF-552. The operator can follow the process by noting the percentage information on the screen. The update takes about 2 minutes from start to these that ZAF-552 is ready for new analyzes.



All settings are saved using this method.

Troubleshooting software

In the event of an error, Zafena can be assisted by reading the system log from the device to understand the error and how to best fix it.

By scanning the barcode "ZAF-TRANSFER-LOG", a copy of the entire system log is activated, which is then compressed and sent to Zafena.

In the system log, all events in the device are recorded, which is very helpful in troubleshooting.

This feature requires the ZAF-552 to have internet access.



The "ZAF-TRANSFER-LOG" function can also be used by the operator to give Zafena access to output data from new meters, sensors and instruments that the healthcare system wishes to have connected to the ZAF-552.

The purpose of the function is to enable the integration of new analytical equipment, without either the equipment being transported to Zafena's facilities or the need for Zafena's staff to visit the place where the equipment is to be installed.

Communication protocols

POC-Workstation has the ability to use one of several standardized protocols to communicate analysis results to EHR / LIS / middleware. Below is a brief description of the most commonly used protocols.

ASTM-LIS2

ASTM, as it is called, is an older, but simple and stable standard.

POC-Workstation sends data structured via ASTM-LIS2, according to the following example: Formatting of the laboratory response data set takes place according to NCCLS LIS2-A2 Vol. 24 No. 33 a revision of ASTM E1394-97.

All ASTM messages are packaged in an ASTM "frame" with modulo 256 checksum, documented in the low-level handshake for ASTM according to NCCLS LIS1-A Vol. 23 No. 7 Before ASTM E1381-02.

Header

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

H.2 | \ ^ & = which characters will be used as delimiters during the transfer,

we will for ease of use only | \ ^ &

H.5 SS291 ^ I485M ^ J113X = ZAF101 (ZAFENA Simple Simon PT product number) ^ SS291 (Indicates which simple simon performed the analysis) ^ I485M (which lotnr the connected simple simon uses) ^ J113X (the lot / version number used in the communication box software for the data transfer).

H.12 P = Production we will only enter P in this field.

H.13 LIS2-A2 = Which standard is used

H.14 20100217162100 = Date and time when this transfer is performed formatted according to AAAAMDDTTMMSS

Patient

P | 1 |||| NKP272M0dVB ||||| |||||

P.2 1 = "Sequence number" We will only transfer one patient per connection so this number will always be 1.

P.6 NKP272M0dVB = LIDnr

Order

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

O.2 1 = Sequence number we will only transfer one order per connection so this number will always be 1.

O.3 NKP272M0dVB = Specimen ID
we will enter LID

no. O.5 3289-6 = Universal test id 3289-6 ar LOINC code for PT

O.6 R = Priority where R = routine we will only enter R in this field.

O.7 = Date and time when the analysis was requested, we will not specify when the analysis was requested as

our system does not handle query calls.

O.12 X = Action code X = specimen or test allready in process. We will not specify anything other than X here. O.16 = "Specimen descriptor". The LIS2-A2 standard lacks a complete list of sample types.

Zafena has chosen to use codes from HL7 "Specimen type". To indicate which sample type was used in the analysis on Simple Simon.

PLAS = plasma (centrifuged anticotagulated sample from citrate tubes / edta)

BLDV = venous blood (slightly diluted in citrate tubes)

BLDC = capillary blood (from the finger)

O.16 example:

capillary blood (from the finger) = BLDC

O | 1 | 80279504 | | 3289-6 ^^ | R ||||| X ||| BLDC ^ ||||| SS639 ^ 524 | F |||||

venous blood (slightly diluted in citrate tube) = BLDV

O | 1 | 80279504 || 3289-6 ^^ | R ||||| | ||| BLDV ^ ||||| SS639 ^ 524 | F |||||

plasma (centrifuged anticotagulated sample from cirtat tube / edta or similar) = PLAS

O | 1 | 80279504 || 3289-6 ^^ | R ||||| X ||| PLAS ^ ||||| | SS639 ^ 524 | F |||||

O.25 SS291 ^ 1234 = Instrument Section Identification

O.25.1 SS291 = which simple simon performed the analysis

O.25.2 1234 = assigned LMC reader number

O.26 F = Final we will only enter F in this field.

Result

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

R.2 1 = Sequence number we will only transfer one result per connection so this number will always be 1.

R.3 3289-6 ^^ = Universal test id 3289-6 is LOINC code for PT

R.4 = Answer in INR with. as a decimal point.

R.5 INR = Unit, we will specify INR as unit.

R.7 N = We will enter N for Normal answer within the measuring range or > when the answer is above 8.0 in.

R.9 F = Final we will only enter F in this field.

R.13 20070803170300 = Date and time the network analysis was performed formatted according to

YYYYMMDDTTMMSS

R.14 SS291 ^ 1234 = Instrument Identification SS291 (which simple simon performed the analysis) ^ 1234 assigned LMC reader number

Terminator

L | 1 | N

L.2 1 = Sequence number we will only transmit one terminator message per connection so this number will always be 1.

L.2 N = Normal termination, We will only enter N in this field.

Poct1A

Document from Clinical and Laboratory Standards Institute POCT01-A2, Point-of-Care Connectivity; Approved standard - the 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. An example of communication is described below.

```
<? xml version = "1.0" encoding = "UTF-8" standalone = "yes"?>
<OBS.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" />
    <NOTE.interpretation_cd V = "N" />
  </OBS>
</PT>
<OPR>
  <OPR.operator_id V = "AUTO" />
</OPR>
<SPC>
  <SPC.type_cd V = "" />
</SPC>
</SVC>
</OBS.R01>
```

FIHR

```
{ "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"}
  }
  ]}]}
```

Views

Users are exposed to different views on the POC Workstation:

Welcome view

The view presented after POC-Workstation is started.

This view provides access to the history and log file, as well as an overview of the meters / sensors that are connected and activated by scanning the instrument tag (unique bar code on the meter). Here you can also see if printer functions are activated, as well as version number, date, time and keyboard.



- History
- System log
- Version
- Date, Time and time zone
- Automatic printing activated
- IPP print activated
- Network status
- Keyboard

Log file

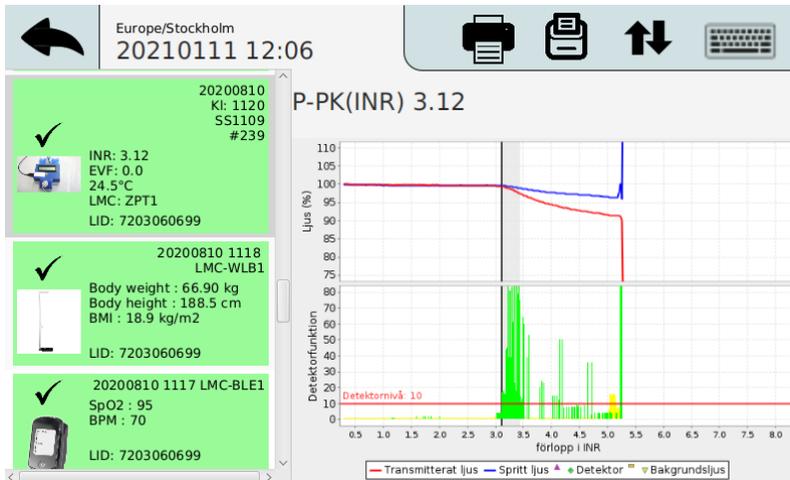
Touch the icon  to read the log file. The system's reactions and any errors the system detects are listed here.

History The

analysis history is accessed by tapping the icon . Here is a list of results and transfers for all analyzes performed with analysis modules connected to the Workstation.

The list of analysis results is mainly for history, traceability and troubleshooting. Översikten är påtagligt rymlig, den kan innehålla resultat från cirka 40 tusen analyser.

Färgkod visar om överföring till LIS/HIS varit framgångsrik (grön), eller inte (orange), eller aldrig företagits (grå). Vissa analytiska moduler överför progressions kurvor över analysreaktionen, dessa kan finnas avbildade i översikten. Samma gäller den skärmbild som visades då analysresultat godkändes eller förkastades. Förflyttning i listan sker antingen med streckodskommandon eller med touch-funktion.

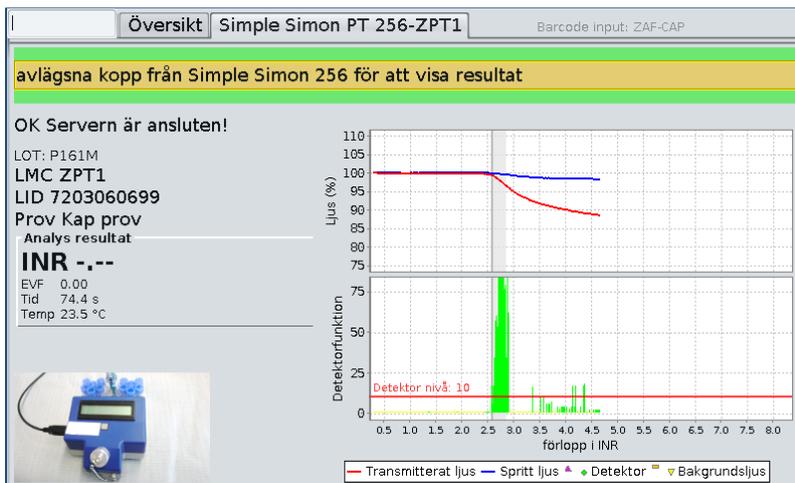


- Analyssvar
- Lista med tidigare analyser
- Markerad analys

Exempel: Historik-vy med mätning med Simple Simon PT Plus

Analys-vy

Den vy där pågående analys presenteras. Detta kan ske på olika sätt baserat på vilken modul som används. Vissa visar grafer och andra bara resultatet av analysen.



- Instruktioner
- Server status
- Mätarens identitet
- Patientens identitet
- Typ av prov
- Reaktionsgraf
- Reaktion
- Klottsignal
- Bakgrundsljus

Exempel: Analys-vy från Simple Simon PT Plus med reaktionsgraf.

Specialfunktioner

Zafena AB utvecklar och tillverkar POC-Workstation. Det öppnar för näst intill obegränsade variationsmöjligheter där kundens önskemål styr.

Tangentbord

Det finns ett inbyggt tangentbord med touch-funktion som kan aktiveras och användas direkt på

POC-Workstation. Denna funktion aktiveras via ikonen  högst upp till höger på Arbetsstationens vy. Via denna funktion hittas även knappar för "Accept", "Decline" och "Print".

Touch-funktion

Zafena POC-Workstation har tryckkänslig display. Det går att använda fingertopparna för att orientera bland Arbetsstationens olika vyer - som ett alternativ till streckkodsläsaren.

Tid

POC-Workstation kan konfigureras att fråga sjukhusorganisationens tids-server vad klockan är för att synkronisera tiden. Finns det ingen tidsserver i det befintliga nätverket kan tiden ställas manuellt. Inställningarna upprätthålls av Arbetsstationens klockbatteri när Arbetsstationen är avstängd.

Fjärrkalibrering

(Detta gäller ännu endast analysmodulen Simple Simon PT)

Vid byte av reagens LOT finns det möjlighet att fjärrkalibrera Simple Simon Plus instrument. Läsaren behöver inte servas och kalibreras av Zafena vid LOT byte, utan hanteras enkelt av användaren. Genom att skanna några streckkoder i valfri ordning kalibreras läsaren till en ny LOT reagens och övrigt förbrukningsmaterial. Dessa streckkoder levererar Zafena när det är aktuellt för LOT byte.

Auto-accept

'Auto-accept' är en funktion som eliminerar kravet att operatören ska godkänna analysen innan den skickas in till det centrala systemet. Denna funktion aktiveras eller avaktiveras genom nedan streckkoder.



CFG-AUTOACCEPT=on



CFG-AUTOACCEPT=off

Det går även att konfigurera 'auto accept' per ansluten instrument-typ genom att lägga till instrumentbeteckningen i streckkoden. Exempel (XXXX representerar LMC-tagen):



CFG-AUTOACCEPT-XXXX=on

Skriv ut streckkoder

Det går att ansluta en 'Brother streckkodsskrivare till POC-Workstation och via en speciell streckkod aktiveras möjligheten att skriva ut text till streckkoder (CODE128). Finns det behov av en streckkodsskrivare i organisationen, kontakta Zafena så skickar vi den nödvändiga utrustningen samt instruktioner. Funktionen streckkodsskrivare nås genom att läsa av streckkoden:



ZAF-BARKOD

Efter att denna funktion är använd, behöver arbetsstationen startas om för att komma tillbaka till "analys-läge".

Skrivare

Kvittoskrivare

Arbetsstationen har en inbyggd skrivare för utskrift av resultat efter analys. Denna funktion aktiveras via streckkod CFG-print



CFG-print=on



CFG-print=off

Internet Printing Protocol

'Internet printing protocol' eller ipp är en funktion som möjliggör utskrift på lokala nätverksskrivare utan behov av speciell drivrutin för skrivaren. Den hjälper molnbaserade journalsystem att nå interna skrivare på kundens lokala nätverk, för att genom arbetsstationen skicka utskrifter i form av PDF-dokument. Man behöver känna till IP-adressen till den skrivare dit utskrifter ska skickas.

Konfigurera önskad skrivare genom streckkoden nedan:



CFG-ipp-printer=

(Exempel IP-address)



192.168.168.191

Aktivera eller avaktivera 'ipp' med streckkoderna nedan:



CFG-ipp=on



CFG-ipp=off

Utseende

Från och med 2020-09 infördes ett nytt användargränssnitt. Det går att växla mellan det gamla och det nya användargränssnittet genom att aktivera FX. Detta görs genom streckkoderna nedan:



CFG-FX=on



CFG-FX=off

Operatörs-ID

Behovet att kontrollera vem som har tillåtelse att utföra analys varierar. Därför finns möjlighet att ställa kraven olika per ansluten instrument-typ, samt olika hårda krav per instrument-typ. Streckkoden som ställer in detta är indelad i två delar; den första berättar vilken instrument-typ det gäller [CFG-ZPT1-OPER=required] (Simple Simon PT). Den andra delen [CFG-ZPT1-OPER=**required**] ställer in hur strängt kravet ska vara.

Registrering och kontroll av operatör finns i tre nivåer;

- *'optional'*
Denna nivå ger möjlighet att lägga till operatörs-ID till analysresultatet som skickas in till centralt system, men det är inget tvång. Denna nivå kan vara ett bra alternativ att börja med för att vänja personalen att lägga till sitt ID till varje analys.
- *'required'*
Denna nivå kräver att ett godkänt operatörs-ID skannas efter varje omstart av arbetsstationen.
- *'reenter'*
Denna nivå kräver att ett godkänt operatörs-ID skannas vid varje analys.

En lista med godkända operatörer per analyt kan läggas in lokalt per arbetsstation, men kan också mottagas från en Data manager eller LIS som har en sådan funktion. Kontakta Zafena för att utforma streckkoder med inställningar som passar era behov.

QC - Kvalitetskontroll

Kontroll av analytisk kvalitet utförs med jämna mellanrum för att verifiera att utrustningen analyserar rätt. För att separera QC-körningar mot vanlig patient analys i det mottagande systemet är det vanligt att utse några LID (Lab-ID) som är dedikerad åt just kontroller. Streckkoden för att ange vilka LID som gäller QC är indelad i två delar;

[CFG-ZPT1-QC=XXXX]

'ZPT1' står för vilken ansluten mätare inställningen ska gälla och 'XXXX' representerar det LID som är dedikerat för QC.

Det går att registrera fler LID genom att separera dem med komma (,).

Exempel:

CFG-ZPT1-QC=990153,990159,990160,990154,990165

Kontakta Zafena för att utforma streckkoder med inställningar som passar era behov.

Ljud

Den inbyggda högtalarens ljudnivå kan ställas in genom nedan streckkoder. Inställningen går från 0, som är helt avstängd, till 1 som är högsta volym.



Uppdatera

Mjukvaran i ZAF-552 behöver inte uppdateras. Detta sker endast för nya funktioner eller nya analyser önskas läggas till.

Uppdatering kan ske på två sätt:

- Byte av Micro SD kort i arbetsstationen.
Ett nytt micro SD kort skickas per post. Arbetsstationen stängs av. Kortet som sitter i byts mot det nya. Arbetsstationen startas. Klart.
- Uppdatering över internet.
Arbetsstationen kan uppdateras över internet genom att [ZAF-UPDATE] skannas på den arbetsstation som behöver en uppdatering. Ingen uppdatering "tvingas" ut, utan alla uppdateringar aktiveras av kunden.

Ord & förkortningar

DHCP

Domain Host Control Protocol

Denna server-tjänst informerar anslutna nätverksenheter om vilka nätverksinställningar enheten ska använda sig av. IP-adress, Nätmask samt Gateway enheten ska använda.

USB

Universal Serial Bus

Standardiserad anslutning för streckkodsläsare, analytiska mätare, tangentbord osv.

DNS

Domain Name Server

Denna server-tjänst informerar anslutna nätverksenheter om vilka IP-adresser som är kopplade till vilka nätverksnamn. Man kan se det som nätverkets telefonkatalog.
(Ex. www.test.se = 23.14.10.11)

NTP

Network Time Protocol

Denna server-tjänst informerar anslutna nätverksenheter om vilken tid det är som gäller.

LIS / LIMS

Laboratory Information System / Laboratory Information Management System

Detta är ett mottagande system för laboratoriesvar, som sedan skickar resultaten in i patientens journal.

HIS

Hospital Information System

Detta beskriver hela sjukhusets informationssystem där alla systemets tjänster inkluderas.

EHR

Electronic Health Record

Beskriver patientens digitala patientjournal.

MAC-adress

Media Access Control-adress

Alla nätverksenheter har unika identifikationsnummer vid kommunikation över nätverket.
(Exempel: EB:27:AA:45:C3:F2)

IP-adress

Internet Protocol adress

En adress som kopplas till nätverksenhetens unika MAC-adress. Ett lånat identifikations-ID för att kommunicera genom nätverket.

Laboratoriet

Arbetsflödet är en av de viktiga delarna i ett laboratorium. Som ett välsmort urverk, flödar prover in och analysresultat ut ur verksamheten. Värdet i att dessa analysresultat digitaliseras beskrivs av Equalis (Swedish EQA; <https://www.equalis.se/en/>): *“Eliminera felskrivningar och säkra analysresultat”* Typiskt förekommande analyser; CRP, INR, ESR, Hb, glukos, urinsticka, HbA1C.....



Läkarkontoret

När det är den personliga kontakten med patienten som står i centrum för besöket, avlastas läkaren genom att mätresultaten digitaliseras rakt in i EHR/LIS. Istället för att ägna mötestid åt att anteckna eller memorera analysresultat kan läkare och patient i större utsträckning ägna mötestiden åt väsentligheter. Typiskt förekommande analyser; blodtryck, längd, vikt, temperatur, puls, syresättning, spirometri.....



Ambulansen

I denna miljö är tid avgörande. Att i realtid digitalisera akuta analysresultat och kommunicera dessa med sjukhusets specialister kan förbättra den ambulerande akutvården. Typiskt förekommande analyser; blodtryck, temperatur, CRP, D-dimer, puls, syresättning, EKG



Appendix A

Instrument specifika inställningar

Simple Simon PT

Simple Simon PT är en våtkemisk metod enligt Owren för att analysera koagulationstid presenterat i INR.

Simple Simon UA

Simple Simon UA avläser urinstickor av märket CYBOW och HealthMate.

“Trace” är första detektionsnivån för vissa av analyterna på urinstickor från CYBOW och HealthMate. Vissa marknader godtar inte 'trace' som svar.

Detta kräver att utrustningen rapporterar 'trace' som, antingen 'negativt' eller 'positivt'. Kontakta Zafena för att utforma streckkoder med inställningar som passar era behov.

Om 'trace' tolkas som 'negativ' finns möjlighet att justera detektionsnivån för 'positiv' Denna möjlighet kan exempelvis användas för att minska eller öka flödet av patienter som behöver vidare diabetes utredningar som resultat av detektion av glukos i urin.

Kontakta Zafena för att utforma streckkoder med inställningar som passar era behov.

Utskrift

Det finns möjlighet att bestämma ordningen som resultaten skrivs ut via den inbyggda skrivaren. Kontakta Zafena för att utforma streckkoder med inställningar som passar era behov.

Enheter

Presentationen av resultat kan ske i SI-enheter eller Arbiträra enheter.

Detta ändras genom nedan streckkoder:

[CFG-DUR1-UNITS=ARB]



CFG-DUR1-UNITS=ARB

[CFG-DUR1-UNITS=SI]



CFG-DUR1-UNITS=SI