

TECAM SMART



Software designed and programmed by Christian Baumgartner, Germany
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1. Installation and Uninstall

1.1. Intended use

TECAM SMART is intended as a tiny LIS.

It is an optional tool to interface with Teco Coatron M and X series and with local laboratory information system (LIS). It is intended to receive results from instrument and forward to LIS as well as receive patient orders from LIS to forward to instrument.



TECAM SMART is not intended nor classified as a medical device software and not subjected to any regulations. The installation and operation is optional and under own responsibility. Read next chapter for further details



Capacity of database:

The database is limited to max. 110.000 results to ensure good performance even on PC with low resources. If the data exceed the limit, then TECAM SMART will automatically delete the oldest 10.000 results without any backup or warning messages. Activate database backup function, if you require older results (read chapter 5).

1.2. Medical Software Classification

- TECAM SMART is optional and not required for the intended use of instrument.
- TECAM SMART is not pre-installed on any hardware nor designed to run on a special hardware.
- TECAM SMART can't create nor manipulate result data
- TECAM SMART doesn't create any information for medical use (diagnostic/therapy)
- TECAM SMART does not change the use of instrument
- TECAM SMART can't receive nor forward invalid data caused by transmission errors, because of transmission protocols of instruments and ASTM1394 standard.

Meddev 2.1/6 article f.1, LIS is not qualified as medical software
classify LIS

TECAM software is not qualified as "Medical Software" and not underlying CE registration.

1.3. Requirements

Windows	Windows 7 or 10 (32 bit and 64 bit) 1.0GHz or faster processor, 1GB of RAM, 1GB of available hard-disk space, 1280x720 screen resolution or greater
Interface:	RS232 (if not supported, use USB to serial adapter and set virtual comm port number between com1 – to 15
Cable:	2x Female Sub D9, crosslink. Pin 2 to 3; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected.
Capacity of Database	110.000 results



The database is limited to max. 110.000 results to ensure good performance even on PC with low resources. If the data exceed the limit, then TECAM SMART will automatically delete the oldest 10.000 results without any backup or warning messages. Activate database backup function, if you require older results (read chapter 5).

1.4. Installation

Start "SETUP.EXE" from the CD or download latest version from internet. Ask local distributor for URL link. The Setup will install all required driver for database access. Your Antivirus software may give a warn. Exclude TECAM SMART from antivirus sonar protection and continue setup.

1.5. Uninstallation

User can remove the program from Windows just like other programs: From Windows' Control Panel select "Add or Remove Programs", Select TECAM SMART and click "Change/Remove" button.

1.6. License & Registration

It is allowed to install TECAM SMART more than one time. The license is always locked to the serial number of the instrument. This license can be installed on any computer, but will work only with the enabled analyser. You will be asked for a license after first start.



Enter correct fingerprint and activation code or import license file. Contact your local distributor if you require a license. It will be sent via email as soon as your request is confirmed by distributor. This process can take several days.

Invalid license message is shown if the activation code is invalid or if the serial number of instrument is not activated.

1.7. Tryout Mode

You can cancel the registration. In this case TECAM SMART will switch to Tryout mode. The software is fully functional, but allows only limited numbers of results and orders. For more information see next chapter.

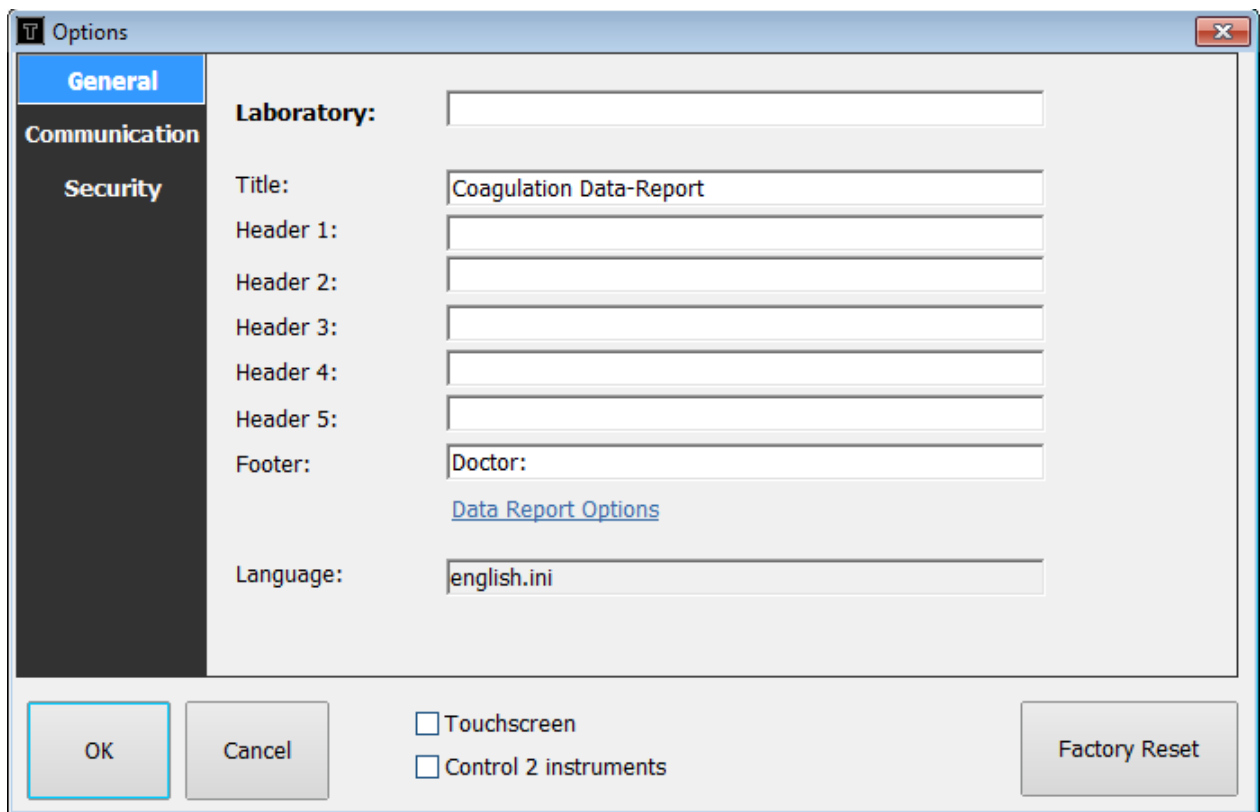
1.8. Compare of licenses

Features	Smart	TryOut
Support of Touchscreen	Yes	Yes
Receive result from analyser	Yes	3x
Receive reaction curve	Yes	Yes
Receive barcode from analyser	Yes	Yes
Save result to database	Yes	Yes
Print cumulative reports	Yes	Yes
Send result to LIS over RS232	Yes	1x
Send result to LIS over TCP/IP	Yes	1x
Result database	Yes	Yes
Patient database	Yes	Yes
Statistical analyze (QC) (Levey Jennings + Westgard)	Yes	Yes
Export data to PDF,XLS, HTML	Yes	Yes
Multi language	Yes	Yes
Test calibration management	Yes	Yes

2. Configuration

	Click on this icon to open the option menu. (Requires login as ADMIN !)
	Click on this icon to connect with instrument. Open menu Help/Logfile RS232 in case of problems.
	Click on this icon to connect with LIS. Open menu Help/Logfile ASTM in case of problems.

2.1. General options



Options

General

Communication

Security

Laboratory:

Title:

Header 1:

Header 2:

Header 3:

Header 4:

Header 5:

Footer:
[Data Report Options](#)

Language:

☐ Touchscreen ☐ Control 2 instruments

Report options: see chapter [Create a report](#) on page 35

Language: Select language file

Touchscreen: Enable , if your display supports touchscreen function.

Control 2 instrument Allows top start TECAM SMART twice and control two instruments with one PC

Factory Reset: Reset TECAM SMART to default and reset table "method" in the database.

2.2. Data report options

See chapter 5.5 *Create a report*

2.3. Communication options

Options

General

Communication

Security

☒ TCP/IP ☐ RS232 (Xon) ☐ RS232 (Xoff) ☐ None

Analyser:

Server-IP: 127.0.0.1

Port: 1005

TimeOut(sec): 10

NAK Repeats: 3

Comm Port:1 Auto

☐ print result automatically

☒ transmit result-1 (s,E)

☒ transmit result-2 (% ,mg/dL)

☒ transmit result-3 (INR)

☐ transmit curve

☒ use patient information from host

OK Cancel ☐ Touchscreen Factory Reset

Mode of LIS: TCP/IP: Connect TECAM SMART to laboratory information system via network. The protocol is ASTM over IP, which allows sending results to LIS and receiving order from LIS (bidirectional communication)

RS232 (ON): Connect TECAM SMART to laboratory information system via RS232. The protocol is TECAM SMART, which allows sending results to LIS and not receiving order from LIS (unidirectional communication). The LIS must acknowledge each result with "ACK" message. Transmission errors are not detected in this mode.

RS232 (OFF): Same as RS232(On), but The LIS must "not" acknowledge each result. Transmission errors are not detected in this mode.

NONE: No LIS is connected

Analyser (*): Enter ID number of instrument. This allows the LIS to identify the instrument.

Server-IP(*): IP address of LIS server

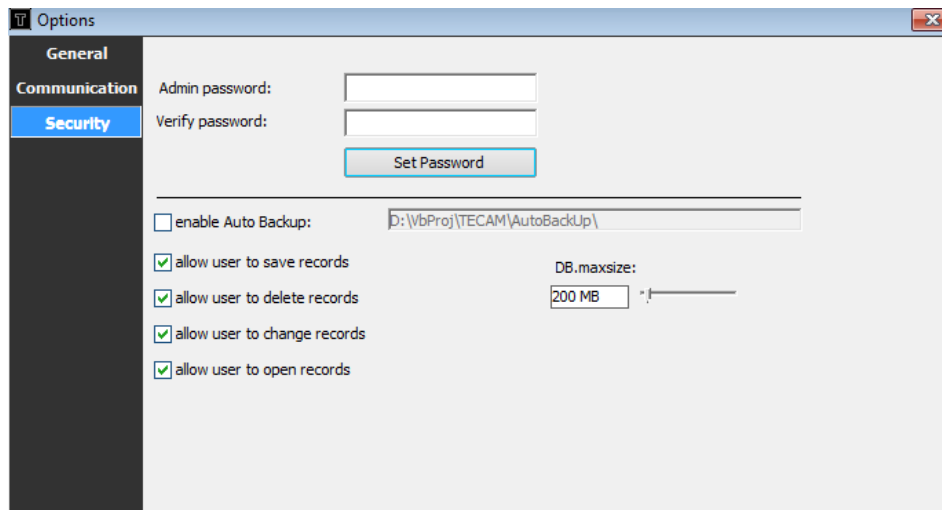
Port(*): Port number of LIS server. Ensure , router and firewall support port forwarding

TimeOut(*): Transmission error is generated, if LIS does not response within time

- NAK repeats^(*): TECAM SMART repeat data transmission in case of transmission error. After X-repeats it will stop and an error message is generated, if LIS do not response within time
- Com Port 1: RS232 port number for instrument communication.
 Auto: TECAM SMART will search for instrument at port Com1 to 15.
 ComX: Set to ComX, if you know the comm port
- Com Port 2: RS232 port number for serial LIS communication (mode = RS232(ON) or OF)
 Protocol: Setup to instrument, which is connected with TECAM SMART
- Print result automatically:
 Result will be printed automatically and immediately when received from analyzer. Activate this function, if you don't use the integrated printer of instrument.
- Request host automatically^(*):
 TECAM SMART will request patient order information from LIS , when patient-ID numbers are received from instrument.
- Transmit result 1,2,3 ^(*):
 Defines which result should be forward to the LIS. The instrument sends upto 3 results per method to TECAM SMART. For PT eg. It will send sec + % + INR.
- Use patient information from host:
 TECAM SMART will request patient name from LIS , when patient-ID numbers are received from instrument. Current name stored in the local database will be overwritten.

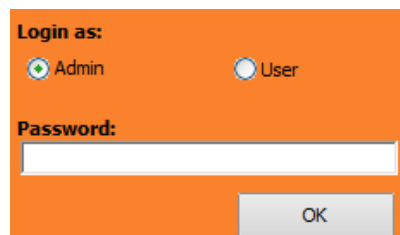
^(*) Only required for mode "TCP/IP"

2.4. Security options



Admin password: Keep it blank , if no admin is used.

TECAM SMART will ask for login at program start, if password is not blank



- Enter Admin password to login as administrator or
- Change to User and keep password blank.

Delete file "TECAM SMART.ini" in the installation folder to reset the admin password

About Administrator and User

Only the admin is allowed to open and change options menu.

Enable Auto Backup: TECAM SMART will back up the database of recent 7 days . This may take several seconds during program start, especially if database is more than 100MB. Deactivate Auto Backup , if database is saved by external backup software.

Allow user to save records: Only ADMIN can save new results, if activated

Allow user to delete records: Only ADMIN can delete results in the database, if activated

Allow user to change records: Only ADMIN can change results in the database, if activated

Allow user to open records: Only ADMIN can open and access database, if activated

DB maxsize: Limit the size of database.100 MB is space for around 10.000 results. The size can be changed any time from 50 upto 3000MB. If you set the limit below current size of database, then TECAM SMART will ask at next start to delete the oldest results in database and compress database.

2.5. Connecting Coatron

TECAM SMART connect automatically at start up.

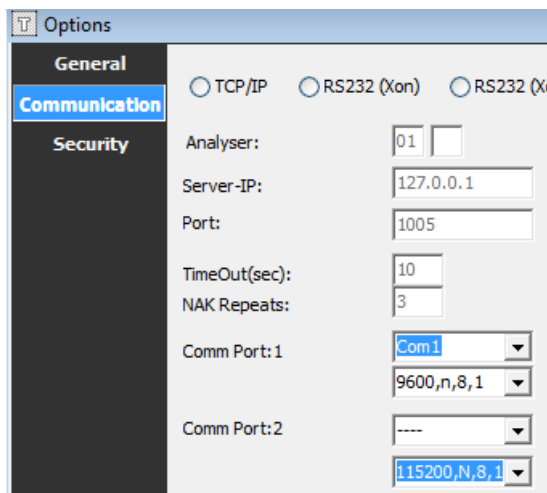
Manual (dis)connect

OFFLINE LIS OFF

- Click on statusbar “offline” to connect with instrument
- Click on statusbar “LIS off” to connect with LIS

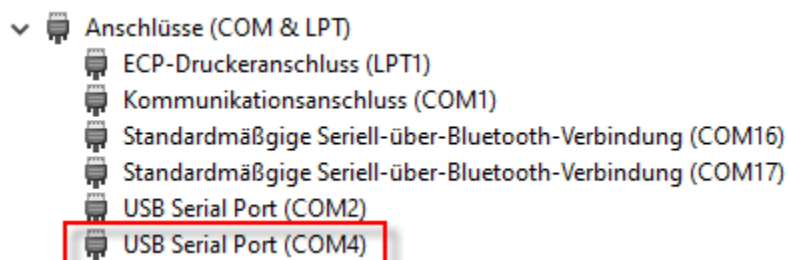
If auto connection failed:

- Check serial port setting at Windows siode (see below , trouble shoot)
- Open option menu, register “Communication”.
- Set Comm Port 1-15 or auto
- Set Baud rate to
 - 1200 for Coatron M1
 - 9600 for Coatron M2, M4
 - 115200 for Coatron X



Trouble shoot:

- Open the Windows device manager and check com port settings

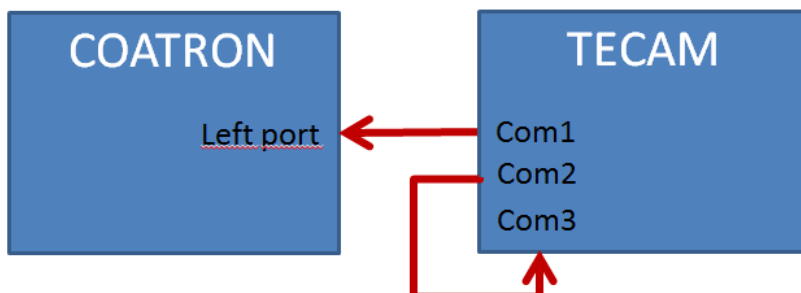


On this PC there 6 serial ports installed used for Bluetooth and others. Com4 is the coagulation analyzer. Set TECAM SMART interface to Com4 instead of Auto.

2.6. Connecting to LIS over RS232

Forward results to LIS over RS232 line. Detailed information about TECAM SMART protocol and format of result message can be provided on request.

Cabling:

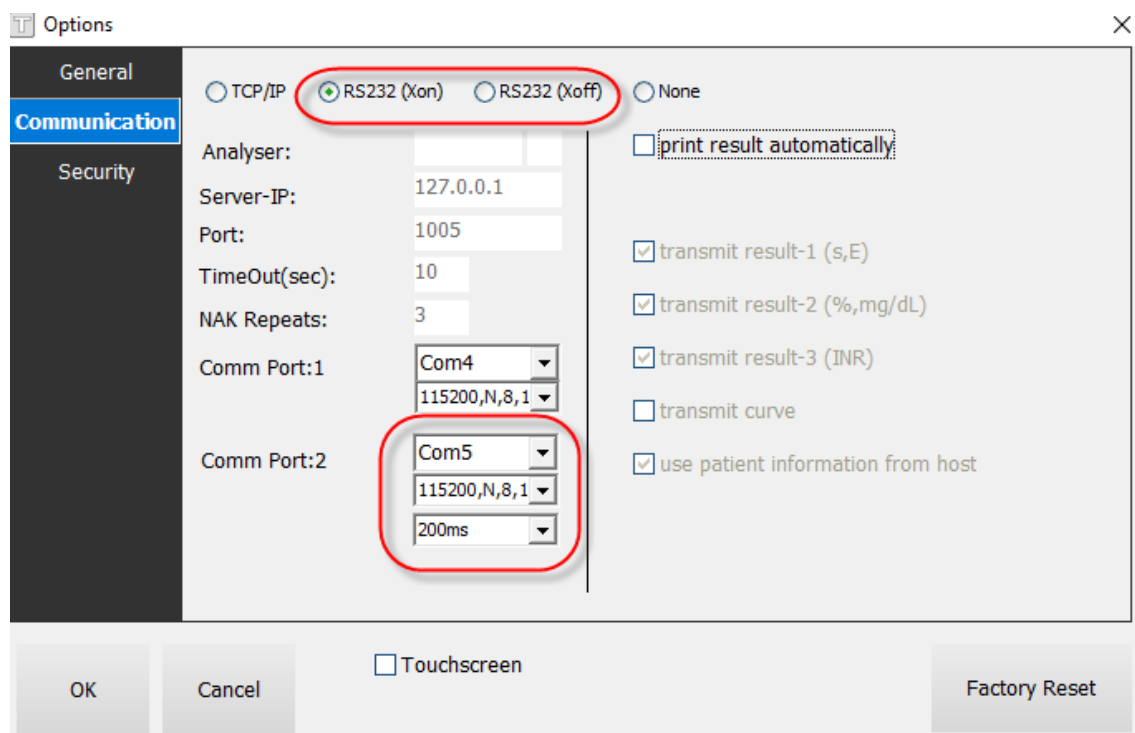


You need 3 comm ports on TECAM SMART side, if LIS and TECAM SMART is installed on same personal computer.

In this example, TECAM SMART talk to Coatron over Com1 and with LIS over Com2.
The input port of LIS software must be configurated as “Com3”

Port settings:

Open option menu communication and set Comm Port-2 as below



- TECAM SMART sends results to LIS over Com5, 115200Baud without handshaking
- TECAM SMART waits 200ms before sending next result

RS232 (Xon): Data transmission with handshaking. Each message must be acknowledged or is repeated max. 3x in case of transmission errors.

STX = ASCII (2)	Start of transmission
ETX = ASCII (3)	End of transmission
DLE = ASCII (16)	DATA LINK
ACK = ASCII (6)	Acknowledge
NAK = ASCII (21)	No Acknowledge

TECAM SMART connect to LIS:

TECAM SMART send: STX DLE ETX

LIS must answer: STX ACK ETX or any other message

TECAM SMART send result LIS:

TECAM SMART send: STX <Result> ETX

LIS must answer within 3sec: STX ACK ETX -> next result

STX NAK ETX -> repeat result

More information about communication and protocol can be read in document "Interface RS232 TECAM SMART".

RS232 (Xoff): Data are sent without any handshake. Data transmission errors are not recognized or handled.

2.7. Connecting to LIS over IP

You can connect fully bidirectionally to any laboratory information system (LIS), which support the ASTM1394 protocol over IP. This means results can be forward to LIS as well as patient orders and information can be received from LIS.

The screenshot shows the 'Options' dialog box with the 'Communication' tab selected. The 'TCP/IP' radio button is highlighted with a red circle. The configuration fields are as follows:

Field	Value
Analyser:	01
Server-IP:	127.0.0.0
Port:	1005
TimeOut(sec):	10
NAK Repeats:	3
Comm Port:1	Auto

On the right side, the following checkboxes are checked:

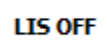
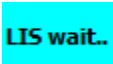
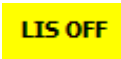
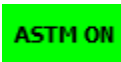
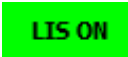
- ☒ transmit result-1 (s,E)
- ☒ transmit result-2 (%mg/dL)
- ☒ transmit result-3 (INR)
- ☒ use patient information from host

At the bottom, there are buttons for 'OK', 'Cancel', 'Touchscreen', 'USB Barcode Scanner', and 'Factory Reset'.

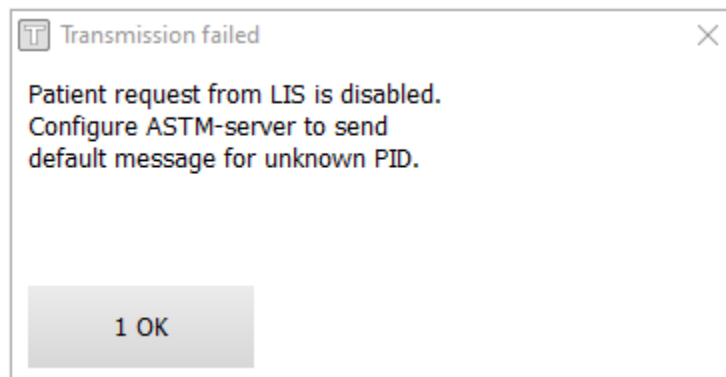
- Connect PC to LAN network
- Enter Analyser-ID: 123^01 (e.g. instrument 123 at station 01)
- Enter IP address of LIS server (local host = 127.0.0.1)
- Enter Port number of LIS server.
- Allow port forwarding at your router and firewall
- Open TECAM SMART database menu and click on methods and edit correct HOST-ID or ask LIS administrator to update LIS method ID numbers to TECAM SMART default values (e.g. PT ID= "1")
- Open menu Help/Logfile ASTM in case of problems.

Checking communication with LIS:

- (1) Set TCP/IP
- (2) Check options "use patient information from host"
- (3) Exit options menu. TECAM tries now to connect with LIS-Server.
- (4) Open the log file in case of problems. Select main menu "HELP\LOG LIS"

	LIS connection is disabled. Click on icon to enable.
	TECAM tries to connect with LIS
	LIS connection failed. Check TCP/IP settings, increase TimeOut setting, allow port forwarding at your router or firewall, open LIS logfile for more help.
	Sending results to LIS and request patient information from LIS is active.
	Only sending results to LIS is active. Configure ASTM-Server to send a default message for unknown PID.

Patient request is disabled:



Reason of message:

TECAM request the name for patientID "123456789000", but receives no answers.

How to solve:

Configure the LIS to return a dummy message for unknown patients.

(De)activate patient request during startup:

Enter menu Option and (un)set option "use patient information from host".

2.8. ASTM Logfiles

Select main menu "HELP\LOG LIS"

Below are typical examples:

Connecting to LIS:

- TECAM connected to ASTM-Server 127.0.0.1 after 547ms
- Request of patient PID='0' failed. Server does not response.

TECAM SMART V7.07.3

ASTM, Server=127.0.0.1:1005

30.03.2022 14:38:06: Analyzer= 01^ -- Connection request IP=127.0.0.1:1005 -----

-- Connection complete after 547ms --

===== Request patient PID=0

0ms: TX <ENQ>

63ms: RV ACK

63ms: TX <STX>1H|\^&|||01^|||||P|97|20220330143806<CR><ETX>F6<CR><Lf>

110ms: RV ACK

110ms: TX <STX>2Q|1|^0<CR><ETX>4A<CR><Lf>

125ms: RV ACK

125ms: TX <STX>3L|1|N<CR><ETX>06<CR><Lf>

141ms: RV ACK

141ms: TX <EOT>

2578ms: TX <EOT>

-- Error TimeOut -- : ASTM Server does not response to request PID='0'.<CR>Configure server to send default message for unknown PID.

Send result to LIS:

Analyser sends Header:

4212ms: Analyser <ENQ>

4243ms: Host <ACK>

4243ms: Analyser <STX>1H|\^&|||01^|||||P|97|20150204130006<CR><ETX>EC<CR><Lf>

4243ms: Host <ACK>

Analyser sends patient information:

4243ms: Analyser <STX>2P|1||Musterfrau^Anne^^|Musterfrau^Anne|||<CR><ETX>7B<CR><Lf>

4259ms: Host <ACK>

4259ms: Analyser <STX>3O|1|131210-0026||R<CR><ETX>9E<CR><Lf>

4259ms: Host <ACK>

Analyser sends result-1 = 13.9s:

4259ms: Analyser <STX>4R|1|^PT^^1|13,9|s|0^0|*||W|||20131210144731<CR><ETX>BF<CR><Lf>

4259ms: Host <ACK>

4259ms: Analyser <STX>5M|1|1||*A<CR><ETX>4F<CR><Lf>

4259ms: Host <ACK>

Analyser sends result-2 = 122,3%

4259ms: Analyser <STX>6R|2|^PT^^1|122,3|%|70^120|*||W|||20131210144731<CR><ETX>39<CR><Lf>

4259ms: Host <ACK>

Analyser sends manufacturer information:

4259ms: Analyser <STX>7M|2|1||*A<CR><ETX>52<CR><Lf>

4259ms: Host <ACK>

4259ms: Analyser <STX>0L|1|N<CR><ETX>03<CR><Lf>

4259ms: Host <ACK>

4259ms: Analyser <EOT>

Request an order for patient-ID = "20100001" from LIS:Trace files:

Analyser sends Header:

34352ms: Analyser <ENQ>

34399ms: Host <ACK>

34399ms: Analyser <STX>1H|\^&|||01^|||||P|97|20150203105442<CR><ETX>F1<CR><Lf>

34399ms: Host <ACK>

Analyser sends Request for Patient-ID "20100001"

34399ms: Analyser <STX>2Q|1|^20100001<CR><ETX>9E<CR><Lf>

34399ms: Host <ACK>

34399ms: Analyser <STX>3L|1|N<CR><ETX>06<CR><Lf>

34399ms: Host <ACK>

34399ms: Analyser <EOT>

LIS sends header

36411ms: Host <ENQ>

36411ms: Analyser <ACK>

36427ms: Host <STX>1H|\^&|||01^<CR><ETX>18<CR><Lf>

36427ms: Analyser <ACK>

LIS sends patient information

36442ms: Host <STX>2P|1|||Mustermann^John^^|||1.1.1950<CR><ETX>87<CR><Lf>

36442ms: Analyser <ACK>

LIS sends order information

36458ms: Host <STX>3O|1|20100001|^1^3^4|R<CR><ETX>A3<CR><Lf>

36458ms: Analyser <ACK>

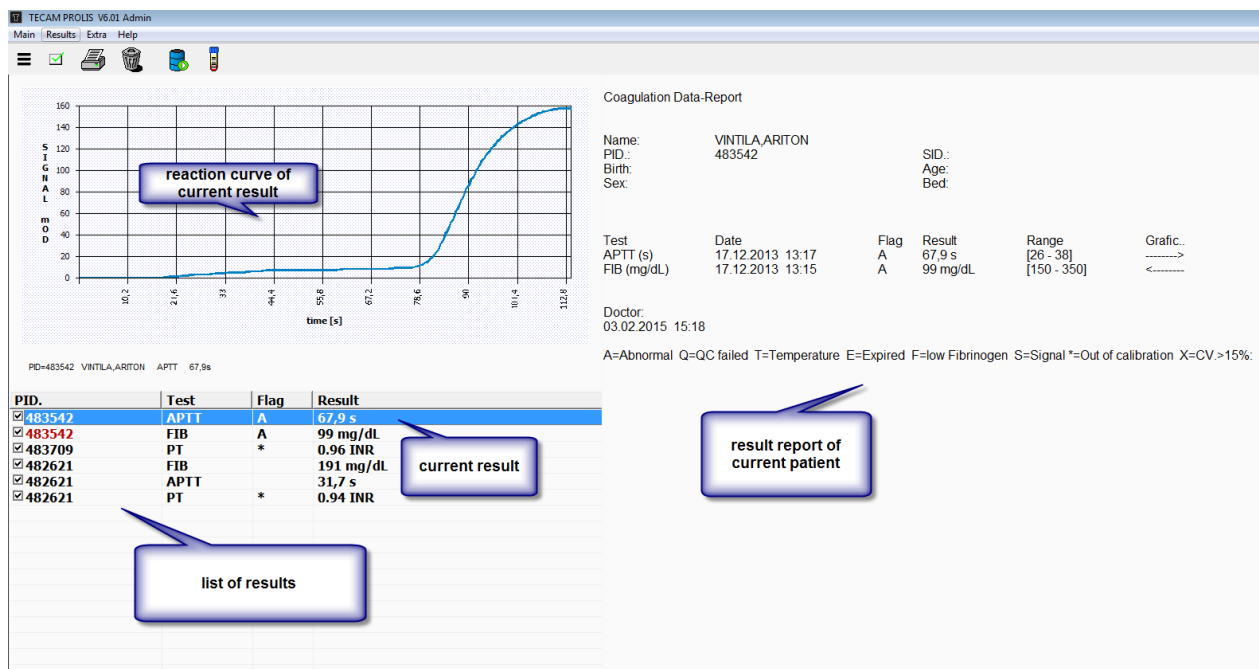
LIS send manufacturer information

36473ms: Host <STX>4L|1|N<CR><ETX>07<CR><Lf>

36473ms: Analyser <ACK>

36473ms: Host <EOT>

3. Result Screen



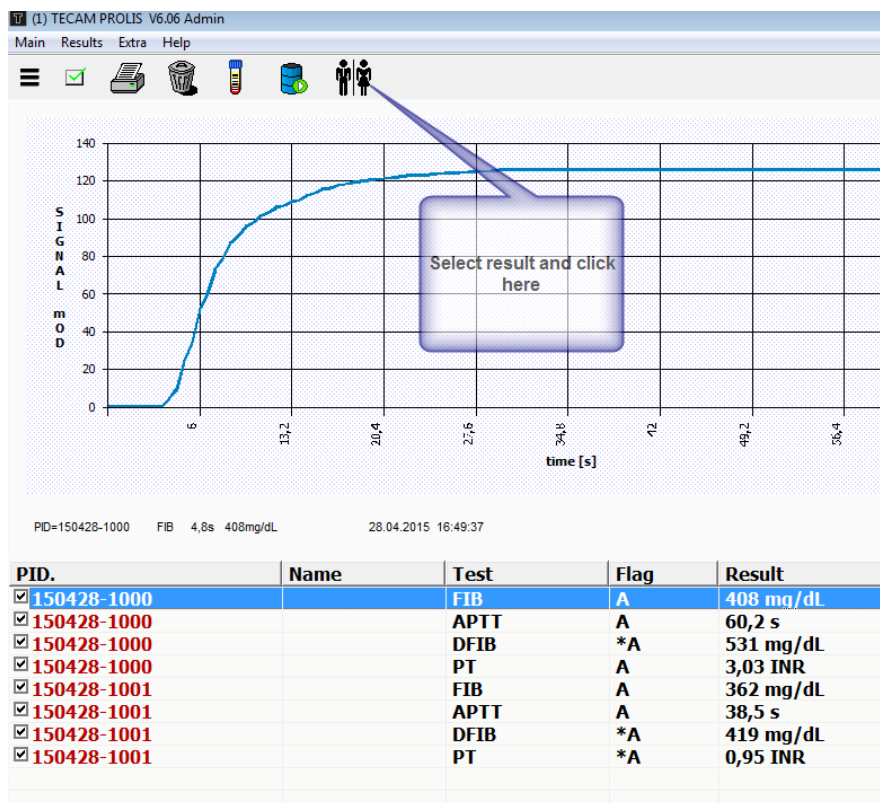
Menu Result:

- Load From Database: Open database and reload results
- Send to host: Send all selected results to LIS
- Remove from list: Remove all selected results from list
- Select: Select all, none or invers results
- Print: Print selected results

Menu Extra:

- Show reaction curve with auto scale: Zoom automatically or manually
- Save, Copy, Print: Save to file, copy to clipboard or print
- Report all units: Display all units in report (e.g. Sec + INR + %). Specific units can be selected in "Database/Methods" for patients and "Database/QC file" for controls,
- Receive average: Show only mean values in report

3.1. Input patient information



Add new patient record

Patient-ID: 150428-1000

Name: Mustermann, Max

Date of birth:

Department:

Sex:

Bed:

☐ QC

OK Cancel Sync

Enter patient information or select "SYNC" to receive it from LIS

3.2. Input ticket information

Voucher:

Included to each box of cuvettes or rinse solution contains.

Required to create a ticket

Ticket:

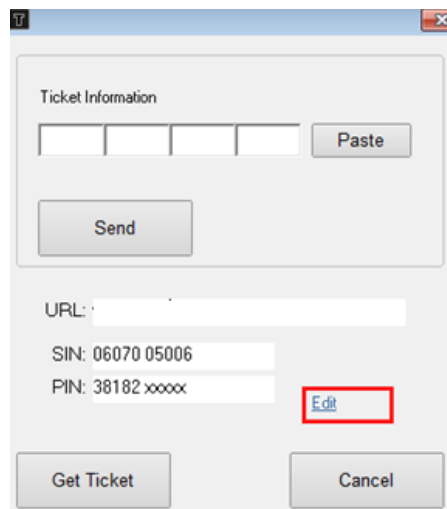
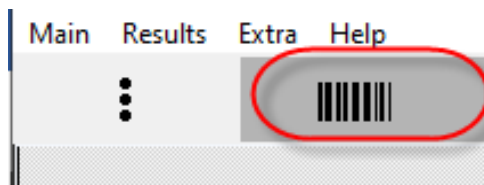
Includes information to

- Activate of box of cuvettes
- Activate of box of rinse tanks
- Reset service interval

The ticket itself can used only one time and one instrument.

Create a ticket:

- 1) Login to Ticket system www.xxxxxx-reg.com. The URL link can be seen during bootup of analyser or when click on barcode icon (see b)
 - a. Connect TECAM SMART with device
 - b. Click on barcode icon
 - c. Use QR code with your mobile device or select "Get ticket", if TECAM SMART is connected to internet



2) Enter Voucher information (VIN + PIN)

The first screenshot shows a 'Voucher' screen with the following information:

Voucher
VIN: 66100 10299
PIN: 75854 77760

The second screenshot shows the 'Create Ticket' screen with the following information:

Create Ticket
Vin: 66100 10299
Pin: 75854 xxxxx
Buttons: Login, Create Ticket

3) Create ticket and transfer to instrument

The first screenshot shows the 'Ticket Information' screen with the following information:

Ticket Information
Product: Clean-B 1.25L
Sin: 0607005006
Quantity: 9
Code: B7G2 G666 012G H30L
Barcode: [Barcode]
Buttons: Save ticket to PDF, Copy Code to Clipboard

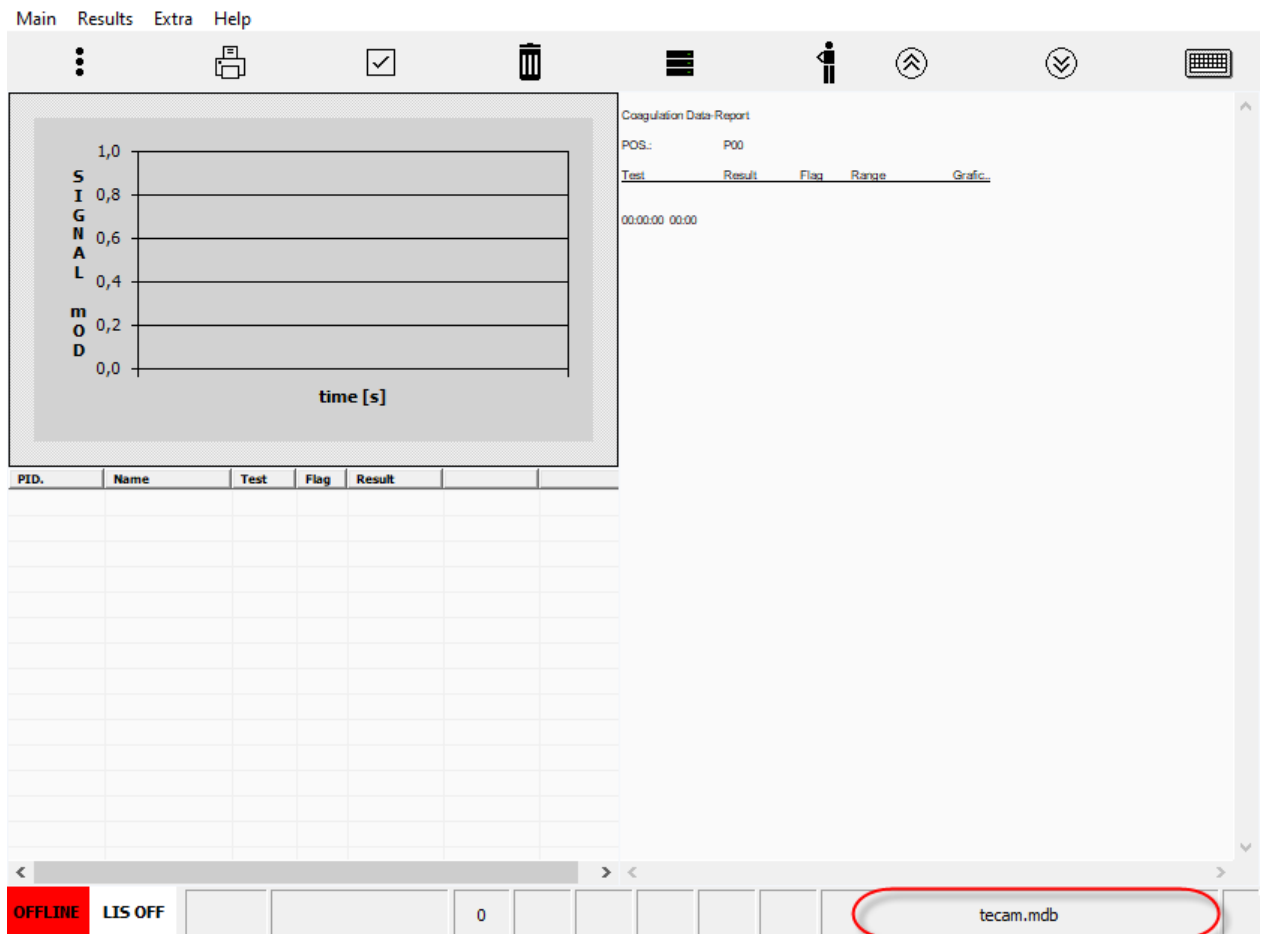
The second screenshot shows the 'Transfer' dialog box with the following information:

Transfer
Ticket Information: B7G2 G666 012G H30L
Buttons: Paste, Send, Edit, Get Ticket, Cancel

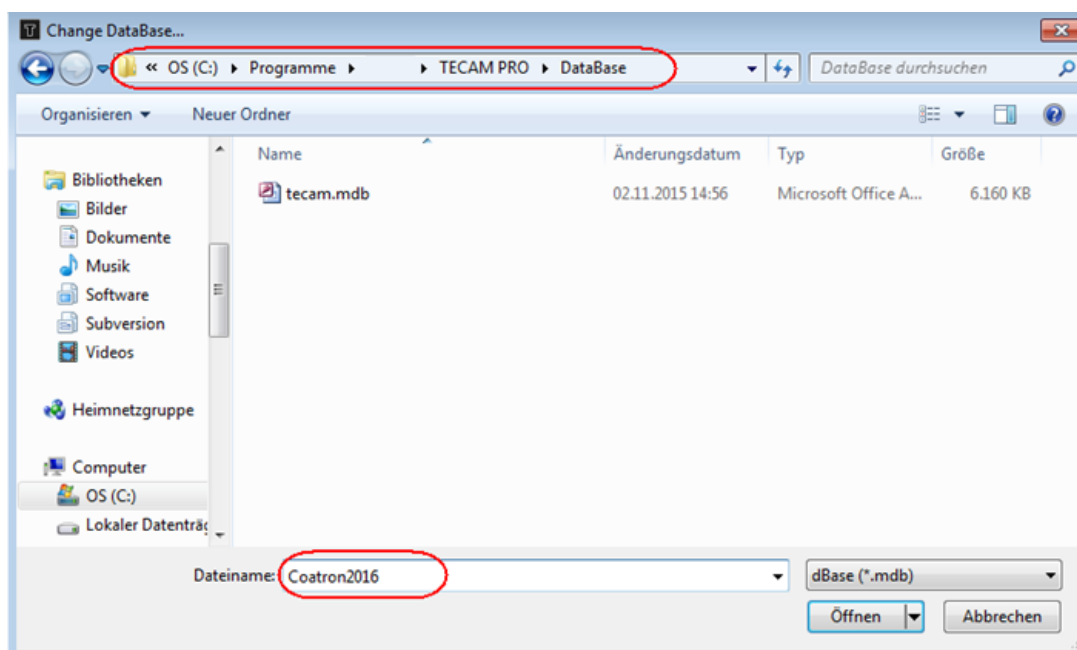
Transfer ticket to device:
-Copy code top clipboard and paste to TECAM. Now you can send it to the instrument.

4. Database Administration

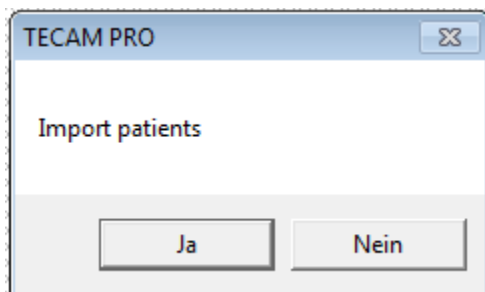
4.1. Creating database



Click to database in the statusbar



Select or create any new directory and enter any name of database.

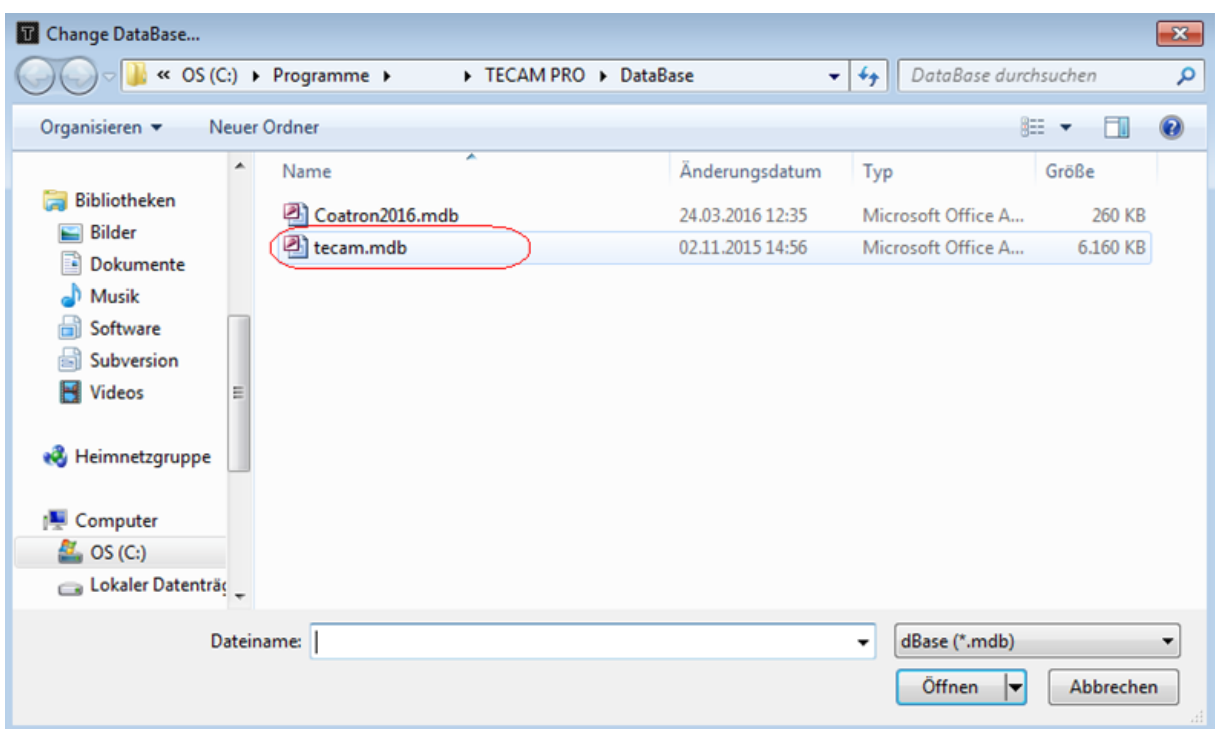


Select yes, if you want to copy the patient ID+name from current database to new database.

4.2. Change database



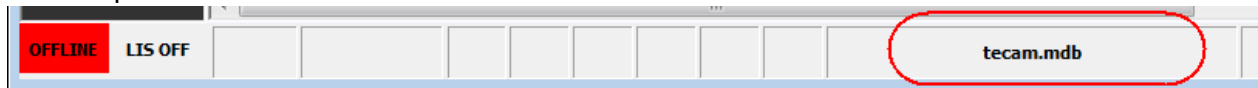
Click to name of database within status



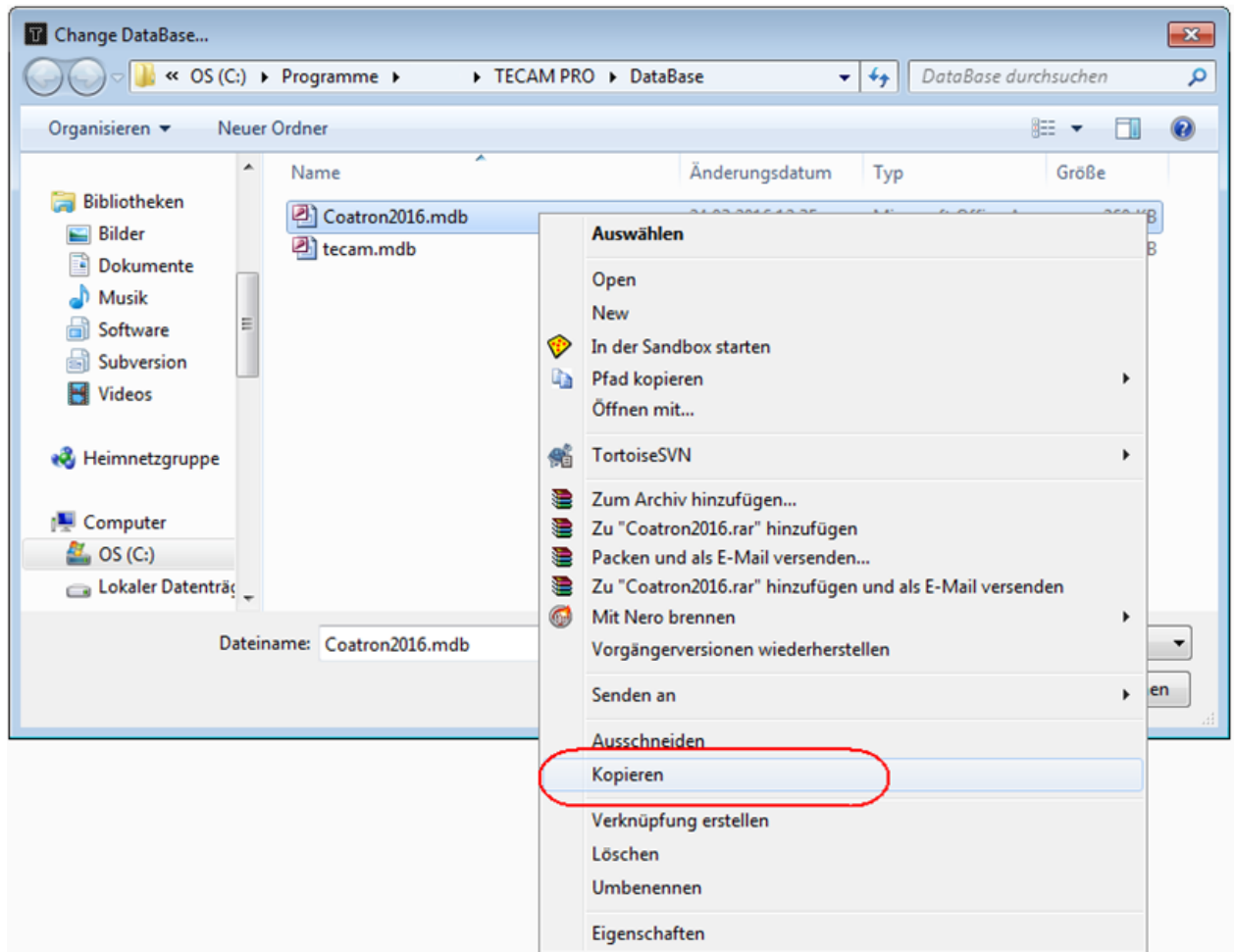
Select any database and confirm

4.3. Backup database

Manual procedure:



Click to name of database within status



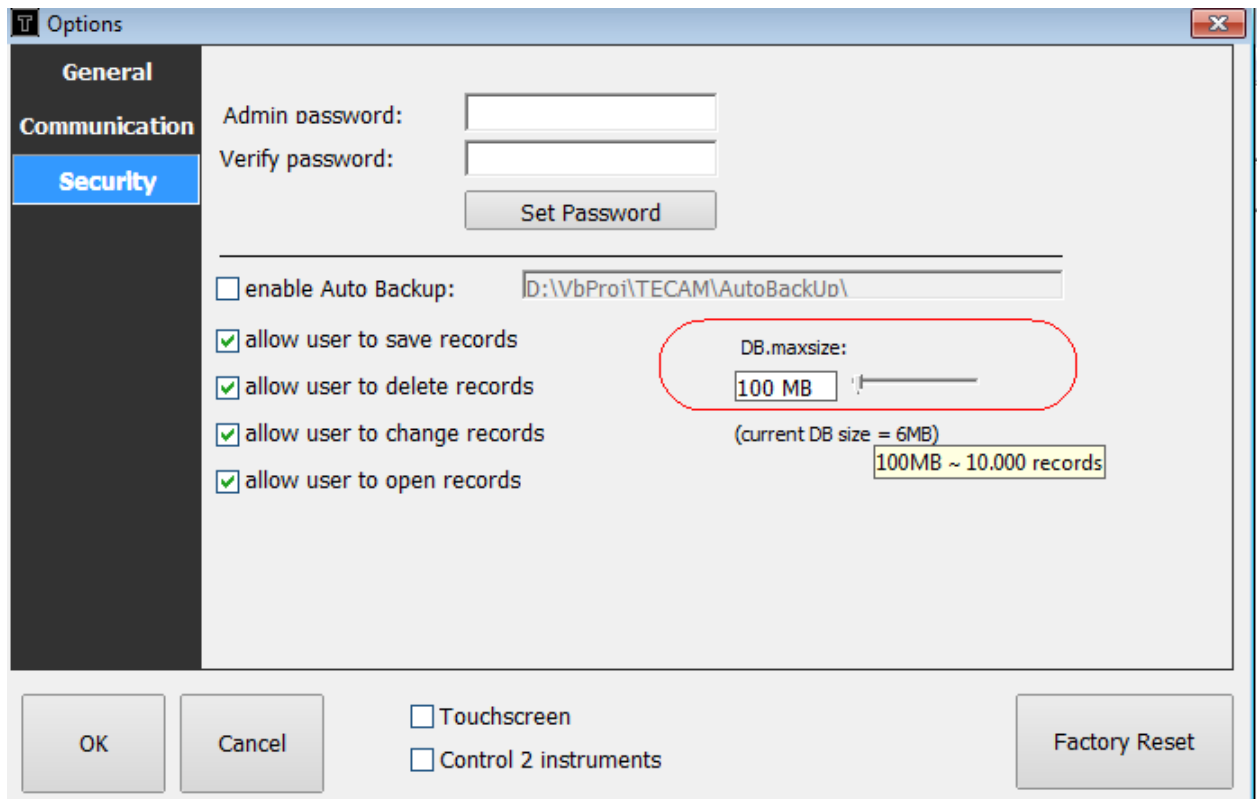
- Click on database with right mouse key and select Copy.
- Change to target directory
- Select "Paste"

Automatic procedure:

- Open Options\Security and check Auto Backup.

4.4. Resize database

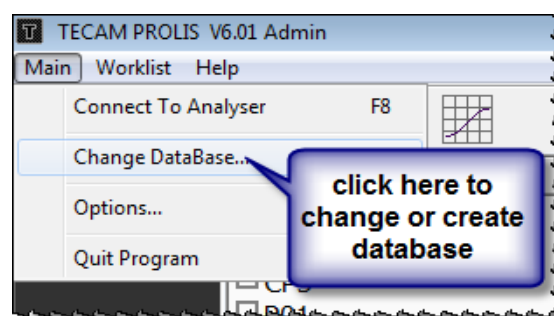
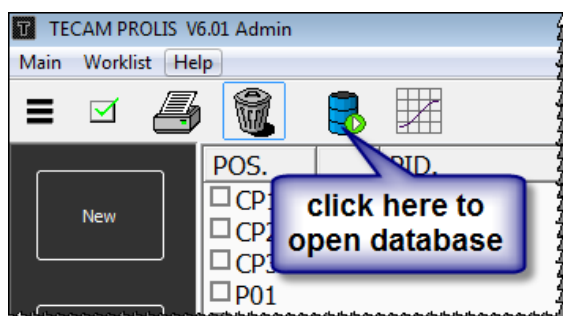
The performance of TECAM SMART may decrease with the size of database depending on the configuration of processor and memory. TECAM SMART allows to limit the database and keep only recent results in database



If maxsize is set below to current db size , then TECAM SMART will ask to delete older result with next restart.

If da size get greaterthen maxsize over time, than TECAM SMART will ask at start to increase the database or delete results !

5. Database Functions



5.1. Result informations

TECAM PROLIS V6.00 Admin

n=309 DB=3MB (2%)

Coagulation Database

Date	Time	Patient-ID	Sample-ID	Name	QC	Test	Lot	Result1	Scale1	Result2	Scale2	Result3	Flag	Wa
15.12.2014	15:19:01	EV1	01004-01	Normal Patient	☐	FIB	10512000	13,3	s	210,0	mg/dL			
15.12.2014	15:19:01	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,0	s	242,0	mg/dL			
15.12.2014	15:19:00	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,3	s	234,0	mg/dL			
15.12.2014	15:18:59	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,5	s	229,0	mg/dL			
15.12.2014	15:18:59	EV1	01004-01	Normal Patient	☐	FIB	10512000	11,9	s	247,0	mg/dL			
15.12.2014	15:18:58	EV1	01004-01	Normal Patient	☐	FIB	10512000	11,9	s	246,0	mg/dL			
15.12.2014	15:15:27	EV1	01004-01	Normal Patient	☐	FIB	10512000	13,3	s	212,0	mg/dL			
15.12.2014	15:15:26	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,8	s	222,0	mg/dL			
15.12.2014	15:15:25	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,4	s	234,0	mg/dL			
15.12.2014	15:15:25	EV1	01004-01	Normal Patient	☐	FIB	10512000	12,3	s	236,0	mg/dL			
15.12.2014	15:15:24	EV1	01004-01	Normal Patient	☐	FIB	10512000	11,7	s	252,0	mg/dL			
15.12.2014	15:15:23	EV1	01004-01	Normal Patient	☐	FIB	10512000	11,8	s	249,0	mg/dL			
15.12.2014	15:08:16	20	01003-02		☐	FIB	10512000	20,2	s	118,0	mg/dL			
15.12.2014	15:08:15	20	01003-02		☐	FIB	10512000	22,8	s	99,0	mg/dL			
15.12.2014	15:08:14	19	01003-01		☐	FIB	10512000	11,8	s	249,0	mg/dL			
15.12.2014	15:08:13	19	01003-01		☐	FIB	10512000	12,6	s	227,0	mg/dL			
15.12.2014	15:02:59	STANDARD 4	01002-04	Calibrator 4	☐	FIB	10512000	28,5	s					
15.12.2014	15:02:58	STANDARD 4	01002-04	Calibrator 4	☐	FIB	10512000	25,6	s					
15.12.2014	15:00:59	STANDARD 3	01002-03	Calibrator 3	☐	FIB	10512000	20,1	s					
15.12.2014	15:00:58	STANDARD 3	01002-03	Calibrator 3	☐	FIB	10512000	21,1	s					
15.12.2014	15:00:57	STANDARD 2	01002-02	Calibrator 2	☐	FIB	10512000	12,7	s					
15.12.2014	15:00:56	STANDARD 2	01002-02	Calibrator 2	☐	FIB	10512000	12,2	s					
15.12.2014	15:00:56	STANDARD 1	01002-01	Calibrator 1	☒	FIB	10512000	7,7	s					
15.12.2014	15:00:55	STANDARD 1	01002-01	Calibrator 1	☒	FIB	10512000	7,7	s					
15.12.2014	13:53:44	26	00067-02		☐	TT		16,0	s					
15.12.2014	13:53:43	25	00067-01		☐	TT		16,9	s					
15.12.2014	13:46:42	26	00066-02		☐	TT		27,6	s					
15.12.2014	13:46:41	25	00066-01		☐	TT		27,8	s					
15.12.2014	13:43:24	26	00065-02		☐	TT		22,8	s					

Database fields:

- Date,Time: Date Time of result
- Patient-ID: Patient Identification number. This number must be unique in the database.
- Sample-ID: Sample Identification number. This number is set always by the instrument and contains two information, which are delimited with '-'. E.g. "001135-005" means worklist-id="1135"; rack position = P05
- Name: Name of patient. Click on this field to add or edit the name
- QC: Mark the sample as patient or quality control
- Test: Name of result method
- Lot: Lotnumber of reagent.
- Result1-3: Results of methods

Database:

- Show records in details view:
All selected results will be reloaded into result screen (see chapter 4).
- Update record
This will change every change in the database
- Delete record: Select records (patient or result) will be deleted from database
- Remove completely: Patient and all corresponding results will be removed from database
- Compress Database: Delete operation will cluster the database. Compress it to remove the clusters.
- Export/Export: Export the tables to Excel , HTML or TXT
- Filters: Apply predefined filters (e.g. show all results from today)

Database:

- Clear filter: Remove all filters from table
- Worklist: Show all results from current worklist. The worklist-id information is stored in the data field "Sample-ID"
- New: Show all results from today, which are not reported yet. Click on report to mark the results as "reported"
- Today: Show all results from today
- Recent days: Enter period and show recent days (show recent 30days)
- Recent values: Enter period and show recent values (show recent 30 results)
- Period: Enter date for begin and end (e.g. Show results from 1.1.2015 to 31.12.2015)
- QC filter:

First click on result, which you want to filter for QC

n=2194 DB=21MB (10%)									
Coagulation Database									
	Date	Time	Patient-ID.	Sample-ID	Name	QC	Test	Lot	Re
	20.11.2014	17:32:07	5	1135-6		☐	PT	10232056	5,8
	20.11.2014	17:32:06	4	1135-5		☐	PT	10232056	5,8
	20.11.2014	17:32:05	3	1135-4		☐	PT	10232056	5,8
▶	20.11.2014	17:32:05	2	1135-3	TECONTROL A	☒	PT	10232056	5,8
	20.11.2014	17:32:04	1	1135-2		☐	PT	10232056	5,8
	20.11.2014	17:32:03	1	1135-1		☐	PT	10232056	5,8

The QC-filter writes now the current patient-id and test into the filter bar. Additionally you can define the period of recent values.

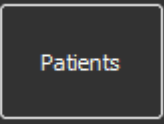
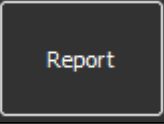
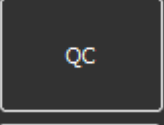
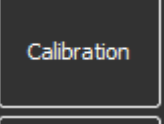
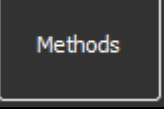
n=1 DB=21MB (10%)									
Coagulation Database									
	Date	Time	Patient-ID.	Sample-ID	Name	QC	Test	Lot	
			=2		TECONTROL A	-	=PT		
▶	20.11.2014	17:32:05	2	1135-3	TECONTROL A	☒	PT	10232056	

The QC-filter can be also applied by double-click on the result !!

Top button bar:

button	description
	Database menu
	Database filter
	Check box
	Show selected records in details,
	Allow administrator to delete selected results from database.
	Update database.
	Input or change patient information.
	Quit current screen.

Left button bar:

	Open table “results”
	Open table “patients”
	Report results
	Run statistical analysis
	Open calibration of methods
	Configure methods like name, test host id and test ranges, etc.

5.2. How to filter results

The filter bar is a very powerful tool to select or find a result.

n=3 DB=21MB (10%)									
Coagulation Database									
	Date	Time	Patient-ID.	Sample-ID	Name	QC	Test	Lot	Result1
					T		PT		>10 & <15
▶	17.12.2013	13:32:22	483602		TURDA,GHEORGHE	☐	PT	10231882	14,5
	16.12.2013	16:16:57	482621		TEMISTOCLE,CATALIN	☐	PT	10231882	14,8
	17.12.2013	12:27:32	483124		TANASE,NADIA	☐	PT	10231882	13,2

You can filter all data fields in combination and apply even operators like = < > & |
Predefined filters will help to define a certain period of results (e.g. recent 7 days)

Examples: Test= "P": show all tests beginning with "P" or "p"
 Test= "=PT": show all tests equal to PT
 Test= "PT | APTT": show all results equal to PT or APTT
 Result1 = ">10 & <15" show all results greater 10s and smaller 15s

5.3. Patient and QC information

New patients can be defined in 4-ways:

1. Receiving patient information from LIS
This requires LIS connection and feature “Use patient information from host” (see chapter 2)
2. Within Test Order Record (see chapter 3).

Test Order Record

Auto-ID 1x : << >> ☐ Auto ☐ Date

Patient-ID: ☐ QC

Name (family,given): ☐ STAT

Date of birth: Age:

Sex:

Department:

Bed:

3. Directly in the table “results”

n=2194 DB=21MB (10%)							
Coagulation Database							
	Date	Time	Patient-ID.	Sample-ID	Name	QC	Test
▶	20.11.2014	17:32:07	5	1135-6	write name	☐	PT
	20.11.2014	17:32:06	4	1135-5		☐	PT
	20.11.2014	17:32:05	3	1135-4		☐	PT

4. In the table “patients”

TECAM PROLIS V6.01 Admin

n=27 DB=21MB (10%)

click here to add new patient

click here

select or filter patients

Patient-ID.	Name	Birth	QC	Sex	Department	Bed
481746	CEAUSU,DUMITRESCU		☐			
482489	CIOCAU,INA		☐			
482886	CONSTANTINESCU,CONSTANTIN		☐			
483154	CASCAVAL,ADRIAN		☐			
483370	COSERIU,VASILE					
483462	CROITORU,EUGENIU					
483619	CARLOANTA,FLORIN					
483674	COMAN,IULIANA					
483687	CONSTANTIN,DOREL		☐			
483746	COSTEA,ELENA		☐			
489440	COCIU,		☐			
491595	CAPRA,VASILICA		☐			
491652	CASAS,MARIANA		☐			
492316	CRISTEA,ION		☐			
492494	CHERBEL,MARIUS		☐			
492637	CIRCIUMARU,IOANA		☐			
492648	CONSTANTINESCU,DANIELA		☐			
494626	CRISTEA,ION		☐			
494665	CIRCIUMARU,IOANA		☐			
494927	COTICIU,OVIDIU		☐			
495103	CARAVELA,MARIA		☐			
495142	CIOCA,ILIANA		☐			

patient memo field

Patient Information File

481746
CEAUSU,DUMITRESCU,

Bed: -

=====

	Click here to delete patient
	Update database.
	Click here to add new patient.

5.4. How to define QC ranges

About ID number of controls:

You should always use the lotnumber of control vial as Patient-ID and add the name of the control

E.g.	96002014	Control,N
E.g.	96002051	Control,N
E.g.	96102015	Control,A
E.g.	96102052	Control,A

This gives you later the chance to analyze the QC with two filters:

“show recent 30 PT of LOT 96002014” or “show recent 30 PT of Control,N”

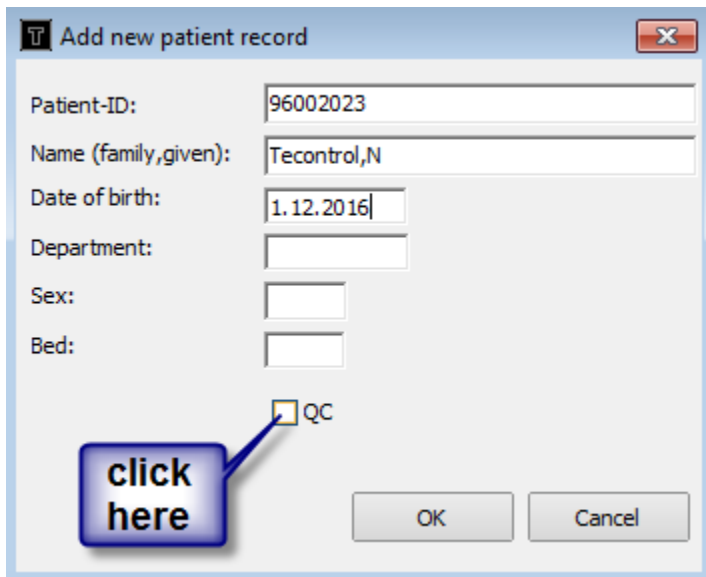
About control ranges:

A certificate of analysis is included in each box of control plasma. Here you can read the target values and ranges of control plasma. Transfer these values later in the database.

Add or edit control plasma information to database:

Quality controls (QC) are handled equal as patients. Only the database field "QC" is set to TRUE.

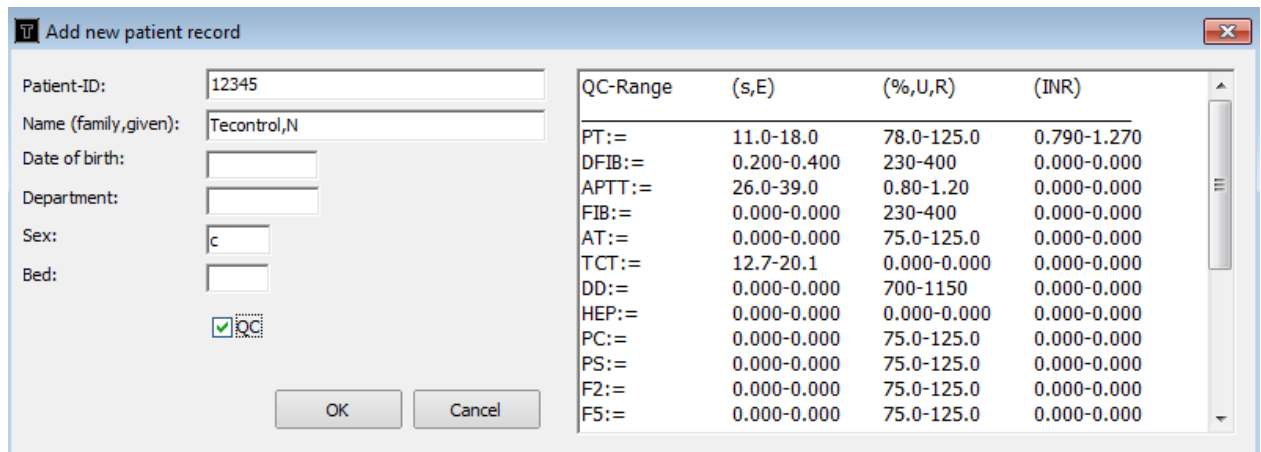
	Click here to add new QC
---	--------------------------



Name

-  Control,N_0001.qc
-  Default_TeControl_A.qc
-  Default_TeControl_N.qc
-  QC2010_A4_ACP.qc
-  QC2010_A4_NCP.qc
-  Tecontrol A PLUS_13.qc
-  TEControl A_1.qc
-  Tecontrol A_96101906.qc
-  Tecontrol,N_96001905.qc

Enter lotnumber , name and expiry date of control plasma and click on "QC". Now you can load or cancel a control file.



QC-Range	(s,E)	(%,U,R)	(INR)
PT:=	11.0-18.0	78.0-125.0	0.790-1.270
DFIB:=	0.200-0.400	230-400	0.000-0.000
APTT:=	26.0-39.0	0.80-1.20	0.000-0.000
FIB:=	0.000-0.000	230-400	0.000-0.000
AT:=	0.000-0.000	75.0-125.0	0.000-0.000
TCT:=	12.7-20.1	0.000-0.000	0.000-0.000
DD:=	0.000-0.000	700-1150	0.000-0.000
HEP:=	0.000-0.000	0.000-0.000	0.000-0.000
PC:=	0.000-0.000	75.0-125.0	0.000-0.000
PS:=	0.000-0.000	75.0-125.0	0.000-0.000
F2:=	0.000-0.000	75.0-125.0	0.000-0.000
F5:=	0.000-0.000	75.0-125.0	0.000-0.000

Update to correct control ranges here or next screen.

n=11							
Patient Database							
Patient-ID.	Name	Birth	QC	Sex	Department	Bed	
1	Sample-1	10.11.1968	☒	c	uro	1234	
2	Sample-2		☐				
20100001	Mustermann,John	19.08.2012	☐				
20100002	,		☐				
20100003	,		☐				
20100004	Sample,4		☐				
20100006	,		☐				
20100007	,		☐				
20100009	,		☐				
20100021	Patient,2		☐				
▶ 96002023	Tecontrol,N	01.12.2016	☒	c			

QC-Range	(s,E)	(%,U,R)	(INR)
PT:=	11.2-16.0	77.0-111.0	0.85-1.22
DFIB:=	0.200-0.400	200-400	0.000-0.000
APTT:=	28.6-41.2	0.000-0.000	0.000-0.000
FIB:=	0.000-0.000	210-328	0.000-0.000
AT:=	0.000-0.000	75.0-125.0	0.000-0.000
TCT:=	14.4-20.6	0.000-0.000	0.000-0.000
DD:=	0.000-0.000	163-338	0.000-0.000
HEP:=	0.000-0.000	0.000-0.000	0.000-0.000
PC:=	0.000-0.000	75.0-125.0	0.000-0.000
PS:=	0.000-0.000	75.0-125.0	0.000-0.000
F2:=	0.000-0.000	75.0-125.0	0.000-0.000
F5:=	0.000-0.000		0.000-0.000
F7:=	0.000-0.000	New	0.000-0.000
F8:=	0.000-0.000	Load	0.000-0.000
F9:=	0.000-0.000	Save	0.000-0.000
F10:=	0.000-0.000		0.000-0.000
F11:=	0.000-0.000	Copy	0.000-0.000
F12:=	0.000-0.000	Paste	0.000-0.000
PLG:=	0.000-0.000		0.000-0.000
APCR:=	0.000-0.000	Insert data + time	0.000-0.000
LA screen:=	0.000-0.000		0.000-0.000
LA confirm:=	0.000-0.000	Print memo	0.000-0.000

Click right mouse button to open context menu:

- Edit control ranges for each unit.
- Keep range to 0.000 -0.000 if unit is not used for result reporting. Read about "Report all units" in chapter "Create a report"
- Click right mouse for context menu
 - New: Create a new control file
 - Load: Load QC ranges from file
 - Save: Save QC ranges to file
 - Copy: Copy QC ranges to clipboard
 - Paste: Load QC ranges from clipboard
 - Insert date: not available for QC sample
 - Print: Print memo field

5.5. Create a report

What you see in the table, is what you get on the report !!!!

TECAM PROLIS V6.01 Admin

Results Patients Report Calibration Methods

click here

apply filters or use predefined report filters

Date	Time	Patient-ID.	Sample-ID	Name
20.11.2014	17:32:07	5	1135-6	
20.11.2014	17:32:06	4		
20.11.2014	17:32:05	2	1135-3	TECONTROL A
20.11.2014	17:32:04	1	1135-2	
20.11.2014	17:32:03	1	1135-1	
20.11.2014	15:23:23	133	1134-24	
20.11.2014	15:23:23	133	1134-29	
20.11.2014	15:23:22	133	1134-25	
20.11.2014	15:23:21	151	1134-23	
20.11.2014	15:23:21	150	1134-22	
20.11.2014	15:23:20	149	1134-21	

Title: Coagulation Data-Report

Header 1:

Header 2:

Header 3:

Header 4:

Header 5:

Footer: Doctor:

Comment: Comment:

☐ Text centered ☒ Grafik left

Pic-X 0,2 Pic-Y 0,2

Grafic.. Font..

☐ New page per patient ☒ New page per sample ☐ New page per day ☐ Report all units ☐ Din A5

☒ New ☐ Worklist ☐ No

Cancel OK

Headlines:	Define up to 5 headlines , foot line to your results report	
Font:	Define font name and size.	
Grafic:	Add a graphic to your report	
Text centered:	Activate if headlines should be centered in the report	
Grafic left:	Show graphic on the top left side. Otherwise it is top right side.	
PIC- XY:	Zoom Grafic	
New page per patient:	Print results of each patient on a new page. The patient is defined by the patient-ID (PID), which is received from sample barcode or LIS.	
New page per sample:	Print results of each sample on a new page. The sample is defined by the sample-ID, which is automatically generated by the Coatron system.	
New page per day:	Print results of each day on a new page.	
Din A5:	Print report on small Din A5 format. Otherwise the format is Din A4.	
Filter:	New:	Report only new results from today
	Worklist:	Report last worklist of instrument
	No:	Do not apply a data filter
Report all units:	The Coatron sends up to three different results for each method (e.g. PT sec + % + INR)	
	Check , if all available results (unit) should be included to the result report	
	Uncheck, if only selected units should be reported.	
	How to disable the units:	
	For patients:	open database and click on „Methods” and change field “Range”. Do not define unit to disable. Read chapter “database” for more information.
	For controls:	open database and click on “Patients”, select ID number of control and change QC ranges. Set unit to 0.000-0000 to disable. Read chapter “Create a report” for more information.

5.6. Statistical analysis

- The QC functions can be applied on patient and QC results. You could e.g. show the recent 30 INR results of a patient in a graphic and see any trends.
- For statistical analysis it requires at least two values
- For Westgard analysis it requires a correct patient-ID, test and qc-ranges . For this the QC filter is helpful.

TECAM PROLIS V6.01 Admin

Results Patients Report QC

n=30 DB=4MB (2%)

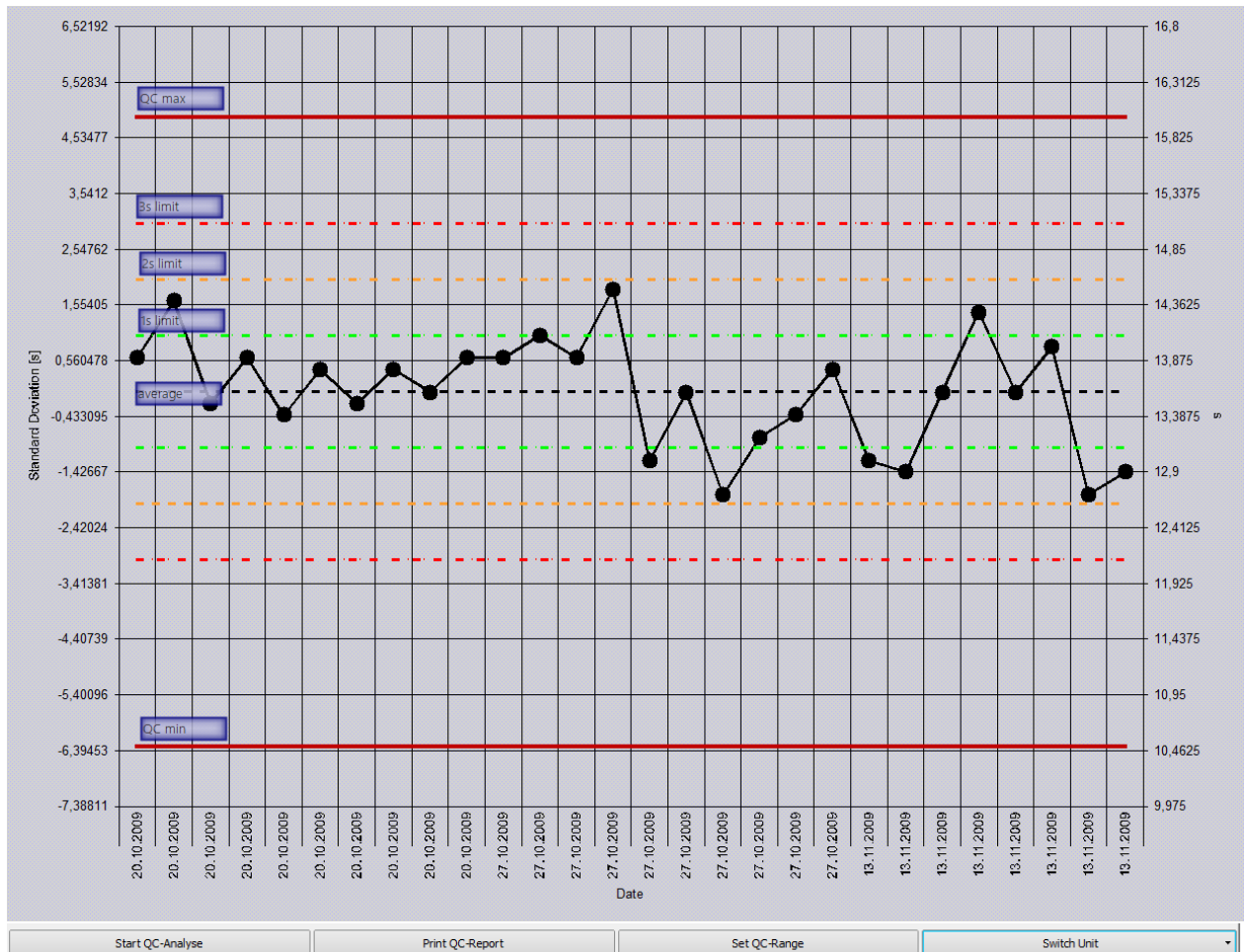
Coagulation Database

Date	Time	Patient-ID.	Sample-ID	Name	QC	Test
		=1		Sample-1	-	=PT
19.11.2013	16:30:31	1		Sample-1	☒	PT
19.11.2013	16:33:13	1		Sample-1	☒	PT
19.11.2013	14:19:56	1		Sample-1	☒	PT
02.12.2013	10:48:35	1		Sample-1	☒	PT
27.11.2013	13:23:30	1	1025-1	Sample-1	☒	PT
25.11.2013	14:42:21	1		Sample-1	☒	PT
25.11.2013	14:43:18	1		Sample-1	☒	PT
25.11.2013	14:47:25	1		Sample-1	☒	PT
27.11.2013	13:22:06	1	1024-1	Sample-1	☒	PT
27.11.2013	13:37:06	1	1027-1	Sample-1	☒	PT

select QC result

click here

Levey Jennings diagram is displayed and the result of statistical analysis:



The left axis scale is the standard deviation of the data series

The right axis scale is the result of the data series.

The Min and Max line is defined by the QC-range

The QC data is only passed, if all results are within MIN-MAX (red line) and no Westgard rule failed

QC PASSED !

Unit: s

☒ QC 10,5 - 16 s

☒ CV. (<12%)

Westgard Rules

☒ 1:2s
☒ 1:3s

☒ 2:2s

☒ R:4s

☒ 4:1s

☒ 10:x

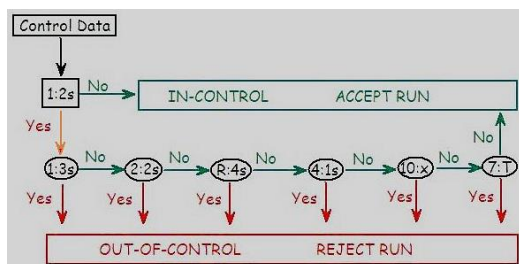
☒ 7:T

Set QC-Range

Print QC-Report

Westgard Analyze

Diagnosing principle of Westgard analyze:



1:2s refers to 1 point is outside 2 SD. If yes, the following rules should be checked; if no, the run is in-control.

1:3s refers to 1 point is outside 3 SD.

2:2s refers to 2 consecutive points are outside 2 SD on the same side of the mean.

R:4s refers to range of 2 points is greater than 4 SD.

4:1s refers to 4 consecutive points exceed 1 SD on the same side of the mean.

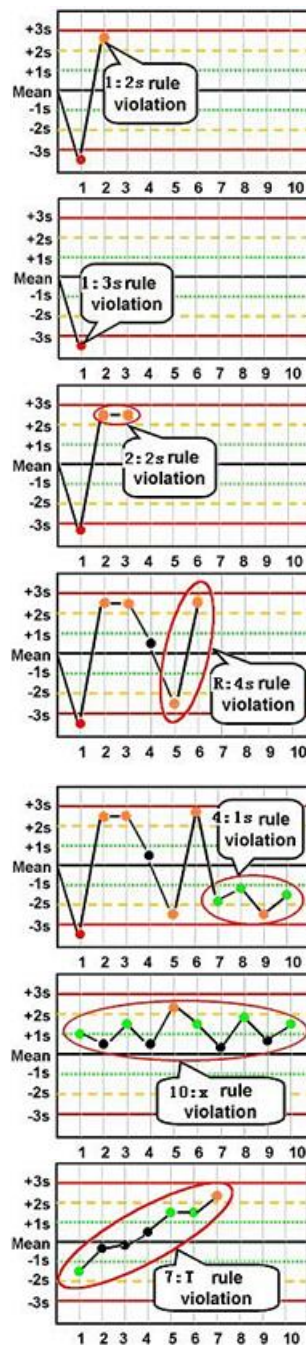
10:x refers to 10 consecutive points are above or below the mean

7:T refers to 7 consecutive points trend in the same direction, i.e., get progressively higher or progressively lower.

Reference: see www.westgard.com

Pathway of Westgard rules

QC is failed, if “rule 1:2s” and any other rules is broken!



5.7. Calibration Data

The Coatron instrument sends automatically information about test calibration together with each result. This gives you later the chance to visualize the calibration curve and trace each result back to its calibration data and international standard.

About calibration:

The Coatron system measures the clotting time of a coagulation test like PT. The clotting time is depending very much on analyzer and reagent and therefore difficult to compare from lab to lab. For this clotting time is converted to an international standard like Quick-% or INR. Calibration curve and reference data are required for the conversion.

About traceability:

Means the ability to track back each result to its calibration data and further to its international standard. For example an INR results requires the ISI value of the reagent and the normal time of the instrument. Both value are stated in the certificate of analysis and stored in the data memory of instrument. The certificate of analysis provides also information about calibration procedure and material like (lotnumber of calibrator or international standard)

TECAM PROLIS V6.01 Admin

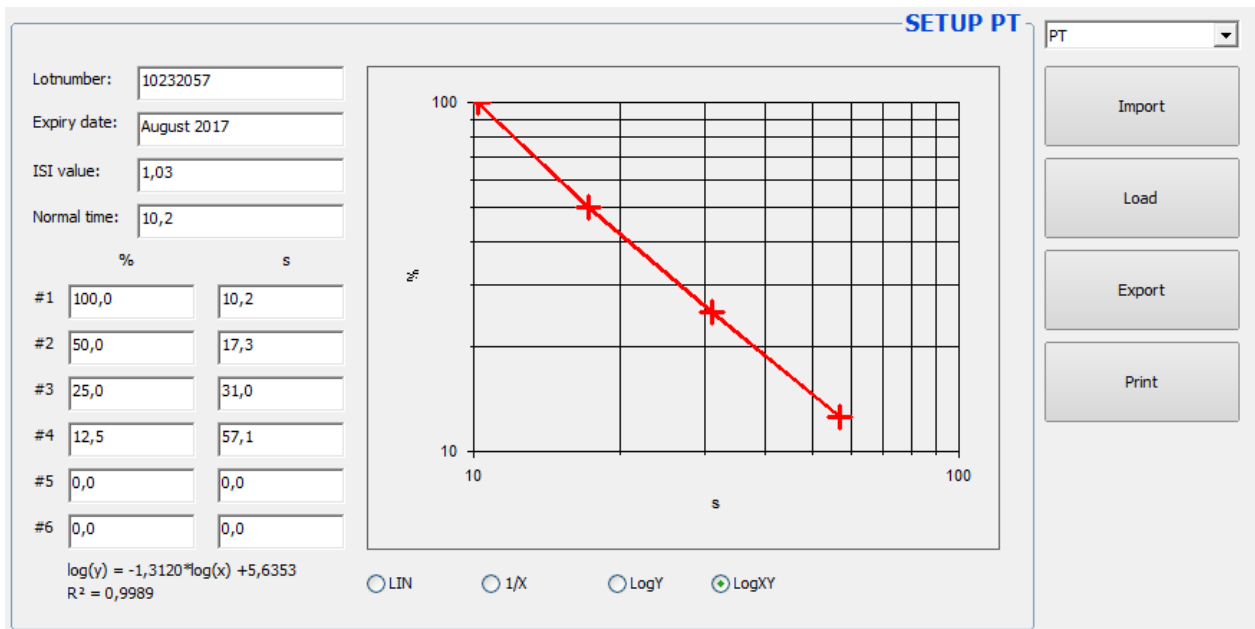
Icons: Menu, Sun, Checkmark, Refresh, Trash, Database, Users, Error

Results
Patients
Report
QC
Calibration
click here

n=319 DB=4MB (2%)
Coagulation Database

Date	Time	Patient-ID.	Sample-ID	Name	QC	Test	Lot	Re
29.01.2015	16:21:24	1010	01169-11		☐	PT	10232057	5,
29.01.2015	16:21:23	1009	01169-10		☐	PT	10232057	5,
29.01.2015	16:21:23	1008	01169-09				10232057	4,
29.01.2015	16:21:22	1007	01169-08				10232057	5,
29.01.2015	16:21:21	1006	01169-07		☐	PT	10232057	5,
29.01.2015	16:21:09	1005	01169-06		☐	PT	10232057	5,
29.01.2015	16:21:08	1004	01169-05		☐	PT	10232057	5,
29.01.2015	16:21:07	1003	01169-04		☐	PT	10232057	5,
29.01.2015	16:21:06	1002	01169-03		☐	PT	10232057	5,
29.01.2015	16:21:06	1001	01169-02		☐	PT	10232057	5,
29.01.2015	16:21:05	1000	01169-01		☐	PT	10232057	5,
09.01.2014	17:37:46	20100021	1051-1	Patient,2	☐	APTT		17

Select result (LOT)



This screen shows the all data and linearity of calibration. Current TECAM SMART version allows editing the data, but it is under discussion to remove this feature due to traceability requirement.

- Test: Select desired test from the drop down box.
- Load: Open test calibration file from PC
- Import: Coatron A: Receive and save calibration data from instrument



Coatron: Go to device , open test selection screen and print setup,

- Export: Download calibration data to instrument



- 1) Coatron don't accept changes of MATH
- 2) Coatron don't accept any changes

- Print: Print out current calibration curve.

5.8. Method information of instruments

	The sequence and name of method must be always equal to the instrument setup. Never change this logic; otherwise it might be that instrument receives a wrong order! For example the test “PT” is stored in the instrument on the first place as “PT”. Therefore it must be in the first line of the table Methods and field “Method” must be named “PT”. Use function “SYNC” to ensure correct sequence.
---	--

(1) TECAM PROLIS V6.04 Admin










Results

Patients

Report

QC

Calibration

Methods

Method	Name	Host-Id.	Range	Profile
PT	PT	1	[70-120%] [0,90-1,15INR]	1
DFIB	DFIB	2	[180-350mg/dL]	0
APTT	APTT	3	[26-38s]	1
FIB	FIB	4	[150-350mg/dL]	1
AT	AT	5	[70-120%]	1
TT	TT	6	[16-24s]	1
DD	DD	7	[100-1500ng/mL]	1
HEP	HEP	8	[0-0,1IE/mL]	0
PC	PC	9	[70-140%]	0
PS	PS	10	[65-150%]	0
F2	F2	11	[70-120%]	0
F5	F5	12	[70-120%]	0
F7	F7	13	[70-120%]	0
F8	F8	14	[70-150%]	0
F9	F9	15	[70-120%]	0
F10	F10	16	[70-120%]	0

click here to open methods

S

%

INR

select method and enter new range

OK

SYNC

Receive method information from analyser

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