User Manual

DIAcheck series

C1 / C2 / C4

(en) English

Manual Revision: 13

Software Version: V1.04.52

REF	Name	Basic UDI-DI:
8080000	DIAcheck C1	09120042244901
8070000	DIAcheck C2	09120042245014
8042000	DIAcheck C4	09120042245090

IVD CE

Copyright Neither the user manual nor any part thereof may be copied, digitally edited or otherwise reproduced without the written permission of DIALAB GmbH. The software for DIALAB GmbH products is the intellectual property of DIALAB GmbH, which reserves all rights of use to the software. The purchaser of a DIAcheck acquires rights of use to this software.

Warranty The DIAcheck series comes with a one-year warranty from the date of delivery or initial installation. It covers all material, functional or manufacturing defects. The initial installation must be registered online, either at www.dialab-reg.com (see the 'Registration' section) or by scanning the QR code on the System ID card.

The warranty is void in the event of failures caused by

- accidents, neglect of maintenance and servicing, misuse or improper use.
- Use of unauthorised reagents, consumables or spare parts
- Unauthorised servicing. All repairs or maintenance must be carried out by authorised personnel.

Conformity The product complies with the essential requirements of the following Regulation: EU 2017/746 on in vitro diagnostic medical devices (IVDR).

Images The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Training Do not carry out operation tasks or maintenance actions unless you have received training from DIALAB GmbH. Leave tasks that are not described in the user documentation to trained DIALAB Service representatives.

Incident reporting Report serious incidents or potential serious incidents related to the product in accordance with the requirements of the manufacturer and your competent authority.

Contact information

DIALAB Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
2351 Wiener Neudorf, Austria
IZ NOE-Sued, Hondastrasse, Objekt M55
Telephone: +43 (0) 2236 660910-0; Fax: +43 (0) 2236 660910-30
Email: office@dialab.at
Website: www.dialab.at

TABLE OF CONTENTS

1 Intended use 4
2 Symbols used in this manual 4
3 Storage and handling 4
4 Safety Guide 5
5 Overview of the system 6
5.1 Comparison of the DIAcheck series 7
6 Principle of measurement 9
6.1 Coagulation method (PT, aPTT, ...) 10
6.2 Chromogenic method (antithrombin): 10
6.3 Immunoassay method (D-dimer): 10
7 Test procedures 11
7.1 Sample collection 11
8 Installation 12
8.1 Contents 12
8.2 Operating conditions 13
8.3 Initial installation 14
8.4 Switching on and off 15
8.5 Screen protector 15
8.6 External thermal printer 16
8.7 External barcode scanner 16
8.8 TECAM SMART 16
8.9 Registration 17
9 Operation procedure 18
9.1 Start screen 18
9.2 Enter patient identification 19
9.3 Selecting tests 20
9.4 Measurement 21
9.5 System settings 22
9.6 Test settings 25
9.7 Check results 27
10 Basic coagulation tests 28
10.1 Quick guide to PT testing 28
10.2 Quick guide to aPTT determination 29
10.3 Quick guide to FIB determination 29
10.4 Control Procedure 30
11 Ticket system 31
12 Service Functions 33
12.1 System information 33
12.2 Optics check 34
12.3 System report 35
12.4 Adjust temperature 36
12.5 Firmware update 37
12.6 Motherboard overview 38
13 Common faults 39
14 Reset to factory settings 40
15 Working with TECAM Smart 41
16 Cleaning and maintenance 42
16.1 General cleaning instructions 42
16.2 Cleaning 42
16.3 Decontamination 42
16.4 Regular maintenance 42
17 Technical data 43
18 Consumables / Accessories 44

1 INTENDED USE

The DIAcheck series consists of semi-automatic, coagulometric IVD devices used in combination with coagulation reagents. This series is intended for the quantitative detection of coagulation, chromogenic and immunoturbidimetric parameters in human citrate plasma. The IVD series is intended to serve as an aid in the diagnosis of haemostatic disorders. For professional laboratory use only.

2 SYMBOLS USED IN THIS MANUAL

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
	Read	Indicates important information and tips.
⇨	**Info**	Describes how the **DIAcheck series** responds to user input.
	Warning	Risk of possible harm to health or significant damage to the equipment if the warning is ignored.
	Danger	Potential risk to operating personnel or equipment due to electric shock.
	Biohazard	Equipment may be potentially infectious due to the samples and reagents used.
	Laser beams	Avoid direct eye contact!

3 STORAGE AND HANDLING

Storage Conditions
0–50°C, max. 12 months in original packaging.

Transport conditions:
No special conditions are required. The general regulations for transport may be applied.

4 SAFETY GUIDE

No liability is accepted if this product has not been purchased from the manufacturer or an authorised dealer.

A. General use

A.1 This device must only be installed in professional laboratories.

A.2 This device must only be operated by a professional user. It is not intended for point-of-care or home testing.

A.3 Please read the user manual in full before using the device for the first time.

A.4 Install the device in accordance with the electrical and environmental conditions specified in the 'Installation' section of the user manual.

A.5 Operate the device as intended and in accordance with the instructions in the user manual.

A.6 Follow the instructions in the manual and the manufacturer's recommendations.

A.7 Use only reagents, consumables such as cuvettes, and (spare) parts that are intended or recommended for use with this instrument. If in doubt, always contact the manufacturer or your local authorised dealer.

A.8 Do not use reagents after the expiry date or the specified shelf life has passed.

B. Use in the laboratory

B.1 Check that the instrument is functioning correctly by performing a quality control test before measuring patient samples.

B.2 Do not operate the device if reagents or liquids have been spilled inside it. Contact your local DIALAB partner.

B.3 Never use cuvettes more than once. Cuvettes must not be washed. They are intended for single use only.

C. Risk of contamination

C.1 Treat all surfaces and materials that may come into contact with plasma or other biological fluids as potentially infectious.

C.2 Avoid direct contact with potentially infectious materials or surfaces by wearing suitable protective clothing.

C.3 Follow the laboratory's hygiene procedures during and after completion of the work.

D. Maintenance and servicing

D.1 Maintenance work must only be carried out by an authorised service centre.

D.2 Decontaminate the device before carrying out any maintenance or shipping it.

D.3 Recycle devices in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) or local regulations for electronic devices.

5 OVERVIEW OF THE SYSTEM

Figure1 : Top view

Home screen (e.g. DIAcheck C4)

Colour touchscreen

The entire surface is preheated to 37°C

1 x reagent position Ø24mm
1 x reagent position Ø22 mm
1 x reagent position Ø22mm, stirred

2 x reagent positions Ø13 mm

10 x cuvette incubation positions (C1)
20 x cuvette incubation positions (C2/C4)

4 x cuvette measurement positions (depending on the C1/C2/C3 version)

Figure2 : Rear view

5V:	Power socket (+ 5Vdc)
PC:	USB: LIS or PC (USB)
SERVICE:	Software update (USB)
PRINTER:	Serial printer (RS232)
BARCODE:	Portable barcode scanner (RS232)

Figure3 : Side view

5.1 Comparison of the DIAcheck series

The DIAcheck series comprises three different devices designated C1, C2 and C4

DIAcheck series Family	C1	C2	C4
Reagent and optical block	Preheated to 37°C		
Preheat cuvettes	10x	20x	20x
Preheat reagent, 24 mm	1x	1x	1x
Preheat reagent, 22 mm	2x	2x	2x
Pre-warm microtubes	2x	2x	2x
Reagent stirrer	No	1x	1x
Printer, RS232	Yes		
Barcode scanner, RS232	Yes, external QR barcode scanner for reading 1D or QR codes		
LIS, USB	Yes		
Firmware update, USB	Yes		

Measurement			
Optical channels	1	2	4
Optical wavelength	620 nm (RED)	405 nm (UV)	405 nm (UV)
Cuvette, total volume	Single, 75 µl	Single, 75 µl	Single, 75 µl
Global coagulation tests	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT
Specialised coagulation assays	No	All factors PS, LA	All factors PS, LA
Chromogenic assays	No	AT, PC, HEP	AT, PC, HEP
Latex-enhanced assays	D-dimer	D-dimer Free PS	D-dimer Free PS
Whole blood tests	Yes (PT INR+%)	No	No

Software functions			
Dual LOT reagent: Manage two different lots for each test	No	Yes	Yes
Test calibration: LOT, procedure and up to 5 points for each test	Yes	Yes	Yes
Reagent barcode: Enter LOT + expiry date or positive LOT recognition	Yes	Yes	Yes
Patient barcode: Entry of patient ID via QR scanner (up to 16 characters)	Yes	Yes	Yes
System barcode: Entry of voucher tickets via QR scanner directly from the mobile device's display	Yes	Yes	Yes
Results database: Save the last 180 results	Yes	Yes	Yes
Double measurement: Performs the patient measurement twice and displays the average	No	Yes	Yes
Stopwatch function: Count up or down the incubation time	1-time	2-fold	4-fold
Identification of results: Patient ID or Sample ID or Auto ID	Yes	Yes	Yes
Real-time clock	Yes	Yes	Yes
Change language	Yes	Yes	Yes
Start test when reagent is added: No need for an expensive starter pipette	Yes	Yes	Yes
Visualise reaction curve: Tecmoni software required	Yes	Yes	Yes
Connection to the LIS via USB or network/ASTM: TECAM SMART software required	Yes	Yes	Yes

6 PRINCIPLE OF MEASUREMENT

The detection of plasma coagulation is based on a photometric principle. No mechanical aids such as stirring rods are required. Blood plasma is placed in a cuvette. Special reagents are added to initiate blood coagulation. The cuvette is illuminated by ultraviolet light during the coagulation process. When the sample begins to clot, a change in light absorption is measured. The time from the start of the measurement to the change in light (turning point) is referred to as the clotting time and is given in seconds [s].
The conversion of the coagulation time into a specific test unit is performed using linear, hyperbolic, semi-logarithmic or double-logarithmic interpolation of the stored calibration points. The current mathematical model is printed under 'Test settings'. Values outside the calibration range are calculated by extrapolation and marked with '*'.

Unit	Info	Decimal Locations	Maximum Value
s	Second	1	-
%	Activity	1	250.0
U	units	0	29,999
INR	International Normalised Ratio	2	99.00
R	Ratio	2	99.00
NR	Normalised Ratio	0	250
mg/dl		0	999
g/l		2	99
IU/ml	International units	2	99
mg/l		2	999
µg/ml		3	9,000
ng/ml		0	27,500
µg/l		0	27,500
IU/ml	International units	2	99.00

R = Clotting time / Normal time
NR = 100 * (normal time / clotting time)
INR = Ratio ^{ISI} (International Normalised Ratio)
IU/ml = IU/ml = International Units (1.00 IU/ml = 100% activity)

6.1 Coagulation method (PT, aPTT, ...)

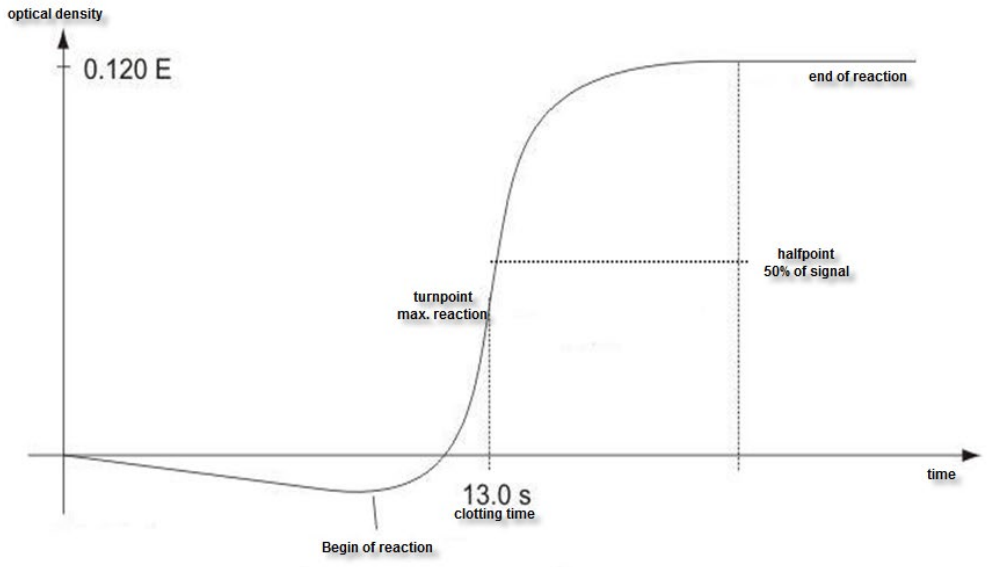


Figure4 : Determination of the inflection point in the coagulation method

The final reaction in the coagulation cascade is the conversion of fibrinogen to fibrin, which is catalysed by thrombin. Fibrin formation leads to a turbidity (higher turbidity level) in the sample, which is measured by the photometer and recorded as absorbance. The result in seconds is the time from the start of the reaction to the point of half the rate of change (half-point).

6.2 Chromogenic method (antithrombin):

The change in the optical signal is not caused by a coagulation reaction, but by the release of colour particles (pNA) that produce a yellow colour. The colour change is measured at 405 nm and expressed as "dE/60sec"; it is proportional to the concentration or activity of the analyte.

6.3 Immunoassay method (D-dimer):

The change in light is caused by antigen-antibody reactions that scatter the light. The antibodies are bound to latex particles to amplify the optical reaction. The change in light is proportional to the concentration of the antigen, such as D-dimer, and is expressed as dE/120sec

7 TEST PROCEDURES

The following tests are used to investigate the human coagulation system, which can lead to bleeding or thrombosis, and to monitor anticoagulants such as heparin or warfarin.

Test	Name	Sample	Method	DIAcheck series		
				C1	C2	C4
PTB	Prothrombin time	Whole blood	Coagulation	Yes	No	No
PT	Prothrombin time	Plasma	Coagulation	Yes	Yes	Yes
APTT	Activated partial thromboplastin time	Plasma	Coagulation	Yes	Yes	Yes
FIB	Fibrinogen	Plasma	Coagulation	Yes	Yes	Yes
TT	Thrombin time	Plasma	Coagulation	Yes	Yes	Yes
ATIII	Antithrombin	Plasma	chromogenic	No	Yes	Yes
DD	D-dimer	Plasma	Immunoassay	Yes	Yes	Yes
Factors	Factors II, V, VII, VIII, IX, X, XI, XII	Plasma	Coagulation	No	Yes	Yes
HEP	Heparin (Anti-Xa)	Plasma	chromogenic	No	Yes	Yes
PC	Protein C	Plasma	chromogenic	No	Yes	Yes
PS	Protein S	Plasma	Coagulation	No	Yes	Yes
PSF	Free protein-S	Plasma	Immunoassay	No	Yes	Yes
VWF	Von Willebrand factor	Plasma	Immunoassay	No	Yes	Yes
LA-S	Lupus-A screening	Plasma	Coagulation	No	Yes	Yes
LA-C	Lupus A -Confirm	Plasma	Coagulation	No	Yes	Yes

7.1 Sample collection

Sample type:	Human citrate plasma
Sample collection:	Venipuncture, 1:10 mixed sodium citrate 3.2% (0.105 M)
Centrifugation:	10 minutes at 1500g
Storage:	Max. 4 hours after collection at room temperature
Bilirubin:	< 50 mg/dl
Haemoglobin:	< 9000 mg/l
Triglycerides:	< 2500 g/l

Sample intended only for the PTB on C1:
Sample type: Capillary blood from a finger prick or citrated whole blood

If there are any discrepancies with the reagent's instructions for use, always follow the instructions on the package leaflet.

8 INSTALLATION

8.1 Contents

Contents of the standard package:

- 1 unit **DIAcheck device**
- 1 Power supply with EU/US plugs and instructions
- 2 x 100 pieces Individual cuvettes
- 5 pieces Reaction tubes, Ø11mm
- 1 piece User manual (not shown in the image below)
- 1 Safety information
- 1 System ID card

Figure5 : Standard delivery package

Optionally available:

- External thermal printer (RS232)
- External barcode scanner (RS232)
- Printer cable
- TECAM Smart Software

8.2 Operating conditions

Environmental conditions:

Operating temperature	15°C to 30°C
Humidity	30–80% relative humidity
Altitude above sea level	< 3,000 m
Mechanical stress	According to IEC/EN 61010-1, 8.2.2
Not permitted	Vibrations, direct sunlight and direct exposure to air conditioning systems.

Electrical conditions:

100–240 VAC, 47–63 Hz, no earthing required (Class 2)

Electrostatic discharge (ESD):

No special requirements for ESD protection (shoes etc.)

Hygiene conditions:

Validate your hygiene management system in accordance with internationally applied Good Laboratory Practice (GLP) or a similar quality standard. All waste material must be classified as potentially infectious. Direct contact must be avoided. Protective gloves are required during operation, maintenance or cleaning.

Equipment environment:

No special requirements.

8.3 Initial installation

Check the packaging of the **DIAcheck series** and accessories for visible external damage. If the packaging is damaged, contact the transport company so that any damage to the device or accessories can be assessed.

The device is ready for use and requires no special procedure.

Initial commissioning:

1. Unpack the device and set it up in accordance with the operating conditions (see previous chapter).
2. Fit the accessories (protective film, printer, barcode, Tecam – see the following chapters)
3. Connect the 5 V power supply
4. Wait until the status LED turns green (approx. 15 mins). The device is now ready for use.
5. Register the device online to start the warranty period.
6. Activate 500 cuvettes (see Chapter 11 "Ticket System").

Keep the original packaging material for future transport

The maximum length of cables connecting to external devices such as printers, barcode scanners or LIS must be less than 3 m to ensure EMC compliance

8.4 Switching on and off

Switching on
Connecting to the power supply

Important information:
The device takes approximately 15 minutes to heat the optical block to 37 °C. It is then ready for measurement. This is indicated by a green dot lighting up in the top right-hand corner of the display in the status indicator. If the status indicator is still not green after 25 minutes, press the status indicator to display the device status and identify the problem.

Switching off
The device does not have a power switch. It must be disconnected from the mains supply. To do this, first remove the mains plug from the socket on the device and then unplug the mains lead.

Standby
The system switches to standby mode if it is not used for 2 minutes. In standby mode, the display brightness is reduced to extend the display's lifespan and reduce power consumption. The next touch anywhere on the display deactivates standby mode.

Power-saving mode
Open the menu and tap the "Sleep" button:

The menu bar appears at the top of the screen and is only available when no measurement is in progress. Power consumption in sleep mode is 0.2W.

Wake-up
To wake the device from sleep mode, touch the display.

The system can be disconnected from the power supply under all operating conditions. There is no risk of damage to the system.

8.5 Screen protector

Requirements:

Type:	Touch-sensitive protective film, clean cloth (wet and dry), peel-off sheet
Size:	Same as display (4.3")

Installation:
Ready for attachment to the display, as described in the inlay
(Clean the display with clean wet and dry cloths and carefully)

8.6 External thermal printer

Requirements:

Type:	Serial RS232 printer
Power supply:	External supply, 24V 1.5A
Cables:	2 x Sub D9, female, straight, max. length 3m
Interface:	RS232, 9600 baud, 8, 1, No

Installation:

The printer is ready to connect. No settings are required.

Do not connect the printer's power supply (24 V) to the DIAcheck series. This will damage the device!

8.7 External barcode scanner

Requirements:

Type:	Serial handheld scanner
Power supply:	5V DC via cable, PIN-9
Cable:	Included with the scanner
Interface:	RS232 9600 baud, 8, 1, No
Settings:	No handshake or protocol. The barcode must end with the carriage return (CR) control character.

Installation:

The scanner is ready to connect. No settings are required.

8.8 TECAM SMART

Requirements:

Licence:	TECAM SMART fingerprint and activation code.
Cables:	USB, Type A to B, max 3m
Interface:	USB
Configuration:	No handshake or protocol. The barcode must end with the carriage return (CR) control character.

Installation:

a) Disconnect the device from the PC.
b) Run setup.exe.
c) Confirm when prompted to install the DIAcheck series driver.
d) Connect the device to the PC.
e) Start TECAM

For further information, please refer to Chapter "15" or the TECAM online help.

8.9 Registration

The device must be registered online for warranty or service enquiries

1) Open the web link www.dialab-reg.com or scan the QR code on the System ID card using a mobile device (tablet/phone) (see Fig. 7).

2) Enter the device's **SIN + PIN**

Both can be found on the instrument's number plate (type plate) or during the start-up process, or on the information screen (tap the green or red LED on the start screen)

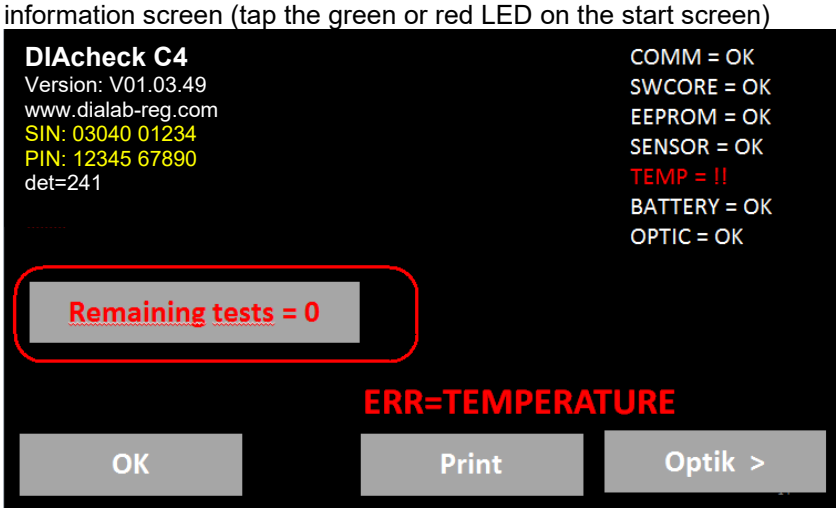


Figure6 : System information

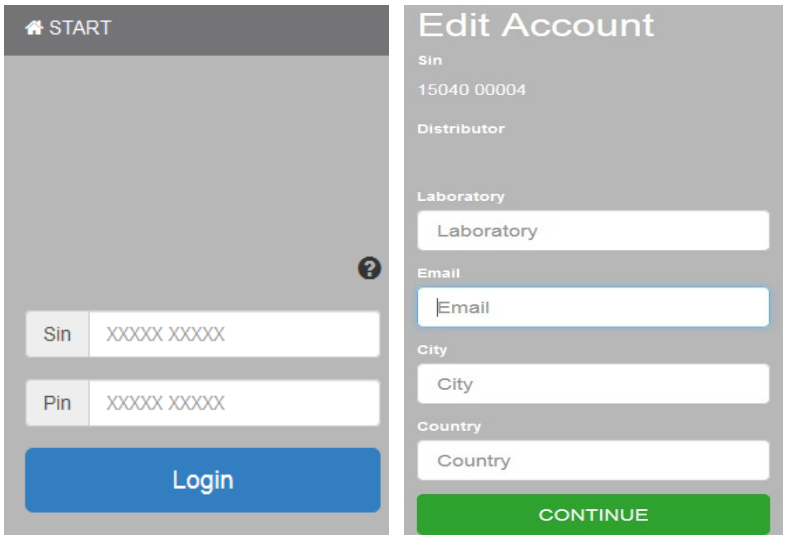


Figure7 : Registration of the DIAcheck series

9 OPERATION PROCEDURE

9.1 Start screen

After booting or pressing the Home button, the following screen is displayed

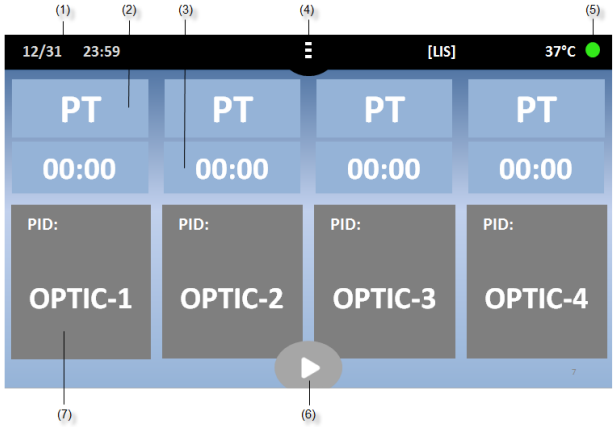


Figure8 : DIAcheck Series C4 start screen

UI element	Name of the element	Function
(1)	Date & Time	Edit date
(2)	Current test	Change test
(3)	Stopwatch	Start/reset the stopwatch or countdown
(4)	Menu or home screen	Open the menu or return to the home screen
(5)	Status display	Display device status/information about the open system
(6)	Multiple start	Activate all channels
(7)	Display: Optic	Channel is inactive. Tap to enter and activate a new PID
	Display: Active	The channel is active. Tap or add reagent to start
	Flashing orange	Measurement in progress. Tap to stop the measurement
	Result display	Tap to enter a new PID

Additional functions:	
[LIS]	Visible when connected to LIS
Green LED	System is ready for measurement
Red LED	Indicates system problems. Measurement is not possible.
37.0°C	Temperature on the reagent block.
Grey buttons	These functions are not available during measurement.
Reduced brightness	Screen saver mode. Tap to reactivate.
Long press	Repeat current function
Green Yellow Red	Green = Ready to measure, no problems Yellow = Ready to measure, minor issues Red = Not ready to measure, major problems

9.2 Enter patient identification

Go to: Home screen/Optics button

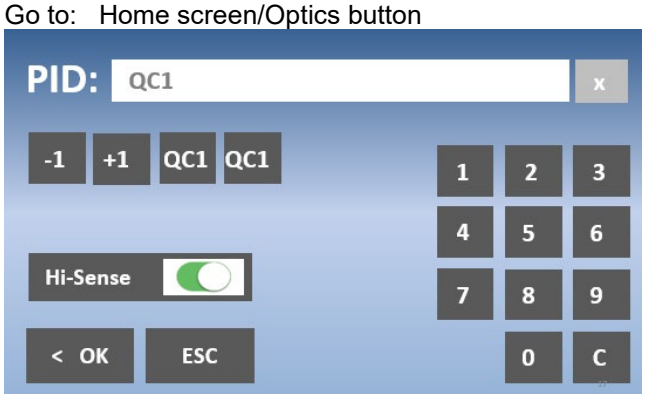


Figure9 : Enter patient ID (PID)

Display element	Function
Numeric keys 0–9, C, X	Enter, change or delete the PID
-1 / +1	Increase/decrease PID. Press and hold for easy adjustment.
QC1 / QC2	Set PID to “QC1” or “QC2”. Useful for quality control and statistics.
Displayed depending on the test: Hi-Sense (Clotting tests), Hi-Dose (for Immmuno tests) or Nothing (for chromogenic test)	
Hi-Sense	Enables very high detection sensitivity for coagulation tests. Useful for highly diluted or lipemic samples or “+++” results.
Hi-Dose	Increases the sensitivity of immunoassays. Useful for samples with very high concentrations above the calibration range, which are incorrectly reported as too low or even false negative.
Additionally	
Long press	Press button > 2 sec.
Sample barcode	PID entry via barcode.

The device automatically stores the last 120 QC and 60 patient results in the EEPROM memory. The most recent result is displayed first. If the result history exceeds the memory capacity, the oldest measurement result is overwritten.

9.3 Selecting tests

Press the Test button on the home screen:

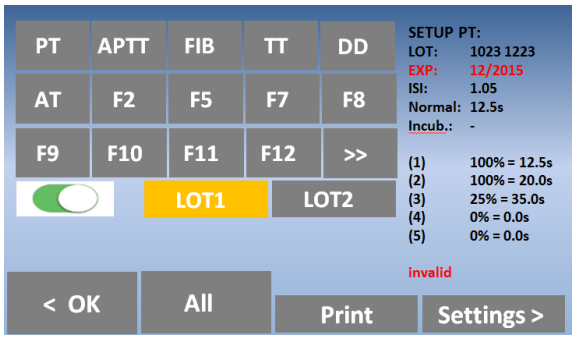


Figure10 : Test selection DIAcheck Series C2/C4

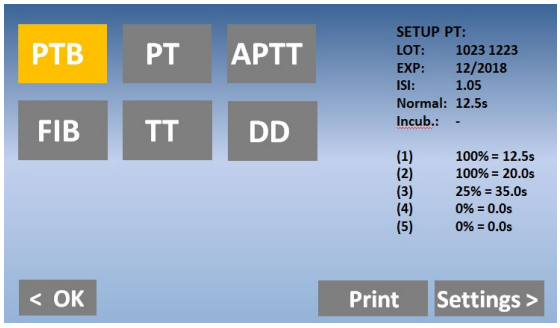


Figure11 : Test selection DIAcheck Series C1

Button	UI element	Function
Test buttons	PT – F12 >> <<	Select test Change test table
On / Off	On / Off	Activate two LOTs per test (not available for DIAcheck C1).
LOT 1/2	LOT 1 / LOT 2	Load the calibration for LOT 1 or LOT 2 from memory.
OK	< OK	Confirm test for the current channel.
All	All	Confirm test for all channels.
Settings	Settings >	Change the calibration of the test.
Print	Print	Print the current test.
Scan reagent barcode	-	Select the current test and batch. A long beep indicates an invalid barcode or LOT.
SET UP PT	Test information field	Calibration data for the current batch and test. Red values indicate invalid data.

About the reagent barcode:
The barcode on the reagent label can be used to switch to the correct test and LOT. Before using the barcode, the test LOT + calibration must be entered in the calibration menu (see chapter Test Settings)

9.4 Measurement

Figure12 : Screen during measurement

Button (7) during measurement	
PID	Patient identification number (max. 16 characters).
Result	PT = 12.5 s, 115% 0.91 INR. +++ = No coagulation reaction detected within the run time.
Mark	f = very low fibrinogen (weak coagulation). F = very high fibrinogen (strong coagulation). * = The result is outside the calibrated range. X = duplicate value deviates by more than 15%.
Error	T = Temperature not 36–38°C. E = Reagent has expired. S = Light intensity too low.
mOD	Current optical density. A change in value of > 50 mOD indicates an ongoing coagulation reaction.
Stopwatch	Current measurement time.
Flashing grey	The optical system is ready to start measuring
Flashing green	The measurement is starting, but the cuvette can still be stirred or touched .
Flashing orange	Do not mix any further and do not touch the cuvette

9.5 System settings

Menu and functions depend on the device version C1 or C2/C4!

Press on the home screen Menu

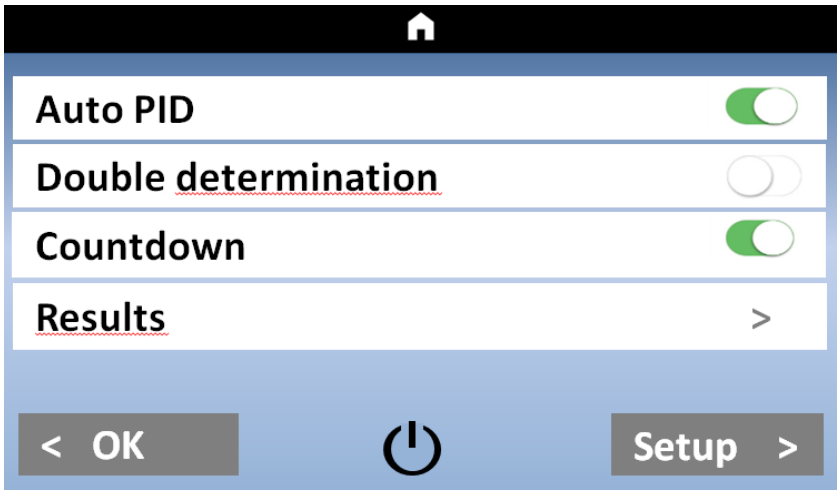


Figure13 : MENU DIAcheck Series C2/C4

Button	UI element	Function
Automatic PID	Toggle automatic PID	Enable/disable the Auto-PID function.
Dual determination	Toggle dual determination	Enable/disable double determination.
Countdown	Toggle countdown	Switch between stopwatch and countdown mode.
Results	"Results" button	Open the results history.
Setup	Setup button	Open the system settings
⏻	Power-saving mode	Put the device into energy-saving mode.
OK/ ⌂	OK / Home button	Return to the home screen.

Automatic PID:
In Auto-PID mode, the user can allow the device to select a sequentially numbered ID for each measurement. By setting the ID manually, you define the starting ID. Each time a new channel is activated, the ID is automatically set to the next higher number.

Auto-PID mode must be enabled to use the multi-start function!

Dual determination:
When using dual determination mode, channels 1 / 2 (DIAcheck C2) or channels 1 / 2 and 3 / 4 (DIAcheck C4) are combined to perform a test with the same ID twice. Both results are combined by calculating the mean value.

Countdown:
Use the stopwatches in countdown mode. The duration of the countdown is defined by the test's incubation time (see "Test settings"). When countdown mode is activated, the stopwatches emit an alarm 5 seconds before reaching zero.

Result:
Pressing the "Results" button opens the screen showing the result history.
Setup:
Pressing the Setup button opens the system settings.

⏻:
Pressing the Sleep button puts the device into sleep mode. To wake the device, tap anywhere on the screen.

OK button / :
Press the OK or Home button to return to the home screen.

On the home screen, select Menu / Settings:

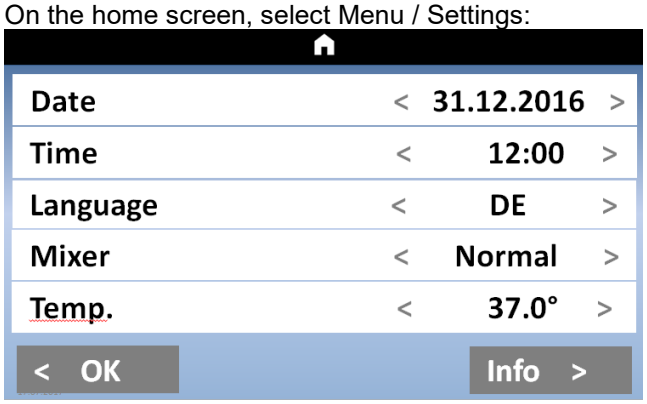


Figure14 : System settings DIAcheck C2/C4 series

Settings/Buttons	Function
Date	Set the system date; press and hold "<" or ">" to scroll through the values more quickly. Tap the date briefly to change the format (EU / US) Long-press the date to reset to the default date
Time	Set the system clock. Long-press to reset to default settings.
Language	Select the system language: DE/EN/ESP/ITA/FR/RO/PL/…
Mixer (not visible for DIAcheck C1)	Some reagents, such as PT-Sediment, need to be stirred. Select the mixer speed here (Low/Normal/High). Place the vial and the magnetic stir bar in the centre position. Adjust the speed until the stir bar ensures proper mixing.
Temperature	Adjust the current temperature of the reaction block. If you press and hold the button, the temperature setting will be reset to the default value. For more detailed information, please refer to the section "Setting the temperature".
OKAY/ ⌂	Return to the home screen.
Info	Open the system information.
< / >	Increase or decrease the value. Touch and hold to scroll.

DE	German	FI	Finnish
EN	English	HR	Croatian,
ES	Spanish	LV	Latvian,
IT	Italian	LT	Lithuanian,
FR	French	PT	Portuguese,
RO	Romanian	SE	Swedish,
PL	Polish	SK	Slovak
DA	Danish	SI	Slovene
NL	Dutch	CZ	Czech
RS	Serbian	HU	Hungarian

9.6 Test settings

On the home screen, press Test / Settings

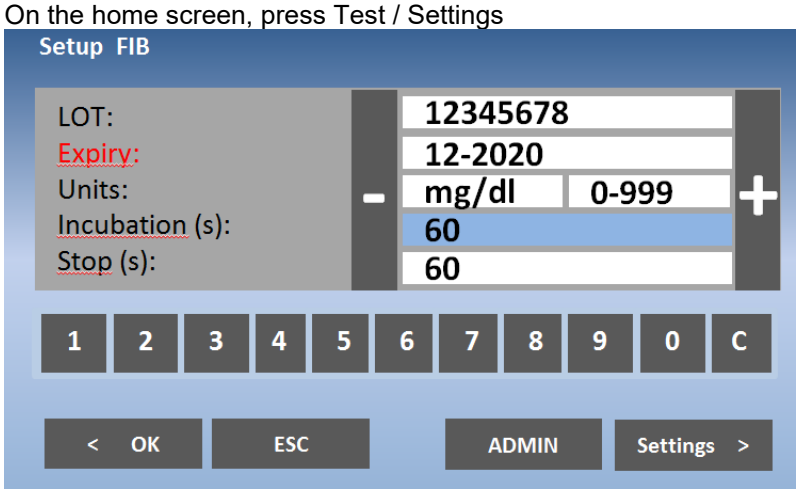


Figure15 : Test setting 1

Setting/Buttons	UI element	Function
LOT	LOT number field	Tap the LOT text field to enter or change the LOT number.
Procedure	"Expiry Date" field	Tap the expiry date value to select the field
Units	"Result Units" field	Tap to change the unit
Incubation	Incubation time field	Press to select the field.
Stop	Stop time field	Press to select the field.
Increase/Decrease	+ or -	Change the value of the selected field.
Numeric keys	0 – 9 and C	Keys for LOT entry. C=Delete
OK	< OK	Save the settings and exit the screen.
ESC	ESC	Exit to test the selection without saving.
Administrator	Administrator	Open the advanced test settings. Visible to administrator users only.
Settings	Settings >	Open the test calibration settings (Screen Test Settings 2)
Barcode:	LOT barcode entry	Scan the reagent barcode to enter the LOT and expiry date.

LOT:
Enter the LOT number of the reagent used for the selected test. If Dual LOT is used, select LOT 1 or LOT 2 on the test selection screen. Both LOT numbers have individual test settings.
Expiry:
Enter the expiry date of the reagent for the selected test (and LOT).

Units:
Select the units to be used for the test results. The available unit is predefined for each test. Range: Limit the results to the unit or calibration range. Results outside the range are reported as ">Max" or "<Min".

Incubation
Required waiting time until the final reagent is added and measurement begins. The time is used for the countdown.

Stop:
Some samples do not clot. Once the stop time has elapsed, the device interrupts the measurement and reports "+++" (no clot detected).

On the home screen, press Test / Settings / Settings

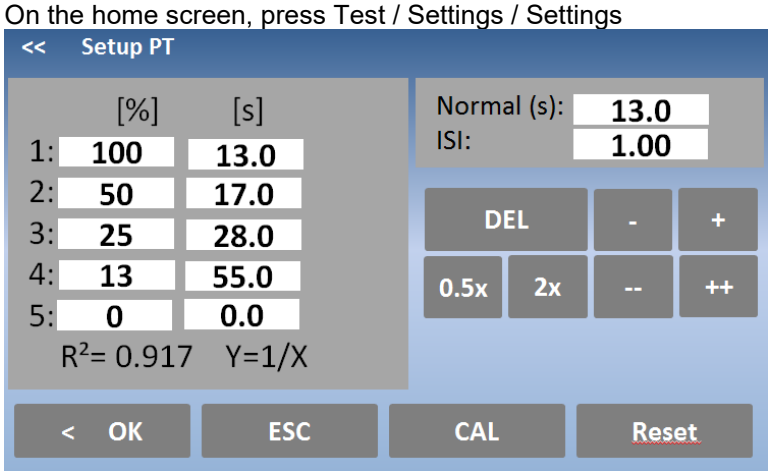


Figure16 : Test setting 2

Settings/Buttons	UI element	Function
Calibration curve values	Value fields	Press to select the field.
Change values	+, -, ++, --	Change values in small or large increments. Use a long press to repeat the change
Double/Half	0.5x 2x	Halve or double values
Delete	DEL	Delete the selected value.
Reset	Reset	Reset all values to their default settings.
Calibrators	CAL	Shift all calibration points according to the serial dilution (1:1, 1:2, 1:4 ...)
OK	< OK	Save settings and exit screen
ESC	ESC	Exit screen without saving.

Calibration curve:
Enter calibration points. Minimum 2 points, maximum 5 points.
Normal:
Reference value for normal clotting time as for PT (MNPT). Only displayed if unit is selected.
ISI:
International Sensitivity Index of the PT reagent. The value is stated on the reagent label.
R²:
Linearity of the calibration as a function of the mathematical model

$R^2<0.5$	not linear	Y=LIN	linear interpolation
$R^2<0.9$	moderately linear	Y=1/X	reciprocal linear interpolation
$R^2 > 0.9$	high linear	Y=logXY	double logarithmic interpolation

9.7 Check results

The device automatically stores the last 120 QC and 60 patient results in the EEPROM memory. The most recent result is displayed first. If the result history exceeds the memory capacity, the oldest measurement result is overwritten.

On the home screen, press Menu / Results

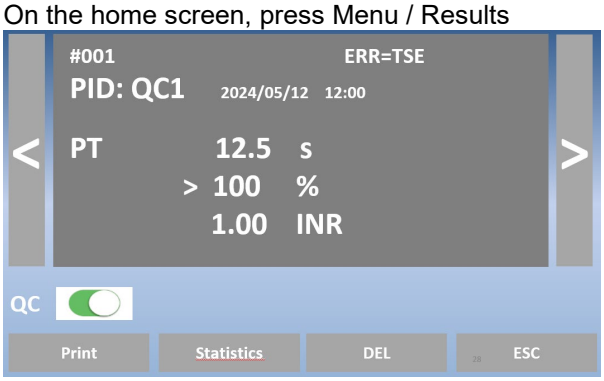


Figure17 : Check results

	Settings/Buttons	Function
	< >	Scroll through the results.
	QC (On, Off)	On= Scroll through QC results (QC1/QC2) Off = Scroll through patient results
	Print	Print the displayed results.
	Statistics	Print and display the QC report for up to 14 values from the current PID test, including the mean and C.V. value
	DEL	Delete current result from memory
	ESC	Exit screen.

10 BASIC COAGULATION TESTS

This section provides only a general overview of how to perform basic coagulation tests using the DIAcheck series. The correct procedure may vary for specific reagents. Always read and follow the instructions in the reagent kit leaflet.

10.1 Quick guide to PT testing

To perform a PT measurement:

1. Switch on the device and wait for the green status indicator (~15 minutes at 37°C).
2. Reconstitute the PT reagent and wait 30–60 minutes before proceeding to the next step.
3. Place the PT vial in the reagent block + stirrer and allow to incubate for at least 5 minutes.
4. Change the test from channel 1 to "PT" by pressing the current test.
5. Place the empty cuvette in the optical unit.
6. Pipette 25 µl of the sample into the cuvette.
7. Press "00:00" to start the stopwatch and wait 120 seconds.
8. Press "OPTIC-1" and enter a PID or scan a sample barcode.
9. Add 50 µl of PT reagent when "Active" flashes. The measurement will start automatically once the reagent has been added.
10. Wait for the result to appear, or touch the optical button to cancel the process.

Multi-activation (not for DIAcheck C1)

1. Open the menu and set Auto PID to On.
2. Place an empty cuvette in each channel and pipette 25 µl of sample into each cuvette.
3. Press the Multistart button.
4. Add 50 µl of PT to each cuvette, moving from left to right.

How to calibrate a PT test

1. Reconstitute the calibrator and wait 15–30 minutes before proceeding to the next step
2. Calibrators
   The target value of the calibrator is specified in the certificate. 100% is assumed as an example.
   IBS, Owrens or $NaCl_{(2)\ solution}$ can be used as sample diluents
   a. 100%: Pipette 100 µl of calibrator into an empty tube
   b. 50%: Pipette 100 µl of 100% calibrator + 100 µl of diluent into an empty tube
   c. 25%: Pipette 100 µl of 50% calibrator + 100 µl of diluent into an empty tube
   d. 12.5%: Pipette 100 µl of 25% calibrator + 100 µl of diluent into an empty tube
3. Test all 4 calibrators as you would for patients and record the clotting time
   (Duplicate measurements are recommended)
4. Enter PT settings and
   a. correct LOT, Exp (read the barcode on the vial label)
   b. Set UNITS to "INR + %"
   c. Enter normal time (=100% result) + ISI (see vial)
   d. Enter calibration in %

10.2 Quick guide to aPTT determination

How to perform an aPTT measurement:

1. Switch on the device and wait for the green status indicator (~15 mins to 37°C).
2. Change the test to "APTT" by pressing the current test.
3. Add CaCl to the instrument and allow to incubate for at least 5 minutes.
4. Place the empty cuvette in the optical unit or in the pre-incubation chamber.
5. Pipette 25 µl of the sample into the cuvette.
6. Pipette 25 µl of cold aPTT reagent into the cuvette.
7. Press "00:00" to start the stopwatch and wait 180–300 seconds.
8. Shortly before the end of the incubation, press "OPTIC-1" and enter a PID or scan a sample barcode.
11. Add 25 µl of CaCl when "Active" flashes. The measurement starts automatically.
12. Wait until the result appears or touch the optical button to cancel the process.

10.3 Quick guide to FIB determination

To perform a FIB measurement:

1. Switch on the device and wait for the green status indicator (~15 mins to 37°C).
2. Change the test to "FIB" by pressing the current test.
3. Reconstitute the FIB reagent and wait 30–60 minutes before proceeding to the next step.
4. Do not place the FIB vial in the reagent block. Room temperature is fine.
5. Place the empty cuvette in the optical unit.
6. Pipette 10 µl of sample into the cuvette.
7. Pipette 90 µl of IBS buffer into the cuvette.
8. Press "00:00" to start the stopwatch and wait 120 seconds.
9. Press "OPTIC-1" and enter a PID or scan a sample barcode.
10. Add 50 µl of FIB reagent when "Active" flashes. The measurement starts automatically when the reagent is added.
11. Wait for the result to appear or touch the optical button to cancel the process.

How to calibrate a FIB

1. Reconstitute the calibrator and wait 15–30 minutes before proceeding to the next step
2. Calibrators
   The target value of the calibrator is specified in the certificate. A concentration of 300 mg/dl is assumed as an example
   Pipette for
   a. 37.5 mg/dl: 100 µl calibrator + 600 µl IBS buffer into an empty cuvette
   b. 30 mg/dl: 100 µl calibrator + 900 µl IBS buffer into an empty tube
   c. 15 mg/dl: 100 µl calibrator + 1900 µl IBS buffer in an empty tube
   d. 10 mg/dl: 100 µl calibrator + 2900 µl IBS buffer in an empty tube

3. Test all 4 calibrators
   a. Add 50 µl of calibrator to the cuvette
   b. Add 25 µl of FIB reagent to start the measurement. Write down or print the clotting times on paper,

4. Enter the FIB settings and enter
   a. correct LOT, Exp
   b. Set UNITS to "mg/dL"
   c. Enter mg/dl calibration

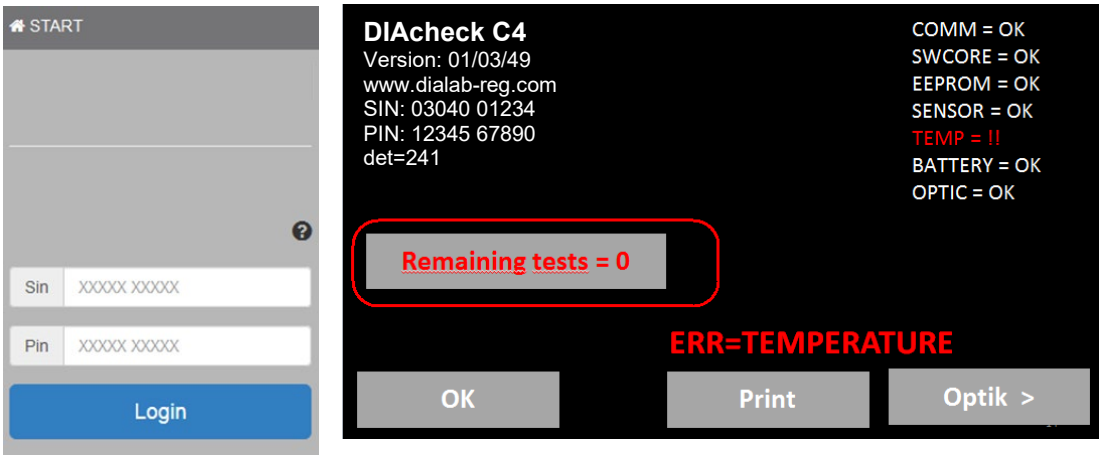
10.4 Control Procedure

For Control and Calibration material and the related Traceability please refer to the corresponding Instructions for Use. It is recommended to only use DIALAB Reagents, Calibrators and Control materials

11 TICKET SYSTEM

1) Log in to the ticket system

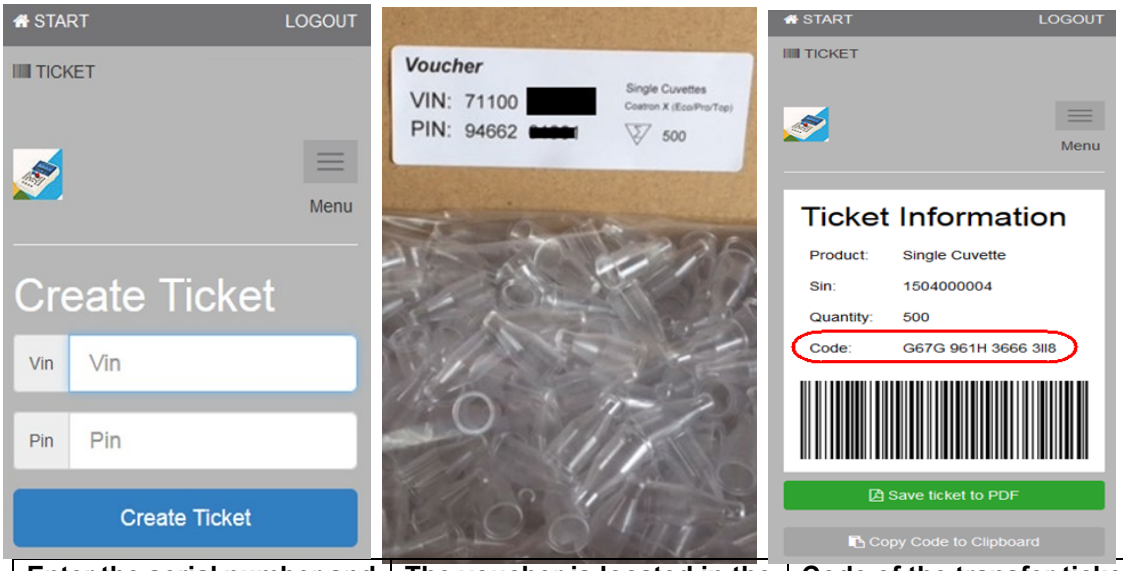
Website: www.dialab-reg.com



Enter the instrument's SIN and PIN! You will find this information on the instrument's number plate (type plate) or on the information screen.

Figure18 : Ticket system, LOGIN

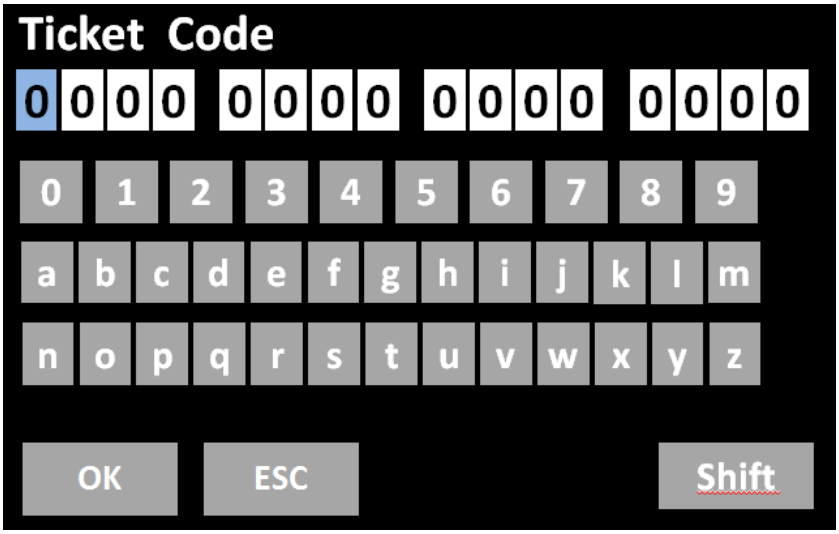
2) Enter voucher



Enter the serial number and PIN of the voucher	**The voucher is located in the cuvette box**	**Code of the transfer ticket for the instrument**

Figure19 : Ticket system, voucher

3) Transfer ticket code to instrument



Open the information screen (tap the flashing red LED) and then select 'Remaining tests=0'. The code can be transferred via manual entry, barcode scanner or TECAM SMART software.

Figure20 : Ticket system, enter code

4) Using the TECAM SMART software

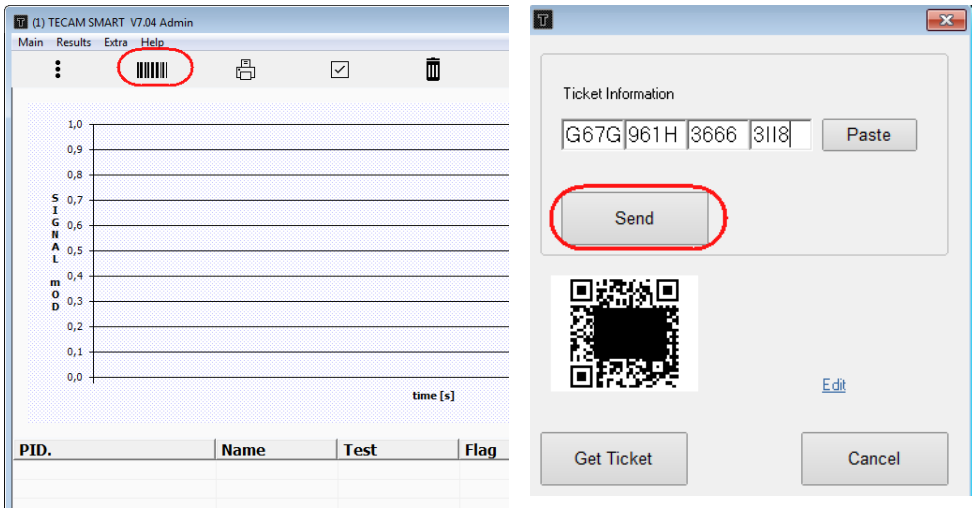


Figure21 : Ticket system, TECAM SMART

a) Use your mobile device to scan the QR code or "Get ticket" when TECAM is connected to the internet
b) Follow the instructions in section (1) of this chapter

c) Paste the code and "send" it to the instrument

12 SERVICE FUNCTIONS

For authorised and trained personnel only. Unauthorised modifications may cause problems and system malfunctions!

12.1 System information

Press the green or red LED on the home screen

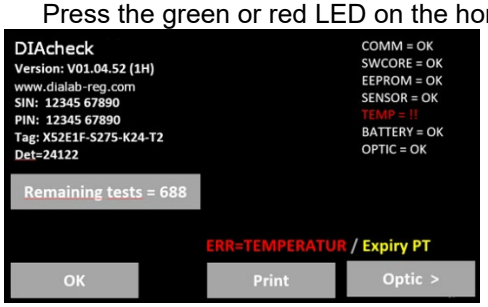


Figure22 : System information

Image element name	Function
DIACheck	Device name
Version	Software version main.sub.build (test logs)
URL / SIN / PIN	Voucher system login + system identification number + PIN
Tag	Service tag required for support enquiries to DIALAB Support
Det	Number of tests performed
Remaining tests	Number of remaining tests
ERR	Number of activated cuvettes. Tap to activate new cuvettes
Visual	Yellow and RED warnings
OK	Open status of the optical system
Print	Return to home screen

System information
Software version, URL link to the registration or ticketing system, System ID number (SIN), Product ID number (PIN). SIN+PIN is required to log in to the ticketing system.
Remaining tests=0:
The system will stop operating when the count reaches zero, and new cuvettes must be activated.
YELLOW warnings
Minor issues

Reagent has expired	Check the expiry date of the reagents
Remaining tests < 100	Activate cuvettes soon

RED warnings
System is not ready for measurement

COMM= Communication with LIS		SWCORE = Software memory overflow	
EEPROM = EEPROM/memory error		SENSOR = Temperature sensor	TEMP= Temperature not 36-38°C
BATTERY = CR2032 on mainboard below 3V			
OPTIC = optical system out of range			

12.2 Optics check

On the home screen, press the green or red LED / Optics

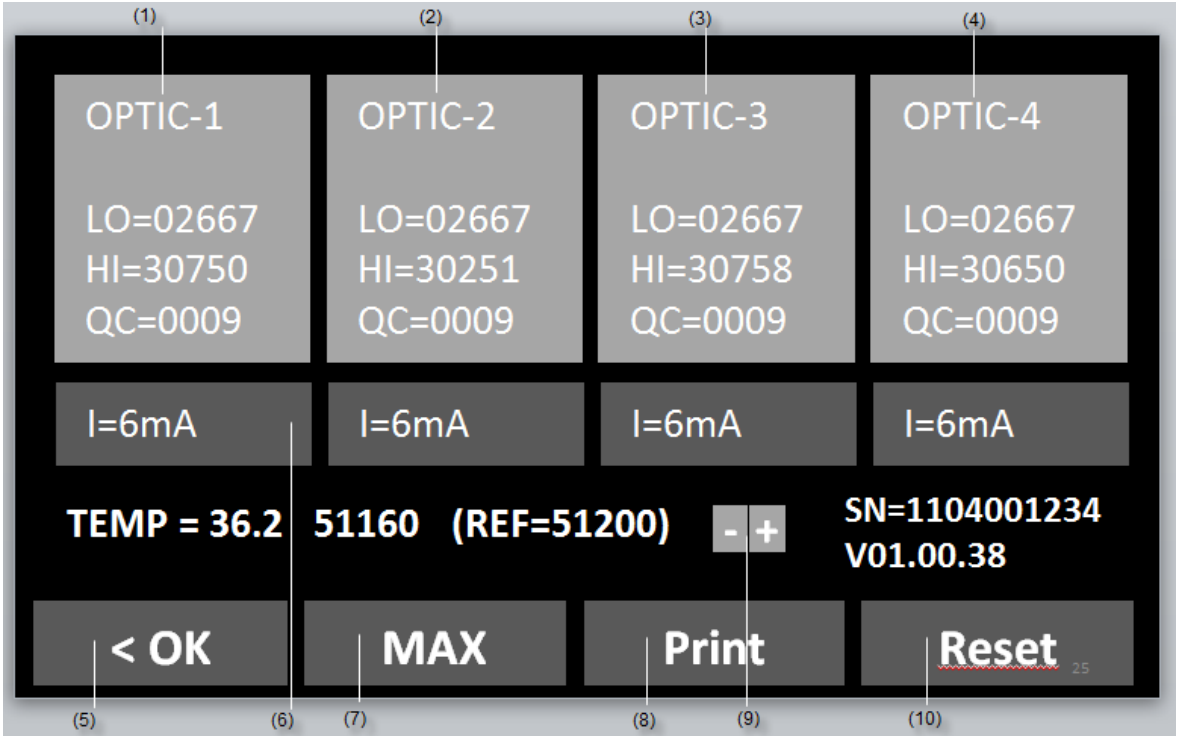


Figure23 : Optics check

Button	Heading	Use function
(1)-(4)	OPTICS xx	Reset QC value
(5)	I=mA	Display and adjustment of LED intensity
(6)	OK	Back to the home screen
(7)	MAX	Set all LEDs to maximum brightness (42mA)
(8)	Print	Print system report (see next chapter)
(9)	+ / -	Change temperature
(10)	Reset	Reset all channels and recalibrate the optics

Screen display	Other signals	Error status	Resolve
LO	Visual signal when the LED is off	> 2900	Replace optical circuit board
HI	Visual signal when the LED is on	< 25000	Remove the cuvette and tap "RESET"
QC	Noise in the optical signal	> 30	Touch the "OPTICS" button
mA	LED power (intensity)	not [3–12 mA]	Remove the cuvette and tap "RESET"
TMP	Temperature in °C	not [36.0 - 38.0°C]	Wait 15 minutes
REF	Temperature sensor signal	not [48000 - 52000]	Adjust temperature or replace sensor

12.3 System report

On the home screen, press the green or red LED / Print

```
SYSTEM REPORT

22 August 2017

System:         DIAcheck
Version:        V1.03.49
VAT No.:              03040 01234
PN:                12345 67890

TEMP:             37.0°C
                  50981 (Target=50992)

Optic:
Lo      Hi      mA      Qc
-------------------------------------------
1:2698  28822   5       6       OKAY
2:2698  29822   6       3       OKAY
3:2698  30822   7       1       OKAY
4:2698  29822   6       0       OKAY

PT=     123
aPTT=   102
FIB=    100
DD=     0
AT=     0

TOTAL 325
```

Date of report

System name
Software version
System ID number
Product identification number

Temperature of the optics and digital value
of the thermal sensor

Optical values
Lo= LED off
Hi= LED on
mA= LED power
Qc= Optical noise
OK= no error
!! = Error status

Number of tests performed

Fault conditions are described in the chapter "Common Faults"

12.4 Adjust temperature

On the home screen, press Menu / Temperature

1. Switch on the device and wait approx. 15 minutes until the system displays 37°C on the screen.

2. Fill a reagent tube/vial with 2 ml of water and place it in a reagent position. Place a digital thermometer in the reagent tube and allow it to warm up for approx. 10 minutes.

3. Press Menu
   Change the current system temperature to the value shown on the thermometer. Wait 10 minutes and repeat the process.
   Common problems:

Fault / Error	Possible cause	Action
System does not reach 37°C	The sensor calibration is outside the permissible range.	Reset to factory settings as described in the chapter "Reset to factory settings"
System display 0.00°C	The sensor is out of range	The ambient temperature must be between 0 and 45°C.
	The sensor or optical LED board is faulty	Replace the LED board

12.5 Firmware update

For authorised and trained personnel only. A sudden interruption to the power supply or data communication during the update process will prevent the device from booting. In this case, the device can only be restored via the JTAG interface.

1. Download flashdisk.exe from the manufacturer's website. Contact your local distributor to obtain the correct URL.

2. Flashdisk.exe is a self-extracting WinZip archive. Double-clicking it launches the update dialogue. Some antivirus programmes may block the self-extracting archive. In this case, extract the file to your desktop and run "Flash.exe".

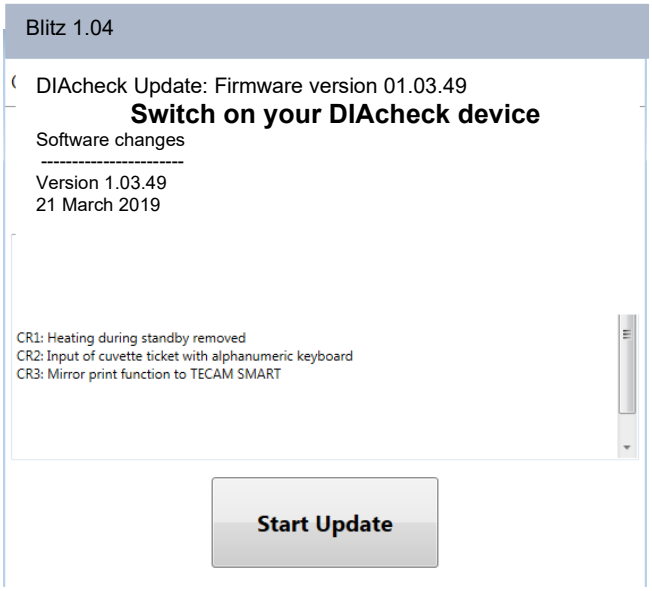


Figure18 : Screenshot of the XFlash tool

3. Confirm "Start update"

4. Remove the USB cable from the device and confirm

5. Connect the USB cable to the instrument's USB "Service" port (= second USB port from the left)

   Flash will now recognise the device and display "CONTINUE". If no device is found, cancel the Flash process and manually install the "FT232.exe" device driver. The file is included in the Flashdisk archive.

6. Confirm "Start update". Once this command is issued, the firmware will be transferred to the device. There is no way to interrupt this process. The update will be complete after approximately 120 seconds.

7. Disconnect the power supply and then the USB cable from the service port. Now connect the device to the power supply. It should boot up and display the correct firmware version.

12.6 Motherboard overview

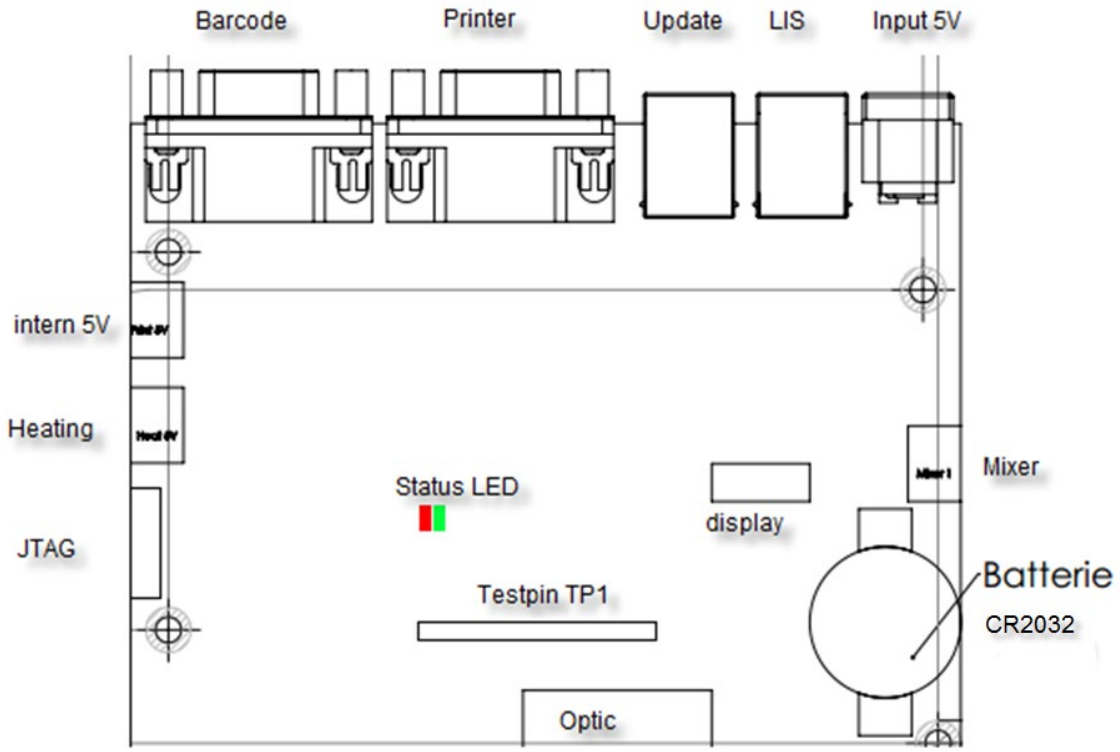


Figure25 : Mainboard

Test pin function:

TP1 = System clock interval, must flash every 1 ms
TP2 = Display of the measured value from SD24
TP3 = Draw start screen
TP4 = Write to EEPROM
TP5 = Read from EEPROM
Miscellaneous = not assigned

Status LED:

green, steady	= everything OK	
red, steady	= EEPROM error	faulty optics and/or motherboard
green, flashing	= Battery < 3.0V	Low battery
Red, flashing	= Temperature sensor	Optics not connected

13 COMMON FAULTS

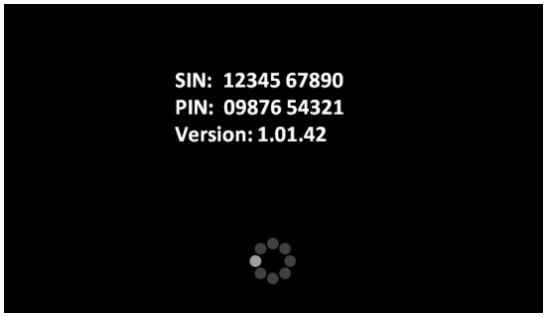
Fault / Error	Possible cause	Action	Responsibility
System not ready	Various causes	Open the system information and check for errors marked in red	User
Remaining tests = 0	No cuvette activated	Create a ticket	User
ERR=Comm	Motherboard fault	Replacement	Authorised service
ERR=SWCORE	Software error or bug	Update firmware	User
ERR=Sensor	Temperature sensor faulty	Replace the optics	Authorised service
ERR=Temp	Temperature of 36–38°C	Please wait 15 minutes	User
ERR=Optical	Optical channel blocked or LED faulty	Remove the cuvette from the optical system, clean the optical system or replace the optical system	Authorised service
ERR=Battery	Low battery	Replacement	Authorised service

Incorrect results	Possible cause	Action
No clot or incorrect clot detected	It is correct that the patient is on anticoagulants or is bleeding	Remove the cuvette and use the needle to check for a clot
	Reagent defect	Visually inspect the reagent for precipitates or clots. Test control plasma to verify this. Prepare a new reagent. Check the diluent/water
	Instrument does not detect clot	Increase the MAX time
	Low fibrinogen or optical interference (lipemic, bilirubin, haemolytic)	Repeat, but enable the Hi-Sense option
Incorrect result (INR, %, mg/dl, ...)	Method not correctly calibrated	Check calibration data and correct LOT

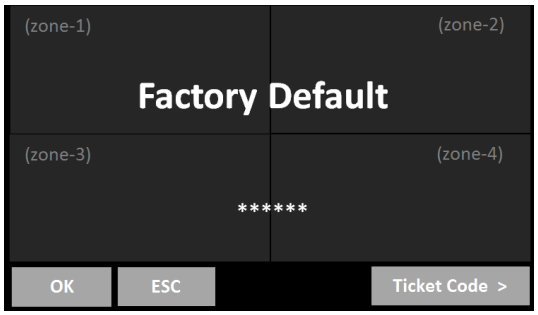
Invalid cuvette ticket	Possible cause	Action
LOT invalid	The voucher has already been used in the system.	Redeem a new voucher www.dialab-reg.com
S/N invalid	The SIN number in the voucher ticket information does not match the instrument's S/N	Enter the voucher ticket code only on the correct target device
Invalid	For some unknown reason, the system is not accepting the voucher ticket	Please contact DIALAB technical support

14 RESET TO FACTORY SETTINGS

Procedure for resetting the system to factory settings:



Welcome screen +



Factory settings

To reset to factory settings:

1. Press and hold the ‘circle’ button for 3 seconds whilst the device is booting up
2. Select "OK". Switch on the device and go to the home screen
3. Confirm the reset

⇨ The date, temperature and test calibration must be adjusted to the factory settings after a reset!

Default values:

- Temperature sensor = 51000
- Mixer = 1;
- Language = EN;
- Dual determination = OFF;
- Auto PID = ON;
- Countdown = OFF;
- All results stored on board will be deleted
- All test calibration data will be reset to default settings

Test calibration:

To reset a PT calibration to factory settings:

1. Switch on the device and go to the home screen
2. Tap any test button
3. Change the test to "PT" and tap "Setup"
4. Enter LOT and expiry date and select units as "% + INR"

15 WORKING WITH TECAM SMART

> ⇨ Detailed information on installation and operation can be found in the TECAM online manual. This is only a brief overview.

The TECAM software is a small local LIS that combines laboratory data management, quality control and research functions in one. It connects the DIAcheck to the "main" LIS and manages the results in its own local database. Flexible filters enable quality control using Levey-Jennings charts and Westgard analysis. Every result can be traced back to the reagent batch and calibration.

Features	Smart
Receive results from the analyser	Results can be reported and managed in a local database
Obtain calibration curve from the analyser	Visualise and manage calibration data for all reagents and batches.
Receive reaction curve	Visualisation of the optical reaction for research, result verification or error analysis
Patient information	Link the patient ID to the name and other information.
LIS communication	Communicate with LIS using the ASTM 1394 standard protocol Received from LIS: patient information Send to LIS: Results
Statistical analysis (QC)	Performance filters enable Quality-Every-Jennings plots and Westgard analyses for both controls and patients
Integrated TECMONI	This is a powerful research tool for visualising the response curve in real time. It is an excellent tool for developing reagents or adapting tests to a device
Print function	Instead of an expensive portable thermal printer, use TECAM as your printer
Ticket system	Activate the cuvette in the simplest way possible. Connect to the ticket system, receive the ticket and send it to the device

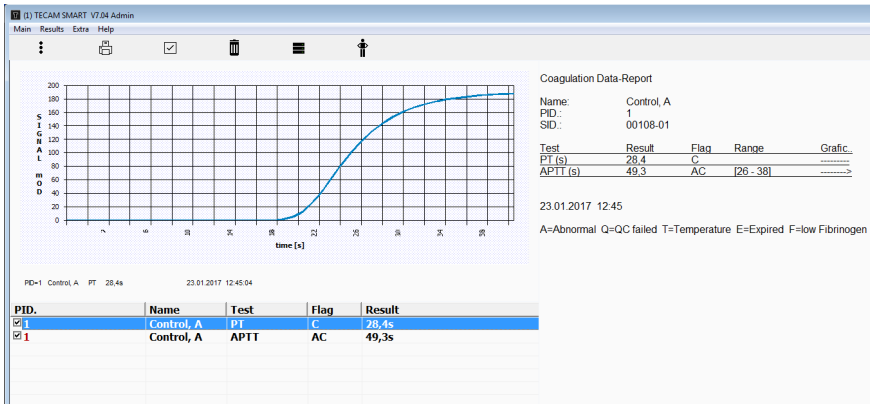


Figure26 : TECAM SMART

16 CLEANING AND MAINTENANCE

16.1 General cleaning instructions

- Clean with a lint-free cotton cloth or swab
- Never allow liquids to come into contact with the optics, the work area or the touch screen
- Keep the device free from dust and moisture.
- If the device is contaminated with liquids, remove the contamination with an absorbent cloth.
- If liquid is accidentally spilled or pipetted into a measurement channel, disconnect the power supply immediately and clean the measurement channel using a pipette and a lint-free cloth. Check the function of the optics in the SERVICE menu.

Consider all surfaces and materials that may come into contact with plasma or other biological fluids as potentially contaminated with infectious material.

Avoid any direct contact with decontaminants or disinfectants.

16.2 Cleaning

- Use only microfibre cloths and no liquid to clean the screen
- Clean up and wipe away any spilled liquids around the work area with 5–10% diluted bleach or water.

16.3 Decontamination

- Use 30% diluted bleach and a standard disinfectant (e.g. Bacillol®AF)
- Decontaminate the work area. Do not apply any liquid to the display.

16.4 Regular maintenance

- No maintenance required

17 TECHNICAL DATA

Device	
Screen	4.3" capacitive touchscreen TFT 480x272
Measurement system	1–4 independent measurement channels LED wavelength 405 nm (C2, C4) / 620 nm (C1)
Cuvette	Single-channel cuvette for optical detection
Positions (preheated)	5 reagent positions at 36.5 – 37.5 °C 20 cuvette positions at 36.5 – 37.5 °C
Reaction volume	The minimum total volume is 75 µl
Power supply	
Nominal input voltage	100–240 VAC, 47–63 Hz
Maximum input current	0.7 A rms
Output power	5 V DC, 5 A
Battery (mainboard)	Lithium CR2032 3V
Power consumption	max. = 14W Idle state < 0.5W
Dimensions	
Dimensions (W x D x H)	225 x 150 x 90 mm
Weight	1.04 kg (excluding power supply)
Operating conditions	
See the "Installation" section	
Noise level	
Noise level	max. 50 dBA
Interfaces	
RS232 (barcode)	Sub-D9, female; 9600 baud/8/1/N; pin 9 is supplied with 5V DC. For external handheld barcode scanners, serial printers
RS232 (printer)	Sub-D9 female; 9600 baud/8/1/N; For serial printers
USB (service, firmware update)	Type B, socket, 115200 baud/8/1/N
USB (LIS)	Type B, socket, 115200 baud/8/1/N; For LIS communication

Typical performance data		
Test	CV.	Range
PT	<3%	0–30 INR
APTT	<3%	15–420 sec
Fibrinogen	<7 %	50–999 mg/dl

18 CONSUMABLES / ACCESSORIES

Cuvettes, (1 pack = 500 pcs.) **with voucher identification code (VID)**
Stirring magnets, 1 pack = 4 pcs. Required for mixing PT reagent
∅ , 11 mm, 1 pack = 100 pcs.
Microtubes, Safe-Lock, with cap∅ 11 mm, 1 pack = 100 pcs.
Reagent adapters,∅ 24.25 mm,→ 22.5 mm ∅ Helps position vials of different sizes on the device
Screen protector set (protective film, clean wipes, remover)
TECAM Smart Software Patient management, reagent calibration management, monitoring, research, statistics, print function, LIS communication (ASTM-1394)
Thermal printer, 57 mm, wide range: 100–240 VAC
Thermal paper, 57 mm, 1 pack = 5 sheets
External QR barcode scanner (1D, 2D) For reading 1D or QR codes for patient IDs, reagents, tickets