



ORALyzer EXpert User Manual



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1 Introduction

Thank you for choosing the **QRALyzer EXpert**. We are confident that this product will become an integral part of your daily work.

Portable testing without an accessible lab is a challenge. Using the wealth of experience obtained from providing reflectometric detection technology to thousands of customers worldwide, the specialists at dentognostics have developed a new generation reader for mobile applications. The **QRALyzer EXpert** is a highly sensitive, robust, and cost-effective measurement system for lateral flow tests. This flexible and reliable system, based on a ready-to-use concept, enables the users to easily run lateral flow tests.

This manual describes how to operate the **QRALyzer EXpert**. Before using the device, it is essential that you read this user manual carefully.

1.1 General information

1.1.1 Technical assistance

At dentognostics, we pride ourselves on the quality and availability of our technical support. Our Technical Services Department is staffed by experienced engineers with extensive practical and theoretical expertise in the use of dentognostics products. If you have any questions or experience any difficulties regarding the **QRALyzer EXpert** products in general, do not hesitate to contact us.

dentognostics customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to the researchers at dentognostics. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact the dentognostics Technical Services Department (see chapter Technical service support).

For up-to-date information about the **QRALyzer EXpert** products, visit www.dentognostics.de

1.1.2 Policy statement

It is the policy of dentognostics to improve products as new techniques and components become available. dentognostics reserves the right to change the specifications of products at any time.

1.1.3 Version management

This document is the ESCA12-DH-1000 User Manual **QRALyzer EXpert** REV 001/2022-06

1.2 Intended use of the QRALyzer EXpert

The **QRALyzer EXpert** instrument is designed to perform reflective optical measurements that can be used to detect and/or quantify target analytes on lateral flow test strips.



The **QRALyzer EXpert** is intended to be used only in combination with lateral flow tests indicated for use with the **QRALyzer EXpert**, and only for applications that are described in the respective handbooks from test manufacturers.

The intended use does not include operation of the device in intensive care units or in operating theaters, unless all specific hygiene and patient safety requirements at these locations are followed by the user.

2 Safety Information

The instructions and safety information in this user manual must be followed to ensure safe operation of the **QRALyzer EXpert**. Please note that if the equipment is used in a manner not specified by dentognostics, the protection provided by the equipment may be impaired.

The following types of safety information appear throughout the Manual.


WARNING 	The term WARNING is used to inform you about situations that could result in personal injury to other persons. Details about these circumstances are provided in the box like this.
CAUTION 	The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment. Details about these circumstances are provided in the box like this.

Note: The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in user's country.


2.1 Proper use

The **QRALyzer EXpert** must be operated by personnel familiar with the use of the associated dentognostics instrumentation. Personnel must have been trained in its use or have read and demonstrated an understanding of this Manual.

As potentially infectious patient specimens will be measured with the **QRALyzer EXpert**, dentognostics recommends to use appropriate personal safety equipment such as gloves. Patient specimens should be handled in accordance with Good Laboratory Practice (GLP) using appropriate precautions. If, despite all precautionary measures, the **QRALyzer EXpert** should come into contact with potentially infectious material, please follow the instructions provided in chapter Cleaning.

WARNING 	Improper use of the QRALyzer EXpert may cause personal injuries or damage to the instrument. The QRALyzer EXpert must only be operated by qualified personnel that have received the respective training. Servicing of the QRALyzer EXpert must only be performed by dentognostics Service Specialists.
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2.2 Electrical Safety

<div>CAUTION</div> <div></div>	Do not expose the reader to strong electromagnetic radiation. It is the responsibility of the user to ensure that a compatible electromagnetic environment is maintained for the instrument in order to guarantee conform performance. This device conforms with the emitted interference and emitted immunity requirements of the standard DIN EN 61326-2-6. The electromagnetic environment of the device should be assessed prior to its application. Do not use this device in proximity to sources of intense electromagnetic radiation because proper use may be disturbed.
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2.3 Environment

If the **QRALyzer EXpert** is to be used in a working environment prone to dirt build-up, clean the device regularly. For cleaning, please follow the instructions provided in chapter Cleaning.

2.4 Environmental hazards

<div>CAUTION</div> <div></div>	Do not expose the QRALyzer EXpert to direct sunlight during operation.
<div>CAUTION</div> <div></div>	Protect the reader from high humidity and contact with liquids.

2.5 Heat hazard

<div>CAUTION</div> <div></div>	Do not expose the reader to excessive heat.
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2.6 Maintenance safety










Perform the maintenance as described in chapter Maintenance. dentognostics charges for repairs that are required due to incorrect maintenance.

2.7 Waste disposal

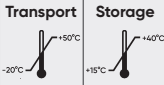


Wastes may contain certain hazardous chemicals or contagious/bio-hazardous materials and must be collected and disposed properly in accordance with all national, state, and local health and safety regulations and laws.

2.8 Symbols on the QRALyzer EXpert instrument

The following symbols may appear on the **QRALyzer EXpert** instrument.

Symbol	Location	Description
	Type plate on the back of the instrument	CE mark for Europe
	Type plate on the back of the instrument	IVD mark, device is intended to be used as an in vitro diagnostic device
	Type plate on the back of the instrument	Serial number
	Type plate on the back of the instrument	Legal manufacturer
	Type plate on the back of the instrument	Date of manufacture
	Type plate on the back of the instrument	Waste Electrical and Electronic Equipment (WEEE)
	Type plate on the back of the instrument	Catalog number
	Type plate on the back of the instrument	Consult instructions before use
IP10	Type plate on the back of the instrument	IP Classification
	Type Plate	Read and understand user manual before using this equipment

2.9 Symbols on the package of the reader

Symbol	Location	Description
Conditions	On the package	Transport and Storage conditions ¹ .
		
	On the package	Keep package dry!
	On the package	Handle package with care!

¹Allowed Temperature range for storage and transportation as specified in the chapter “Technical Data” on page 42.

3 Functional Description

3.1 Hardware



1	Touch display	5	Ethernet port (RJ-45)
2	Power button with LED	6	USB port (type A, 3times)
3	Drawer for test cassette	7	Connector for power supply
4	Handle	8	Type Plate

- 3.2 Contents of the kit
- **QRALyzer EXpert** instrument
 - Quick Start guide
 - Power supply including international connection adapter
 - Network Cable and USB to Ethernet Adaptor

4 Unpacking and Set-up Procedures

4.1 Unpacking of the QRALyzer EXpert

Take out the **QRALyzer EXpert** from its transport case, place it on a stable and leveled surface and check whether it contains all items as listed in chapter Contents of the kit.

Carefully examine the instrument to make sure that it has not been damaged during the shipment. In case of damage or any parts missing (refer to chapter Contents of the kit), contact immediately your supplier.

4.2 Setup and connection of the QRALyzer EXpert

Place the **QRALYZER EXPERT** on a stable and leveled surface.

Plug the power supply cable (low voltage end) into the connector at the back side of the device (pos.7 in chapter Hardware). Plug the power supply cable (mains end) into a power outlet. Make sure that the cable is plugged in properly on both sides.

It is possible to use different drawers according to the test used. These can be exchanged as needed. The standard drawer is a flexible drawer suited for test strips and cassettes as well. If used with test cassettes, the white frame can be removed (see picture 2) and the test cassette can be placed in the inside tub. If test strips are used, then the white frame must be inserted and test strips can be placed into the middle of the 3 grooves (see picture 1).



Installation

4.3 Requirements

The **QRALyzer EXpert** is a highly sensitive and precise optical device. The result can be influenced by vibrations e.g. if the device is used close to vibrating machines.

The device has internal correction for normal levels of ambient light. Highly intense light falling into the test strip insertion port can cause serious interference with the measurement and must be avoided where possible.


4.4 AC power connection

The **QRALyzer EXpert** must only be used with the power supply provided with the device.

4.5 Hardware installation / Accessories

Installation of power supply options and accessories:

- External power supply: connect external power supply to power port. „A blue LED light in the power switch will indicate the connection to a power supply.
If you would like to power your device with an external power bank, ask your dentognostics Sales Representative for appropriate models.
- Thermal printer: The **QRALyzer EXpert** can be connected to a Dymo TM 450 label writer with large address labels (101 x 54mm) via USB.

<p>CAUTION</p> 	<p>Be aware not to plug in the power supply cable of the DYMO printer into the QRALyzer EXpert. This can cause permanent damage to the QRALyzer EXpert.</p>
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- External Barcode Reader: An external barcode reader (Model Zebra DS 2208) can be used to enter the sample ID instead of using the GUI keyboard. Plug in the USB cable of this barcode reader to a free USB port at the rear side of the **QRALyzer EXpert**.

Note: The Barcode reader must be configured for text entry prior first use. For this, scan the barcode “USB KEYBOARD (HID)” from the Zebra Quick start guide to configure the barcode appropriately. For further instructions, refer to the user manual of the Zebra Barcode scanner.

4.6 Relocating the QRALyzer EXpert

The **QRALyzer EXpert** is a mobile device that can be relocated easily. Make sure that general operating conditions are always met (see Technical Data).

5 General Operation

5.1 Powering the QRALyzer EXpert on and off

Switch on the device by pressing the power button (Pos. 2 in chapter Hardware). The device will show a standard black screen and switches after 15 seconds to a boot screen. After successful initialization of all components, the home screen is visible.

Switch off by pressing the power button for at least 1 second. The Reader will ask for confirmation on the GUI before shutting down.

Note that the blue LED will keep turned on even if the device is turned off.

5.2 Instrument startup

Push the power button, the operating system and application will boot up.

The internal self-check routine will be performed to check if the values from internal reference standards are within the defined tolerance range. If the measured values of the internal reference standards are outside the tolerance range a warning message will be displayed.

Note: Please make sure, that the original drawer is inserted (see chapter Unpacking and Set-Up Procedures).

First Log In

The reader will have the user management be turned on by default. To log in, use the default user which is pre-installed named “ADMIN”. The initial password is “0000”

User management can be configured in the menu under System/Settings/Admin Areas/User Management (see chapter User Management). New users can be added, passwords can be changed and user management can be turned off.

5.3 Menu Structure

The graphic below shows the menu structure of the **QRALyzer EXpert**

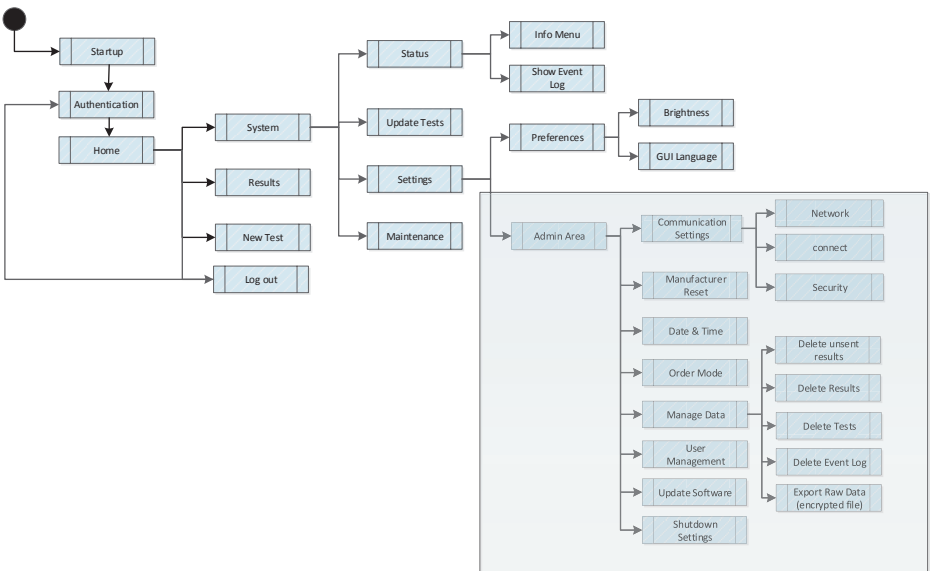


Figure 1: GUI menu overview of QRALyzer EXpert. The menus in the Blue shaded box indicate functions which are available for administrators only

The following chapter will describe the 3 main menus of the GUI

- Perform a New Test
- Results menu
- System status, test update, settings and maintenance

When the System has started successfully, the home screen is visible. It is divided into several parts (see numbers)

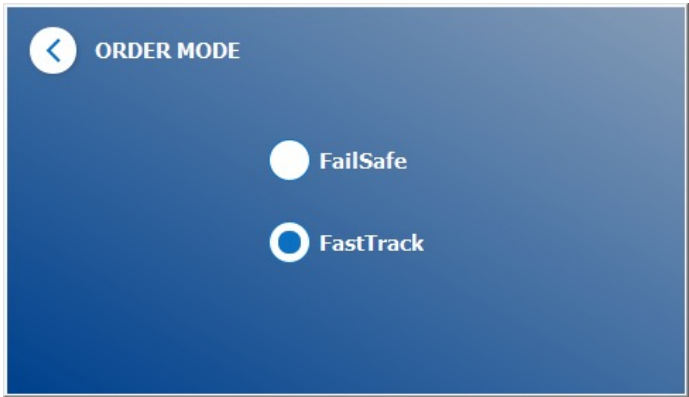


1	Button to start a new measurement
2	Button to review results
3	Button to view status and change settings
4	Button to log off from device
5	Status Bar displaying Date/Time and status symbols if applicable

6 Instrument Usage

6.1 The 2 ordering workflow modes

The **ORALyzer EXpert** offers 2 ordering modes which can be selected in the Instrument Settings with “administrator” rights (See chapter Instrument Settings)



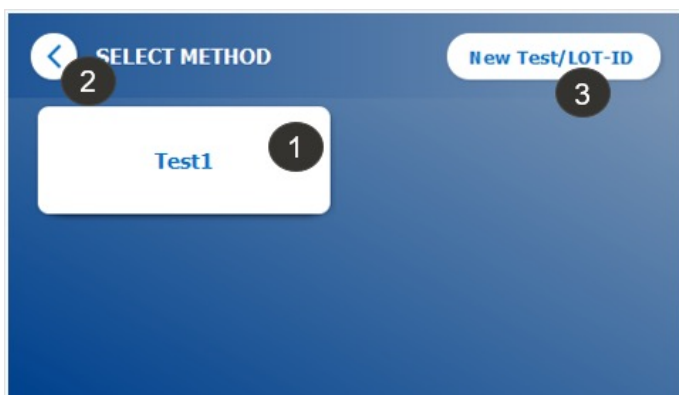
The main difference between these two modes is, that the “FailSafe” mode will require always the reading of a method barcode card, while in the “FastTrack” mode, the user can select the desired test method from a list of installed tests.

6.2 Starting a Test in the FastTrack Mode

To start a new run, press the “Start new Test” button on the home screen.

Step 1: The following screen will show all installed tests which can be selected by a click on it (1). If the desired test is missing in the list or no test is installed so far, click on “New Test / LOT-ID” (3) to import a new test method from the barcode card, which is in the package of your test kit. The GUI will guide you through the required steps to import a new method.

- For further instructions and troubleshooting for method import refer to chapter “Update Tests”

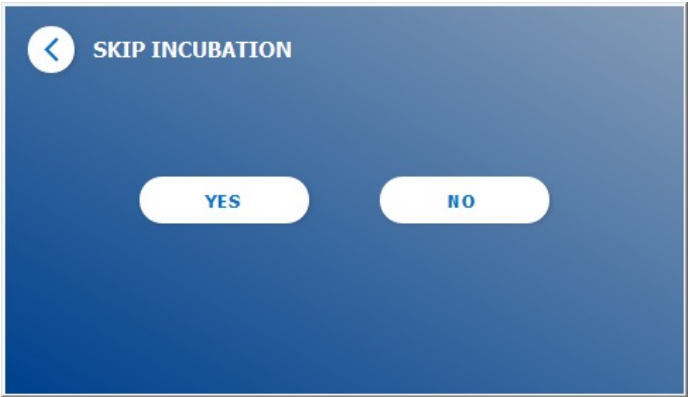


To return one step back, press the back button shortly (2). If this button is pressed long, the GUI returns always to the home screen.

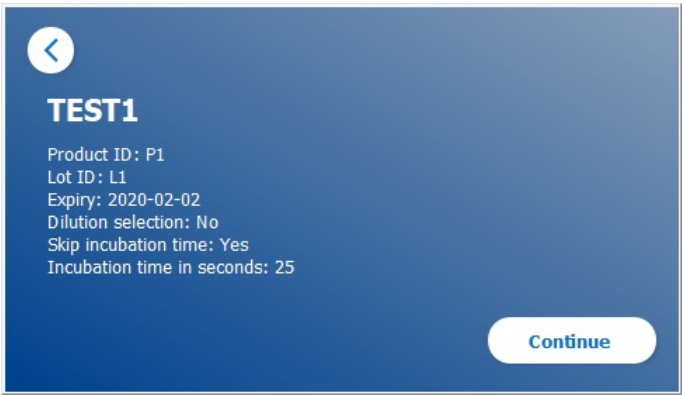
Step 2: If the desired test is selected, the GUI proceeds to the LOT selection screen where you choose the desired LOT Number for your chosen test. Again: If the LOT number is missing, you can import the actual test with the right LOT number.

Step 3: The next step will ask you if you want to skip the incubation time for your lateral flow test.

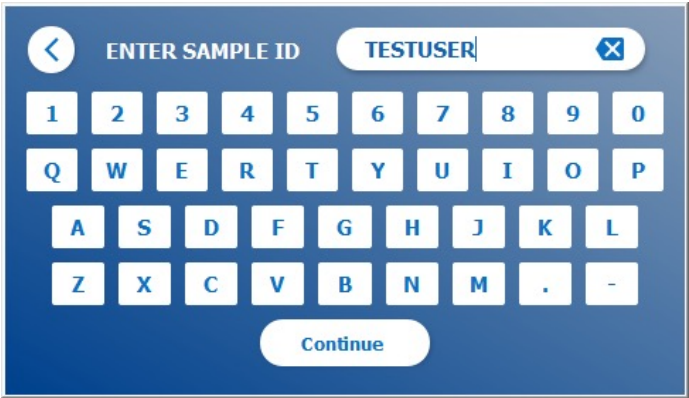
- **Note:** This step will only occur in the FastTrack Mode and only, if the selected method allows to skip the incubation time. This is a setting which the test manufacturer can determine.



Step 4: After this selection, a summary window appears which summarizes all test specific choices of the user.



Step 5: Press “Continue” to proceed to the sample entry screen. Here you enter the sample ID either via the keyboard on the GUI, or via an external barcode scanner (see Chapter Hardware installation / Accessories)

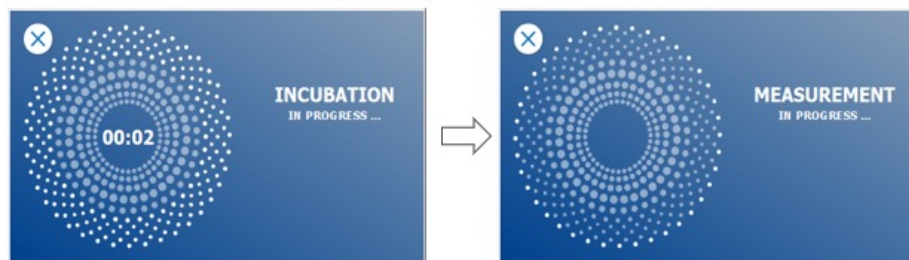


Step 6: The “Continue” button appears if at least 3 characters are entered. Pressing “Continue” leads to the final screen before the measurement starts and prompts the user to insert now the loaded test cassette into the drawer.

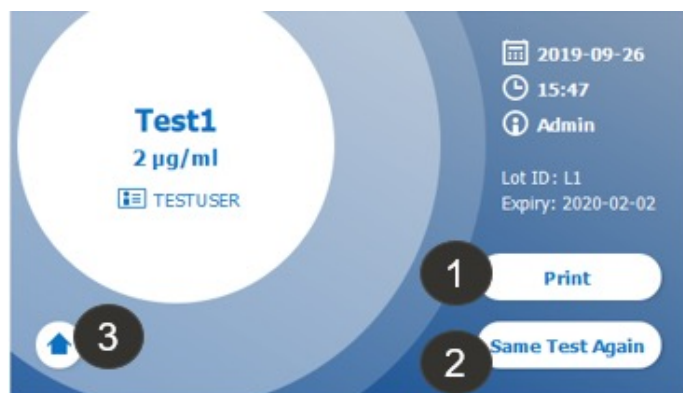


Step 7: Start the reaction of your test or if it is already incubating, insert the test cassette now into the drawer. Ensure to have the test cassette placed in the correct orientation, close the drawer and press immediately “Start Measurement”.

Your run will now start with or without incubation time dependent of your choice



Step 8: After measurement, the result is displayed in a result summary screen:



The result can be printed (1) if a printer is connected, or the same test using the same settings can be repeated (2) or the screen can be left to the home menu (3).

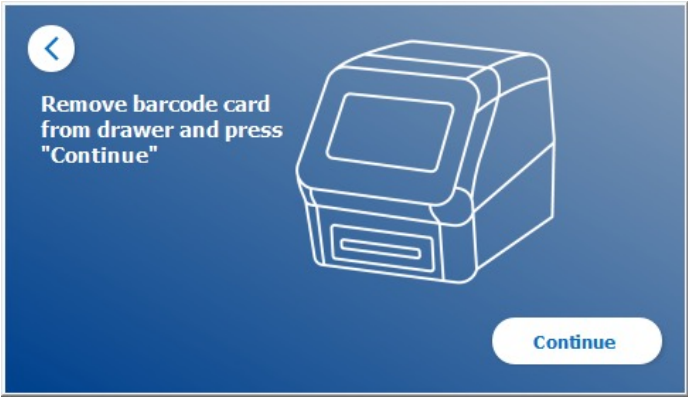
6.3 Starting a Test in the FailSafe Mode

If your reader is configured to operate in the FailSafe mode, the ordering options are limited. The workflow starts with a screen, prompting the user to insert the test barcode card. Insert the barcode card and start the reading process.



- For further instructions and troubleshooting for method import refer to chapter "Update Tests"

The GUI prompts you to eject your barcode card and press continue

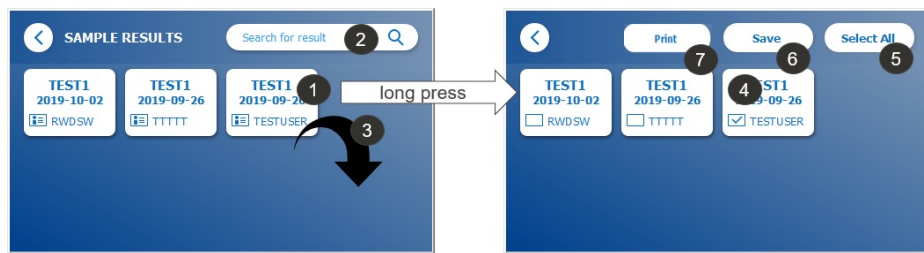


The reader has now loaded all method specific settings to perform the run. The further ordering workflow is identical to the FastTrack Mode from Step 4 onwards.

- The incubation time cannot be skipped by the user in the FailSafe Mode
- The option "repeat same test again" in the result screen is not available in the FailSafe mode

6.4 Review Results

The result screen shows all test results in a tile view. Different actions for filtering are feasible.



Nbr	Action
1	Short press on a tile opens the single result view with all result details (see Step 8 in ordering workflow).
2	Enter test name, date or username to apply a filter result for this attribute. The results will be displayed immediately.
3	Swipe over the result list to scroll down the list

Long press on a result tile opens a menu with additional actions

Nbr	Action
4	Mark those results which shall be exported or printed
5	Select or unselect all results
6	Save selected results to an USB stick in csv format
7	Print selected results

7 System and Settings

The System Menu offers 4 main sections for

- reviewing status information of your reader like actual SW version, IP address or serial number.
- Update the test menu
- Change device settings
- Maintenance of the device

7.1 Status

Press System / Status to enter a menu where you can choose to show device information. There are 2 options available:

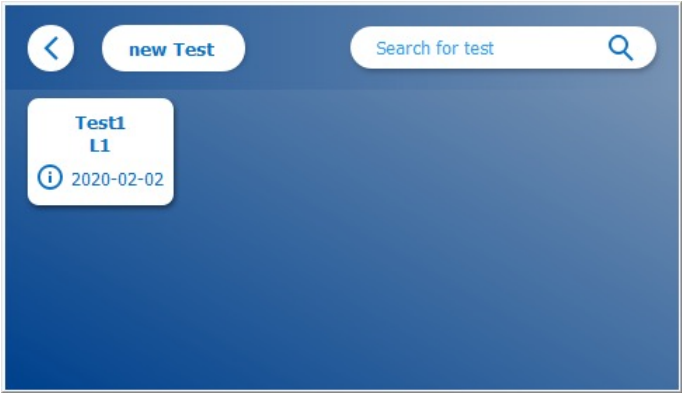
- 1. Info Menu: to display IP address, device name, device ID, serial number, Software ID, software version and operating system version
- 2. Show event log: shows a chronological list with device actions like log in attempts, device actions and error messages. This list can be exported on an USB stick

Both menus can be left via the “back” button

7.2 Update Tests

Enter this menu, to update the device with new test methods.

- This menu is accessible for each user level, since methods can only be added and no methods can be deleted.



The menu shows an overview of all installed test methods. Via the search field, filtering for a set of dedicated test methods can be applied. To import a new test method, press “new Test”. A window prompts you to insert now a barcode card, which contains the test method to be imported.



Make sure, the barcode card is positioned on the left upper side of the drawer. Your drawer will contain a small bar to give you an edge for the card which shall be placed above (see red arrow).

- **The import of a new method takes some time (up to 1min)**
- **In case you get an error message that your barcode card cannot be read, try following actions and retry import:**
 - **Rotate barcode card by 180° to change the order of the 2 barcodes from top to down**
 - **Ensure that the barcode card is not bent or has blots on the barcode**
 - **Change slightly its position in the drawer**
- **In case that despite of the above mentioned actions, your barcode does not get read, contact your support for further help.**

The system will prevent to import already existing test methods.

7.3 Settings

The settings menu is split into a protected area for the administrator (called Admin Area) and a non-protected area for all users, called Preferences

7.3.1 Preferences

Within the menu preferences, the user can select to adjust the screen brightness (80% is the default level) and to select the device language.

The desired language will be immediately applied by pressing a tile of the available languages.



7.3.2 Admin Area

This menu can only be accessed with administrator user level. If the user management is turned off, this menu is freely accessible.

In this menu, the user can change the following reader settings:

- **Date & Time** of the reader
- **Manage Data** to delete installed test methods or results
- **User Management** to add, administrate and delete user
- **Update Software** to install an instrument software update
- **Order Mode** to choose between the Fail Safe mode and Fast Track mode
- **Manufacturer Reset** to delete all data and methods from the reader
- **Communication Settings** to configure network connections for data transfer
- **Shutdown settings** to configure the time when the reader shuts down by itself



7.4 Menu Structure in the Admin Area

7.4.1 Date & Time

Enter this menu to change date, date format and time of the **QRALyzer EXpert**.



You can select between 2 date formats (2) which are yyyy-MM-dd and yyyyMMdd. Change values using the up and down arrows beside the date and time numbers (3). Save your selection by pressing “save” (1).

7.4.2 Manage Data

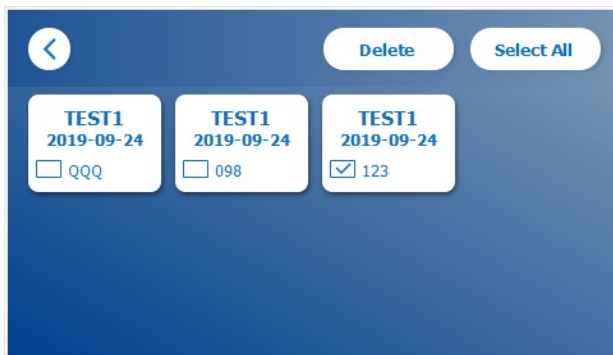
In this menu you can delete data or export the result data base. The user has following functions available:

- Delete methods
- Delete results
- Delete event log
- Delete unsent results (in case the device is connected to a connect server)
- Export raw data

The menus work quite similar

Choosing the desired item (Test method or results) shows you an overview of all existing test methods or results. The text search function allows to search and filter for individual results or test methods.

Press long on a tile will open the selection mode in which you can select individual or all tiles. If at least one tile is marked, the “Delete” button gets active and selected tiles can be deleted.



7.4.2.1 Show and delete unsent results

If the device is established to report its results to a connect server, this menu shows unsent results. This can happen due to network interruption or a server issue. In case the connection to the server is working again, the device will automatically try to push out all remaining results. However, if the user decides not to send unsent results to the server, he can delete them in this menu from the queue. This will only prevent selected results from being sent. Results still remain on the device.

7.4.2.2 Export raw data

This menu allows to export the whole result data base to an USB stick. Sometimes these data are needed for troubleshooting purpose or further analysis. The file is encrypted and can only be accessed by the test provider.

7.4.3 User Management

The **QRALyzer EXpert** can be used with user management which is turned on by default. The user management offers a protection of the device against non-authorized access and use of it and protects the device against change of settings and non-authorized deletion of data.

It can be chosen between 2 user level:

- **Administrator:** who can change settings and delete data in the Settings menu
 - **LabUser:** who can use all functions except the settings in the administrator area.
- See chapter Menu Structure for an overview of the GUI structure and visualization of administrator menus

7.4.4 Update Software

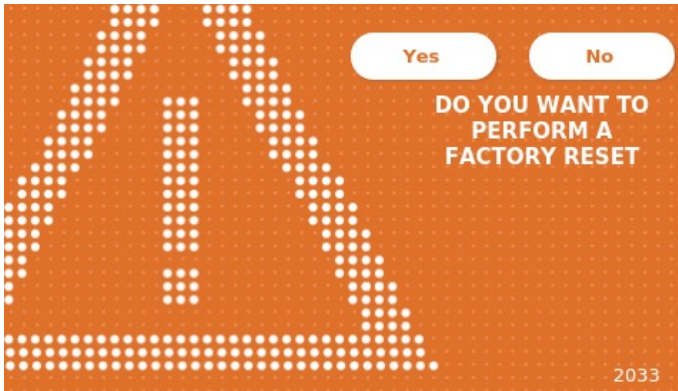
The user can update here the instrument software by plug in an USB stick containing an instrument SW update or a language update to add additional language files to the reader.

7.4.5 Order Mode

Choose here between the FastTrack or the FailSafe Mode (see chapter: The 2 ordering workflow modes)

7.4.6 Manufacturer reset

Pressing the button “Manufacturer reset” will open an orange warning screen asking for confirmation to proceed:



If the user proceeds, the following data get deleted from the reader:

- Deletion of all measurement results, test methods and entries in event log
- Deletion of all users, except default user which is the default administrator user
- Reset password of default administrator user to “0000” and turn user management “off”
- Set back language to “English” and screen brightness to 80%
- Set all Communication Settings to OFF and set default entries.
- Set Order Mode to FailSafe

7.4.7 Communication Settings

In this menu, the user can manage network connections and is able to set up the connection to the “connect” software, an external server/client solution to manage and view results from external devices.

The menu offers 3 sub menus called

- **Network**
- **Connect**
- **Security**

7.4.7.1 Submenu Network within communication settings

In this menu, the network properties of the reader can be configured such as its IP address, its subnet mask, the default gateway. Alternatively DHCP (Dynamic host configuration protocol) can be turned on and the reader will receive its network configuration from a DHCP server.

← NETWORK ⏻ DHCP OFF

IP ADDRESS: 127.0.0.1

SUBNET MASK:

DEFAULT GATEWAY:

Save

Settings and changes get saved by pressing the “save” button.

7.4.7.2 Submenu Connect within communication settings

If the reader shall report its results to the “connect” software, the connect functionality needs to be turned “on”. Now the connect server IP address and port number need to be entered and changes need to be saved.

← CONNECT ⏻ ON

ADDRESS: 127.0.0.1

PORT NO.: 8000

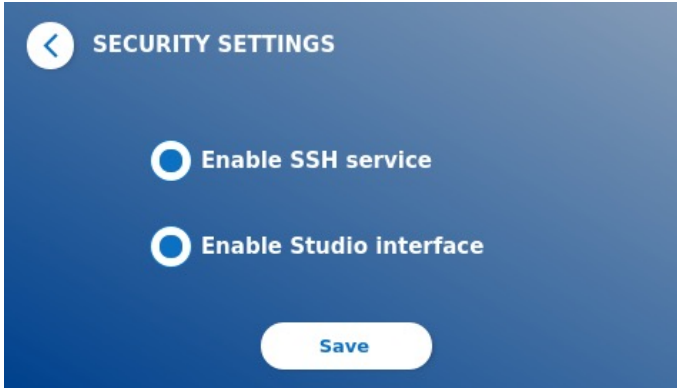
Test Save

A “Test” button will ping the server and show a success message in case, the connection could successfully established.

7.4.7.3 Submenu Security within communication settings

This menu allows enabling or disabling dedicated network ports and services to increase network security. The SSH service (secure shell protocol) can be turned on to be able to connect to the reader using user ID and PW and the ports to the developer software can be enabled.

- **Note:** These connections are disabled by default to guarantee highest network security.

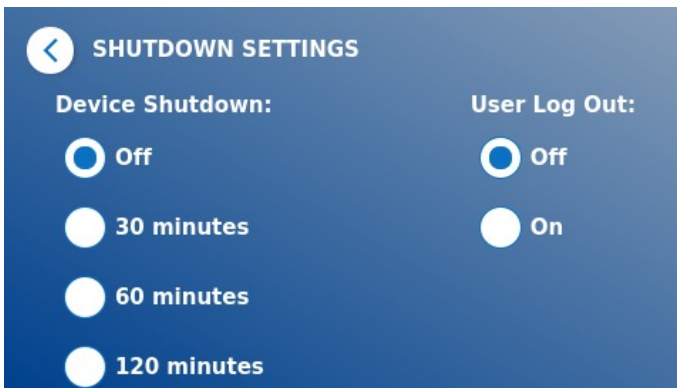


7.4.8 Shutdown Settings

Enabling an automated device shuts down and an automated auto log off will increase device security, protect components like display and save energy.

The user can select between 3 different time periods after reader inactivity until the system will shut down.

If automated user log off is turned “on” the user will automatically be logged of after 10 min of GUI inactivity and the device GUI is protected against unauthorized use.



8 Maintenance

This section is intended for qualified users with maintenance tasks. The instructions provide the user with necessary information on proper maintenance and care of the **ORALyzer EXpert**.

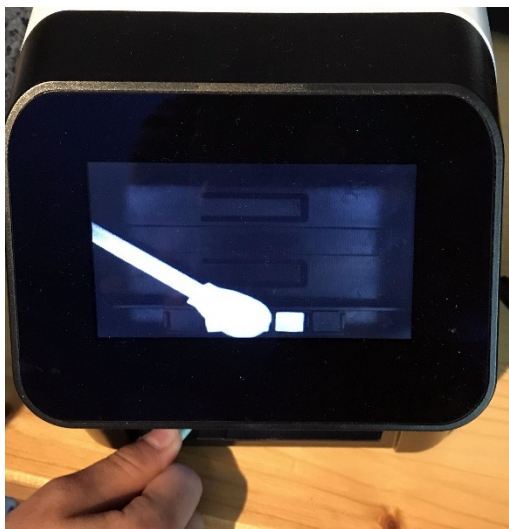
Note: the safety information must be read thoroughly and understood before starting maintenance and servicing work.

8.1 Menu "Maintenance" within System menu

In case the device will prompt a warning during self-test, stating that the optical system did only partially or did not meet the required values, the user can clean the internal reference material using swabs, provided by your test supplier. Entering this menu will show a live view of the inside device and will turn on the light inside the system. The user can now clean the internal reference material and restart the device for another attempt for the self-check.

Steps to clean:

- Turn on the reader
- Ensure to have a lint free swab (recommended: Techspray, Super-Tip Foam Swab, Product 2306)
- Completely eject the drawer of the reader
- Go to System / Maintenance -> the live stream starts
- Inspect the inside room of the reader and carefully clean dust and dirt particles mainly sitting on the inside reference material appearing white on the live stream.



- Note: This mode can only be left by performing a hard shutdown, meaning that the power button needs to be pushed for at least 6 seconds until the device turns off immediately. After restart of the device, the reader will perform a self-check and will enter the main menu.

8.2 Cleaning

In order to clean the device, use a damp cloth. If the dirt is persistent, rub the surface of the device with a cloth that has been moistened with 70-80% alcohol dissolvent. Do not use aggressive cleaning agents such as acetone. If the inside of the device is contaminated, contact service.

For more persistent stains and for disinfecting the instrument, it is possible to clean the surface with a cloth dipped in 1% bleach (1% active chlorine) followed by wiping with water. The procedure can be repeated 2-3 times. It is also possible to use the 80% alcohol dissolvent to wipe off the remaining traces of bleach.

Spillage of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas wiped with 1% bleach (1% active chlorine). Materials used to clean spills, including gloves, should be disposed of as bio hazardous waste.

The test cassette holder should be cleaned using dust free swabs or appropriate cloth.

When cleaning the drawer, note that the moving surfaces are treated with silicone oil. Cleaning with solvent at these surfaces leads to a loss of lubrication. This can lead to increased wear and even to a stiff drawer. If you have any questions about lubrication after cleaning, please contact the technical service support.

8.3 Device self-check

The **QRALyzer EXpert** is a highly sensitive optical device for quantitative measurements. In order to check the status of the main mechanical, electronic and optical components of the instrument, a self-check is performed after the device has been switched on. In case of calibration failure, a warning message is displayed on the screen of the device.

If that happened, the **QRALyzer EXpert** prevents further measurements but is still usable to review results and change any settings. The user is required to contact the manufacturer in such case. Note that the measured signal may change due to the following reasons:

- Contamination of the optical parts
 - Electromagnetic interferences
 - Temperature/Humidity changes
 - Mechanical movements
 - Wrong drawer
- **NOTE: Please make sure, that the original drawer is inserted (see chapter Unpacking and Set-Up Procedures).**

8.4 Troubleshooting and Messages

Following table lists information or error messages which might pop up including potential mitigation measures:

Message on GUI	potential root cause	possible user action
Barcode not found Check barcode on test card and retry" Err: 2001	No barcode is in the drawer. Only one of the two method barcodes found. Barcode not readable	Check barcode card in the drawer and retry
"Invalid barcode / method. Err. 2002	Protocol incorrect (e.g. cassette barcode instead of method barcode inserted)	Check barcode card in the drawer and retry
"Test expired. Check expiry date of test" Err: 2003	Expiry date of test is exceeded.	Check Expiry Date of Test or Date on Device
"Test <-> cassette mismatch. Err. 2004 and Err. 2016	The chosen method does not correspond to the barcode on cassette (Product ID and/or LotID).	Insert cassette that corresponds to chosen method.
"Test already exists" Err. 2012	The users try to import a method with Product ID and Lot ID, which is already stored on the reader.	Delete existing method on device with same name and LOT
"No Cassette found Err: 2006 and Err. 2010	Cassette size incorrect or no cassette inserted	Verify to have the correct cassette inserted
"Wrong cassette orientation Err. 2007 and Err. 2017	Cassette facing the wrong direction	Flip Cassette by 180° and retry
"Device error" Err 2009 and Err. 1003	Failure at self-check mechanism	Failure at self-check mechanism
"System error. Text: xx Number: yy Mode: zz" Err. 2000	Potential Hardware or Software Error	Reboot device or call service if error message persists
„Maintenance recommended. Err. 2011	Self-check values are in warning limit	Perform maintenance inside device

8.5 Technical service support

In case the instrument requires service by the manufacturer, the customer has to contact dentognostics under reklamation@dento.de. The customer will get all necessary information and instructions to send the device back for repair.

dentognostics shall authorize the return by providing the customer with a Return Material Authorization (RMA) number which from this point on should be used as reference number on all correspondence pertaining to the repair of the device.

The device shall be decontaminated and free of pathogens and infectious materials so that they are safe in handling in a non-biological safety laboratory. The customer is obliged to sign the “Declaration of Contamination Status” document which he obtains from the Service Team. A copy of the signed declaration must be sent prior to shipping to dentognostics and the original document must be placed in the package with the returned device.

The device must be returned in the original packaging. If not available anymore, please inform dentognostics.

- **Note: The corresponding device will be excluded from further processing if the customer does not supply dentognostics with a filled and signed “Declaration of Contamination Status”.**

For additional information, support and technical service, please contact:

dentognostics	For customers in the USA:
Ober der Mühle 39	DENTOGNOSTICS USA INC.
42699 Solingen	515 N Flagler Dr.
Germany	Suite P-300
	West Palm Beach, FL 33401
service@dento.de	service@dentognostics.com
www.dentognostics.de	

9 Technical Data

dentognostics reserves the right to change specifications at any time.

Dimensions and weight of the instrument

Dimensions	H / W / D: 150 x 150 x 150 mm (6 x 6 x 6 in)
Weight	Approx. 1.2 kg (2.6 lb)

Mechanical data and hardware features

Test format dimensions	Determined by the drawer for the respective test
User Interface	Interactive 10.9 cm (4.3 in.) touchscreen
Noise	< 10 db(A)
Connections	3 x USB, Ethernet
Memory capacity	Up to 99 test methods and up to 300 test results
Operating conditions	15-35 °C (59-95 °F), humidity < 70 %, not condensing
Transport Conditions	-20 - to 50°C
Storage Conditions	+15 to +40°C
IP-classification	IP10
Allowed pollution degree	2

Optics

Optical system	5 Mpix camera (8Bit)
Signal detection	Colorimetric
Colorimetric detection	Colloidal gold, colored latex beads, carbon particles, etc.
Measurement time	< 20 seconds
Surveillance	Internal reference check among solid standards

Power requirements of the instrument

External Power Supply	Input: 100-240 V AC, 0.5 A, 50-60 Hz; Output: +12 V DC / 1.67 A Plug to ORALyzer EXpert with 1.5m cable to power supply*
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Optional Accessories

1. External printer	5. Printer labels
2. Dymo 450 Label Printer	6. Dymo large address labels (101mm * 54mm)
3. Barcode reader	7. Cleaning Swabs
4. Model Zebra DS 2208	8. Techspray, Super-Tip Foam Swab, Product 2306

- *Note: The use of other accessories, other converters and other cables than the one which are listed above may increase ELECTROMAGNETIC EMISSIONS or may result in a reduced electromagnetic immunity of the device which may lead to a faulty operating mode.


10 Compliance information for EMC tests (IEC 60601-1-2 Tables)

10.1 Guidance and manufacturer’s declaration – electromagnetic emissions

The QRALyzer EXpert is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions Test	Device compliance to IEC 60601-1-2:2014 (4th edition)	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Fullfilled	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Fullfilled	

10.2 Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

The QRALyzer EXpert is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2:2014 (4th edition)	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / Burst IEC 61000-4-4	±2kV on power supply lines, 100kHz repetition ±1kV for input/output lines, 100kHz repetition	±2kV on power supply lines, 100kHz repetition ±1kV for input/output lines, 100kHz repetition	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Surge IEC 61000-4-5	+/-2kV line to line	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	100 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The QRALyzer EXpert is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2:2014 (4th edition)	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips and voltage variations on power supply input lines IEC 61000-4-11	-100 % for 10 ms -100 % for 20 ms -30 % for 500 ms -100 % for 5 s	-100 % for 10 ms -100 % for 20 ms -30 % for 500 ms -100 % for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or a battery.
Radiated RF electromagnetic fields IEC 61000-4-3	3V/m, 80-2700MHz, 80% AM at 1kHz modulation for Professional Healthcare Facility Environment	10V/m, 80-2700MHz, 80% AM at 1kHz modulation for Professional Healthcare Facility Environment	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\times\sqrt{P}$ from 150kHz to 80MHz $d=1.2\times\sqrt{P}$ from 80MHz to 800MHz $d=2.3\times\sqrt{P}$ from 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted disturbances by RF fields IEC 61000-4-6	3 V, 0,15 MHz - 80 MHz 6 V (in ISM bands) 80 % AM at 1 kHz	10 V, 0,15 MHz - 80 MHz 6 V (in ISM bands) 80 % AM at 1 kHz	

The QRALYZER EXPERT is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2:2014 (4th edition)			Compliance Level			Electromagnetic Environment – Guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test freq. [MHz]	Band	Immu- nity Level [V/m]	Test freq. [MHz]	Band	Immu- nity Level [V/m]	Do not expose the reader to strong electromagnetic radiation or next to other equipment in stacked form. If this cannot be avoided, this device and the other devices should be observed to ensure that they are working properly. Also ensure that RF communications equipment (including antenna) is not placed closer than 30 cm (12 inches) to any part of the ESE Quant Flex, including cables. It is the responsibility of the user to ensure that a compatible electromagnetic environment is maintained for the instrument in order to guarantee conform performance. This device conforms with the emitted interference and emitted immunity requirements of the standard IEC DIN EN 61326-2-6. The electromagnetic environment of the device should be assessed prior to its application. Do not use this device in proximity to sources of intense electromagnetic radiation because proper use may be disturbed. This device conforms to EN IEC 61326- 2-6 and IEC 60601-1-2.
	385	380 to 390	27	385	380 to 390	27	
	450	430 to 470	28	450	430 to 470	28	
	710	704 to 787	9	710	704 to 787	9	
	745			745			
	780			780			
	810	800 to 960	28	810	800 to 960	28	
	870			870			
	930			930			
	1720	1 700 to 1 990	28	1720	1 700 to 1 990	28	
	1845			1845			
	1970			1970			
	2450	2 400 to 2 570	28	2450	2 400 to 2 570	28	
	5240	5 100 to 5 800	9	5240	5 100 to 5 800	9	
	5500			5500			
	5785			5785			



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