

Version 1.0

with



R. 4 ( E 0402 



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# 1 Introduction

Blood should be stored at two (2) to five (5) degrees Celsius to maintain as long as possible. Under optimal conditions the shelf life is 42 days. In practice, healthcare has shorter storage times, according to surveys, between 20 and 25 days. One reason for this is that blood bags, when they leave the controlled and safe environment within blood centers and comes out in health care, they are stored in a manner that is not always safe. This can include the radiator is broken; shipments will take longer than expected or blood bags that are picked out of the fridge but not used. These uncertainties mean that medical personnel, to be on the safe side, are forced to throw blood because they do not always know what temperatures it is exposed to.

QTA Tracer System<sup>®</sup> eliminates the uncertainty as it continuously measures the temperature of the blood and stores the information. The QTA Tracer is attached to the blood bag to verify the quality of the blood over the blood bags whole lifetime. When personnel take up the blood bag, the QTA Tracer is activated and it responds with a green or red light depending on whether the blood is healthy and can be used or if it must be discarded.

# 1.1 Background

This user manual is part of the QTA Tracer System<sup>®</sup> version 1.0

# 1.2 Purpose

The purpose of this document is to give knowledge to end users of the QTA Tracer and the QTA Access Point.

# 1.3 Audience

The audience of this document is end users of the QTA Tracer System<sup>®</sup>.

# 1.4 System requirements

The following accessories is needed to use the QTA Tracer System®

Accessory	Description
PC with Windows 7	Note book, Lap Top or stationary PC, 2Mb
	RAM, Physical storage > 100Mb
	Delivered by distributor or by the local IT
	department on the hospital.
Bluetooth 4.0 Single Mode USB Dongle	Delivered by distributor
Bar code reader reading 2D bar codes	Delivered by distributor
QTA Tracer	Delivered by distributor





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The QTA Tracer system is based on a PC with the QTA Tracer System<sup>®</sup> software installed, a Bluetooth USB dongle, a Barcode reader and QTA Tracers. Figure 1 displays the QTA Tracer system.



#### Figure 1. The QTA Tracer System®

# 1.7 System function

# 1.7.1 QTA Tracer

The QTA Tracer is attached to a blood bag to measure temperatures and calculate if the blood is valid according to specific configuration parameters that is defined by each blood center.

There is no specific rule when to attach the QTA Tracer to the blood bag, because it depends on the unique process that is used on each blood center.

The QTA Tracer has a motion detector that activates the tracer so that it starts showing the status of the blood and sets it in communication mode.

The QTA Tracer is labeled with the following labels	:
---	---

Label	Description
<ul> <li>Image: A second s</li></ul>	<ul> <li>Blood is ok, (green light), functional.</li> </ul>
×	X - Blood is not ok, (red light) nonfunctional.
126÷3	This is a bar code including the Bluetooth address for the QTA Tracer.
	The Bluetooth address is the unique identifier (serial number) for the QTA
	tracer and the address is also printed in plaintext below the bar code on
3c2db/84e/65	the QTA Tracer.
	Use this unique id when reporting a claim.
	Scan this bar code using QTA Access Point to connect to a QTA Tracer.
T	Waste Electrical and Electronic Equipment (WEEE) Statement. Return
X	product to distributor.
	Read the manual before use.
° ♠	QTA Tracer includes Bluetooth technology.
<b>REF</b> 10001	QTA Tracer product number.
( E <sub>0402</sub>	CE Certified by notified body 0402.

# 1.7.2 QTA Access Point

The QTA Access Point is a PC installed with the QTA Tracer System<sup>®</sup> and a Bluetooth USB Dongle inserted in the USB port.

To start or readout stored information from the QTA Tracer the QTA Access Point is needed. QTA Access Point is used to:







- Start a new QTA Tracer logging
- Readout status and temperatures from QTA Tracer •
- Release blood from quarantine •
- Readout stored information on the QTA Tracer •

To configure the QTA Tracer System<sup>®</sup> a QTA Access Point Configurator is needed. The QTA Access Point Configurator stores configuration parameters in the database that is used by the QTA Access Point.

QTA Access Point Configurator is managed by the QTA Tracer System distributor or the local system manager.

#### 1.8 How the QTA Tracer defines the blood status

The blood status is shown with the following label symbols in both QTA Tracer and QTA Access Point:

- 1. I Blood is ok (green light), functional
- 2. X- Blood is not ok (red light), nonfunctional
- 3. ( )no light- Blood is not ok, the QTA Tracer is not operating as it should

The blood status is calculated by the QTA Tracer and is marked as 👅 - Blood is not ok, if one of following conditions is true:

- If the blood has been exposed to too low, or too high temperature
- If the blood has been exposed to the different temperature ranges for too long. • The temperature ranges are configured in the database.
- If both of the following start logging delays not has been reached: •
  - Start time delay Wait for a specific time, specified in the configuration 0
  - Start at temperature Wait for a specific temperature is reached, specified in the configuration
- If the blood not has been released from quarantine
- If an error occur in the QTA Tracer.







# 2 Installation

The installation process of the QTA Tracer System<sup>®</sup> is described in the installation instructions. The installation is performed by personnel from distributor or Tridentify. The installation can be done by a local system manager that has gone through a training program how to set up the QTA Tracer System<sup>®</sup>.





# 3 Usage

# 3.1 Start a new log

To start a new QTA Tracer log, follow these steps:

- 1. Start QTA Access Point.
- 2. Select the "New log" tab.
- 3. Scan barcodes that is configured for selected ISBT class. For example:
  - Donation Identification no
    - If configured to be editable, then it is possible to insert a value that not needs to comply with ISBT 128 standard. This can be done manually or by using a barcode reader.
  - o Blood group
  - Collection date
    - If configured to be editable, then it possible to insert a value manually using keyboard or by selecting a date in the calendar.
  - Expire date
  - Product code
- 4. Activate the QTA Tracer by moving it, tilting it. One of the LED diodes will then flash, green or red.
- 5. Scan the bar code on the QTA Tracer using the bar code reader.
- 6. The Access Point notifies that logging has started with a sound signal and as shown below in Figure .

QTA Access Point - QTA Tracer System	
Eile Language Help 0	
QTA Tracer Id: New Log Status	
ISBT class RED BLOOD CELLS	
Donation identification no:	
Blood group	
Product code:	
Collection date:	
Expire date:	
Clear all fields	

Figure 2 New QTA Tracer logging

# 3.2 Read status using QTA Tracer

To see if the blood is valid on the QTA Tracer, follow these steps:

- 1. Turn on the QTA Tracer by moving it.
- 2. The status of the blood is indicated by
  - 🗸 Blood is ok (green light), functional
  - X Blood is not ok (red light), nonfunctional
  - ( )- no light- Blood is not ok, the QTA Tracer is not operating as it should





# 3.3 Read QTA Tracer status using QTA Access Point

To read a QTA Tracer status using a QTA Access Point, follow these steps:

- 1. Select the "Status" tab. Status is shown as below in Figure .
  - 2. Activate the QTA Tracer by moving it, tilting it. One of the LED diodes will then flash, green or red.
  - 3. Scan the bar code on the QTA Tracer using the bar code reader.

QTA Access Point - QTA Tracer System		
<u>E</u> ile <u>L</u> anguage <u>H</u> elp	_ 1	
071 7-000		
QIA Iracer	1	
10: 78C3E36C6410	~	
New Log Status		
Time remaning	Estimated exp.date	
Temperature < 1°C 0 days, 0 hours, 0 minutes		
Temperature < 10°C 41 days, 11 hours, 24 minutes	2015-12-08 01:22	
Temperature < 24°C 0 days, 23 hours, 42 minutes	2015-10-28 13:40	
Temperature < 30°C 0 days, 3 hours, 57 minutes	2015-10-27 17:55	
Tracer status		
Blood valid:		
Blood released from quaratine: 🗸		
Tracer status: Running		
Min temperature: 24		
Max temperature: 24		
Tracer battery level: 100%		
Blood bag information		
Donation identification no: S00121000000602		
Blood group: 2800 - AB RhD negative		
Product code: E3846V00		
Collection date: 27 okt 2015 14:54		
Expire date: 19 aug 2010 23:59	Print label	

Figure 3 Read QTA Tracer

# 3.3.1 Time Remaining and Estimated exp.date:

Calculated time left and expiration date for the temperature intervals entered in the QTA Access Point Configurator are shown in the top table.

"N/a – Priority exceeded" means that the QTA Tracer will never be able to calculate expire date for this temperature interval anymore, because of that a temperature is measured within a temperature interval with higher priority. Priorities on temperature intervals are configured in the QTA Access Point Configurator.

#### 3.3.2 Blood valid:

In Figure 3 the blood is valid, the QTA Tracer is in status: **Running** If tracer still has status: **Wait for start** the blood status will be invalid How QTA Tracer defines the blood status is described in 1.8.

#### 3.3.3 Blood released from quarantine:

Showing if the blood is released from quarantine or not.

# **3.3.4** Tracer status:

The Tracer status can have the following modes:

- Running QTA Tracer log temperatures and calculate if blood is valid
- Wait start QTA Tracer wait for one of the following to be true
  - o Start time delay Wait for a time, specified in the configuration
  - Start at temperature Wait for a temperature is reached, specified in the configuration
- Error An error has occurred on the QTA Tracer.
- Configuration Configuration not completed. Log not initiated.







Min and max temperature of temperature log. Since QTA Tracer version 1.0.7

## **3.3.6** Tracer battery level:

Showing if the battery level is ok or not. The percentage shows how many percent it is left before the battery is empty depleted.

## **3.3.7** Blood bag information tab:

The blood bag information that is stored in the QTA Tracer for the current log.

## 3.3.8 Print label

Click on button "Print label" to print the new "Expiry date"







# 3.4 Manually release blood from quarantine

To release blood from quarantine manually, the release blood from quarantine configuration must be set to manual mode, se QTA Access Point Configurator manual.

To release blood from quarantine, follow these steps:

- 1. Select the "Status" tab. Status is shown as below in Figure .
- 2. Activate the QTA Tracer by moving it, tilting it. One of the LED diodes will then flash, green or red.
- 3. Scan the barcode on the QTA Tracer using the bar code reader.
- 4. If the blood is not already released, use one of the following options to release blood:
  - Use the push button "Release blood from quarantine" or \_
  - Scan the barcode on the screen to release blood

See below in Figure .

5. The QTA Tracer is automatically disconnected when the blood is released. See below in Figure .

Tracer			
78c5e57283dd		·	<b>QTA</b> <sup>ACCESS</sup> POINT
ew Log Status			
Time	remaning	Estimated exp.date	
Temperature < 1°C 0 da	iys, 0 hours, 0 minutes		
Temperature < 10°C 41	days, 23 hours, 19 minutes	2015-10-22 09:14	
Temperature < 24°C 0 d	lays, 23 hours, 59 minutes	2015-09-11 09:53 Release blood from	
Temperature < 30°C 0 d	lays, 3 hours, 59 minutes	quarantine quarantine	•
Tracer status			
Blood valid:	×		
Blood released from quar	atine: 🗙		
Iracer status:	Running		
Max temperature:	22.5		
Tracer battery level:	100%		
Blood bag information			
Donation identification no	b: \$0012100000602		
Blood group:	2800 - AB RhD negative		
Product code:	E3846V00		
A 1 1 1 1 1	08 101 20 10 08:53		

Figure 4 Release blood







Trace         Status           Trace         Status		
Id       Image: Control of the second s	OTA Tracer	
It:		OT/
New Log         Stats           Ime remaning         Estimated exp.date           Image: Status         Image: Status           Blood vald:         Image: Status           Max temperature:         Image: Status           Trace value:         Image: Status           Blood gap: Iformation         Image: Status           Donation identification no:         Image: Status           Blood gap: Status         Image: Status           Product code:         Image: Status           Expire date:         Image: Status	Id:	
Time remaining       Estimated exp.date         Tracer status       Image: Status status         Blood vald:       Image: Status status         Blood vald:       Image: Status status         Min temperature:       Image: Status status         Min temperature:       Image: Status status         Blood bog information       Image: Status status         Blood bog information       Image: Status status         Blood bog information       Image: Status status status         Donation identification no:       Image: Status s	New Log Status	
Tracer status Biood valid: Biood valid: Biood valid: Biood elessed from quaratine: Tracer status: Min temperature: Min temperature: Tracer status: Biood bags information Donation identification no: Biood graup: Product code: Collection date: Expire date:	Time remaning Estimated exp.date	
Tracer status Tracer status Biod valdi: Biod valdi: Biod valdi: Biod relased fron guaratine: Tracer status: Win temperature: Min temperature: Tracer battery level: Biod bag information Donation identification no: Biod group: Product code: Collection date: Expire date:		
Tracer status Blood vald: Blood vald: Blood released from guaratine: Tracer status Montemperature: Max temperature: Max temperature: Tracer battery level: Blood bag information Donation identification no: Blood group: Product code: Collection date: Expire date: Expire date:		
Tracer status         Blood vald:         Blood vald:         Blood reased from quaratine:         Tracer status:         Min temperature:         Min temperature:         Tracer battery level:         Blood bag information         Donation identification no:         Blood toge:         Collector date:         Expire date:         Expire date:		
Tracer status Blod valid: Blod released from quaratine: Tracer status: Min temperature: Max temperature: Tracer battery level: Blod bag information Donation identification no: Blod group: Product code: Collection date: Expire date: Expire date:		
Trace status Blood valid: Blood released from guaratne: Trace status: Max temperature: Max temperature: Max temperature: Trace battery level: Blood bag information Donation identification no: Blood bag information Donation identification no: Blood soup: Product code: Collection date: Expre date: Expre date:		
Tracer status Blod valdt: Blod valdt: Tracer status: Tracer status: Tracer status: Min temperature: Max temperature: Tracer battery level: Blod bag information Donation identification no: Blod stog information Donation identification no: Blod group: Product code: Colection date: Expire date: Expire date:		
Tracer status Blood vald: Blood released from quarative: Tracer status Blood released from quarative: Blood released from quarative: Tracer status Min temperature: Tracer status Min temperature: Tracer status Blood grage Blood grage Froduct code: Collection date: Expire date: Expire date: Expire date:		
Tracer status Blood vald: Blood vald: Blood vald: Tracer status: Min temperature: Min temperature: Tracer battery level: Blood sog information Donation identification no: Blood sog in: Free temperature: Collection date: Expire date: Expire date: Expire date:		
Tracer status Blood valdi: Blood released from quaratine: Tracer status: Win temperature: Max temperature: Tracer status: Blood bag information Donation identification no: Blood grap: Product code: Collection date: Expire date: Expire date:		
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# 3.5 Change language

Select "Language" in the menu and pick one of the languages in the drop down list, see figure 5.



