VerePLEX™

veredus laboratories

VerePLEX™ Biosystem
SYSTEM & SOFTWARE (VPLX-BSYS)
Instructions for Use

Always keep this IFU near the instrument
Read carefully prior to operating the instrument

IFU-PLX-RA01-1002

Revision History

Revision	Date	Description of Change
1.0	November 2016	Initial Release
1.1	Jun 2017	Renaming of linked TCS to Base and Satellite. Added LAN connection.
1.2	Sep 2017	Update of E@syControl auto sending behavior. Change document number.

Table of Contents

Chapter **1**

1 General

This instructions for use (IFU) include important information related to the operating safety and maintenance of the VerePLEX™ Biosystem instrument. The IFU is an important part of the product. It must be read carefully and completely before setup and first use of the instrument and must be kept near the instrument at all times. If additional requirements on accident prevention and environmental protection exist in the country of operation, this IFU must be supplemented by appropriate instructions to ensure compliance with such requirements.

The IFU for this VerePLEX™ BioSystem is valid for versions of the following instruments:
- Temperature Control System   TCS - 03
- Optical Reader   VOR – 02
- Touch Monitor   TOM – 01
- Laptop (optional)   VPLX-VLP
- 2D Barcode Reader (accessory)   VPLX-VBR
- Software VerePLEX™ Version 5.3.1 which consist of:
    - E@syControl 2.9
    - E@syCheck 4.2.0 and above
    - E@syManager 3.6

The default system consist of the Touch Monitor, Optical Reader and 2D Barcode Reader connected to a Base Temperature Control System. Additional Satellite Temperature Control Systems may be added to the Base system.

Within the VerePLEX Biosystem software suite,
- The 2D Barcode Scanner facilitates data entry and also is used to enter the VereChip calibration data in E@syControl for sending the thermal cycling protocol to the Temperature Control Systems (TCS).
- E@syCheck is used to control the Optical Reader (OR) for image capture.
- E@syManager is for the assigned administrator to manage and control items such as User Accounts and BioApplications.

1.1   Symbols occurring in the text

⚠	Warnings and cautions appear in a grey box and are marked by a warning triangle ⚠ .

🛈	Notes, i. e. important information for the user appear in a grey box and are marked by an information sign 🛈 .

1.2   Symbols occurring on the instruments

All the labeled symbols placed on the TCS and OR units are designed and created in compliance with the standard below:

EN ISO 18113-3: 2009	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use

Rear panel labels are showed in the below picture.
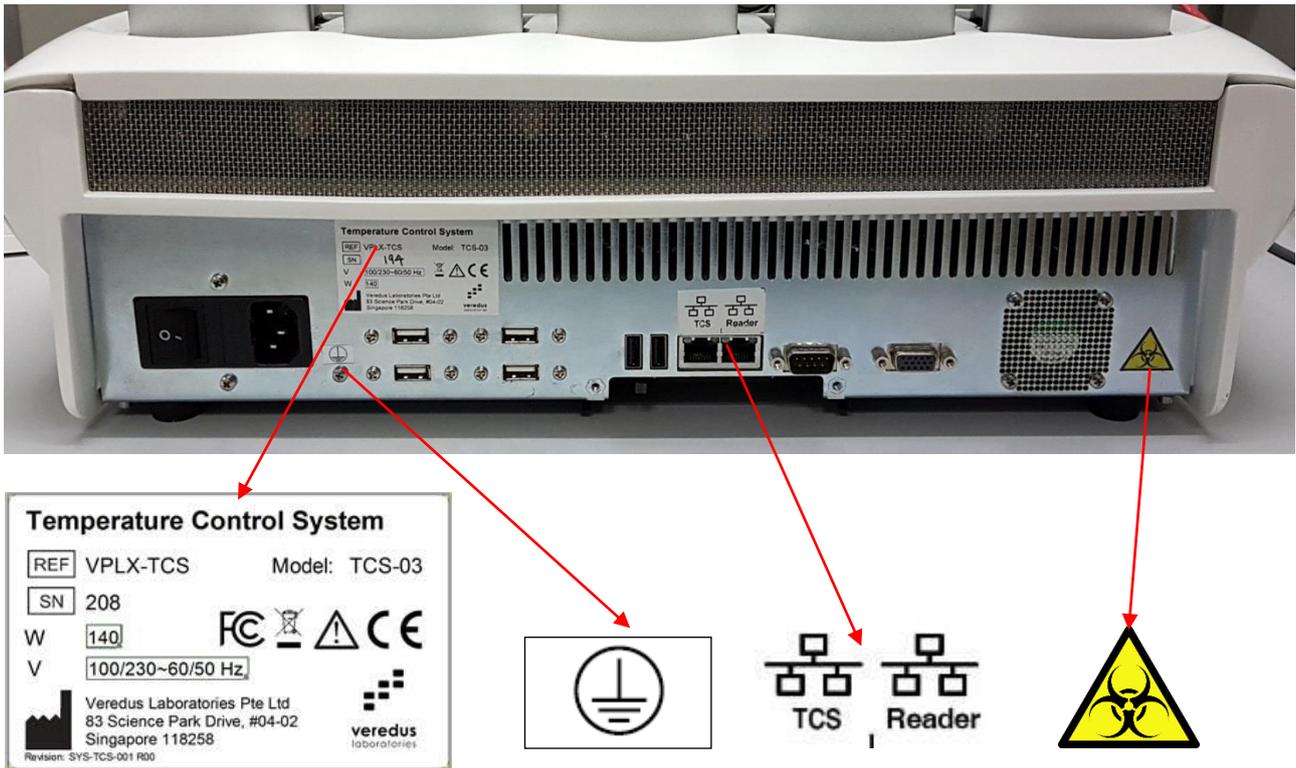
Fig 1: Rear view and panel of TCS
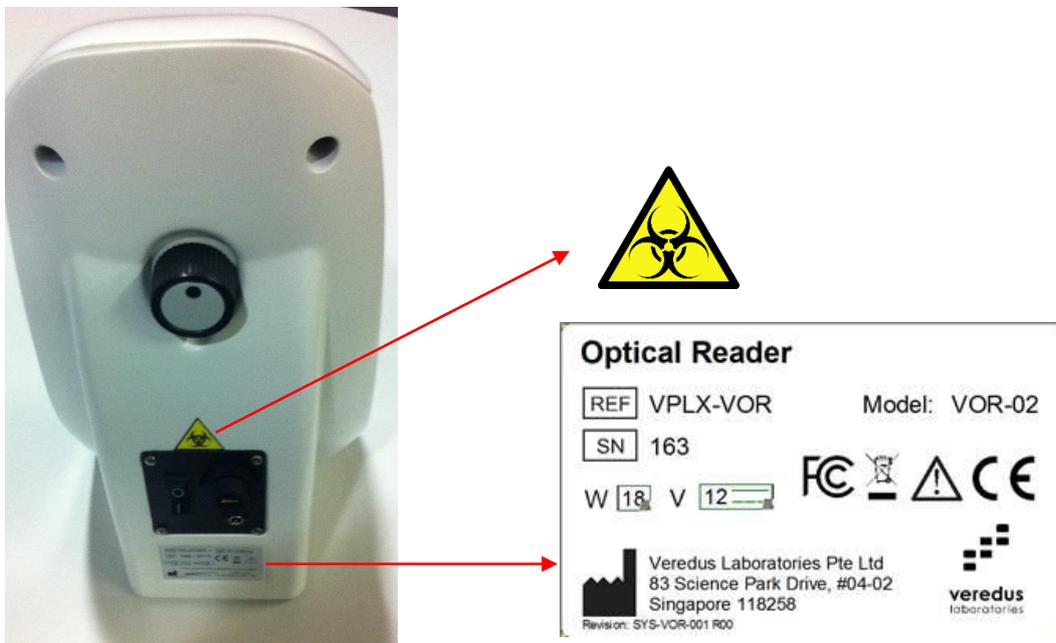
Fig 2: Rear view and panel of OR
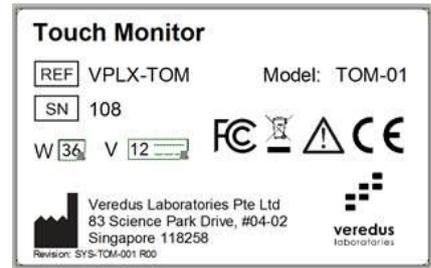
Fig 3: Rear view and panel of TOM

Inside each TCM is the following label.
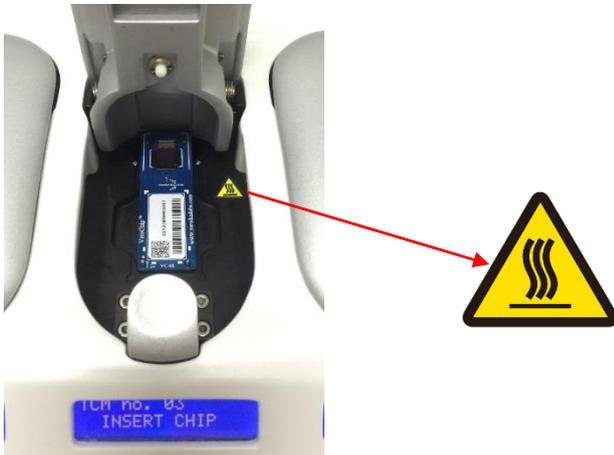
The labels shown in the table below are on the instruments and refer directly to the safe use of the system.

Symbol	Description
	Manufacturer
SN	**Serial Number**
REF	**Catalogue Number**
	Alternating Current
	Direct Current
	Protective Earth (Ground)
CE	**CE mark Symbol**
FCC	**FCC mark Symbol**
	Do not dispose in waste bin
	General warning, caution, risk of danger
	Biological Risk.
	Warning, hot surface
■	**Stop TCM runs**
►	**Start TCM runs**
≡	**Scroll through TCM information**
TCS Reader	**Ethernet ports for OR and additional TCS connection**

Be sure to read and comply with the safety instructions, warnings and cautions in chapter 2.

1.3   Designed use / improper use of the instruments

The instruments are designed for applications in biology and molecular diagnostics are to be operated together as a set and also according to the instructions contained in this IFU.
Any other use outside of this IFU is considered an improper use of the product.

1.4   Qualification of personnel

The instruments together with the various VereChip applications are intended for professional use and may be operated only by trained laboratory personnel.
All laboratory personnel designated to operate these instruments must read this IFU carefully and must be familiar with all technical features before attempting to operate.

1.5   Identification

The TCS, OR and TOM instruments are identified with the following labels at the back.

- **Instrument**: Name of instrument
- **REF**: Catalogue Number
- **Model**: Model version of the instrument
- **SN XXX** is a progressive serial number

The VerePLEX™ Biosystem with TOM works with the following software version:
- VerePLEX™ Software Version 5.3.0 (Or later)

1.6   Storage and handling

Recommended storage and transportation environmental conditions:
Temperature range   [-10 °C to 50 °C]
Relative Humidity   [20% to 80%]
Pressure   [7.2 psi to 15.3 psi]

Recommended operative environmental conditions:
Temperature range   [+10 °C to 30 °C]
Relative Humidity   [20% to 80%] non-condensing
Pressure   [12.0 psi to 15.3 psi]

1.7   Warnings and precautions

- DO NOT use the instruments in instances where the external casing integrity is questionable.
- DO NOT connect the device to a power source that is not properly earthed (grounded).
- DO NOT open TCM cover lids while PCR or hybridization is in progress.
- DO NOT touch the pogo pin where the chip has to be contacted when the TCM is turned on.
- DO NOT use with older versions of software.

1.8   Intended purpose

The TCS has been designed and developed to control the temperature in the embedded reaction chambers of the chip. The OR has been designed and developed to acquire the microarray image of the chip and the TOM is designed to work as the main user interface with the Base TCS.

All instruments work in combination with the VereChip and 2D Barcode Reader and are part of the whole system. They are not to be used separately.

Chapter **2**

2 Safety

2.1 Safety regulation

Before setting up the system, some important warnings are mandatory:
1. The instruments may be operated only according to the instructions contained in this IFU. Any other use is considered an improper use of the product.
2. Do not operate the instruments in extreme humidity or where condensation can short the internal electrical circuits of the unit.
3. The TCS and OR instruments are CE-marked and are designed and manufactured in compliance with the standards below:

2014/35/UE	Low Voltage Directive
2014/ 30/UE	EMC Directive
CEI EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CEI EN 61010-2-010	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-010: Particular requirements for laboratory equipment for the heating of material
CEI EN 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
CEI EN 61326-1	Electrical equipment for measurement, control and laboratory use. EMC Requirements. General requirements
CEI EN 61326-2-6	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
EN ISO 18113-3	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use

4. Always connect the power supply to a 3-prong, grounded AC outlet rated 3 A 100–120 V or 1.5 A/220–240 V using the AC power cord provided.
5. Do not remove fuses in the TCS. If they need to be replaced, please refer to label (T 2A) placed on the rear panel.
6. Always connect the Ethernet port to a Local Area Network by using Ethernet cable provided.

7. To ensure adequate cooling of the TCS and stable base for image acquisition of the OR, place the instruments on a clean, flat surface, and be sure that there is at least 4 inches (10 cm) clearance around each side of the unit. Make sure that the bench space is free of any foreign objects or debris that could block the fan vents or can obstruct the power and Ethernet cord so that it is difficult to operate the disconnecting device.
8. The usage of protective gloves or other protective means in order to operate with the instruments is not mandatory.
9. Always avoid touching the TCMs lids during temperature program run to reduce the risks of burns from surfaces if the temperature exceeds the allowed limits.
10. All instruments have been tested and complied with the FCC official limits. They are FCC-marked with accordance to the FCC standard 47 CFR part 15 subpart B.

2.2 Electromagnetic Interference

These instruments complies with Part 15 of the FCC rules. Operation is subjected to the following conditions:
1. These instruments may not cause harmful interference.
2. These instruments must accept any interference received, including interference that may cause undesired operation.

These instruments have been tested and found to comply with the EMC standards for emissions and susceptibility established by the European Union at the time of manufacture.

2.3 FCC Warning

Warning: Changes or modifications to the instruments not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: These instruments have been tested and found to comply with the limits for a Class B device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in an industrial setting. These instruments generate, use, and can radiate radio-frequency energy and, if not installed and used in accordance with the IFU, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Note Regarding FCC Compliance: Although the design of the instrument has been tested and found to comply with Part 15, Subpart B of the FCC Rules for a Class B device, please note that this compliance is voluntary, for the instrument qualifies as an "Exempted device" under 47 CRF § 15.1039c0, in regard to the cited FCC regulations in effect at the time of manufacture.

Chapter **3**

3   System Overview

3.1   TCS General Description

The TCS is an electronic appliance to set and control thermal cycles for PCR and Hybridization reactions that run the chip. It provides five TCMs that run five independent temperature programs (Fig. 1). Each module is controlled by an electronic board (TCM-EB) based on ST7 microcontrollers technology. The TCS is based on a control algorithm implemented as firmware (FIRM) for the ST7 microprocessor. The FIRM in according to this thermal control algorithm will drive embedded heaters and an external cooling fan to allow high gradient and performance thermal cycles.

The TCS can operate in the following manner:
- : The software running natively off the embedded computer board in the TCS Satellite TCS: TCS has to be connected to a network switch or directly to a laptop by means of a point to point LAN cable connection TCS.

Each TCM gets user commands by:
- the front panel dedicated to each module, the operator pushes the START button to start running, the INFO button to scroll the information in the LCD, the STOP button to stop the running,
- the E@syControl software application that runs on a standard laptop

The E@syControl allows users:
- to send the Temperature Protocol that contains the temperature cycles for PCR specific to each application type,
- to verify the calibration data,
- to communicate to single TCMs.

The TCS is able to multiplex commands received via E@syControl by using an internally embedded PC that will pass them to the specified TCM via RS485 standard communication. The secondary aim of the embedded PC is to collect temperature data from TCMs and to send them to the E@syControl. This latter will show trends of temperatures into appropriate windows.
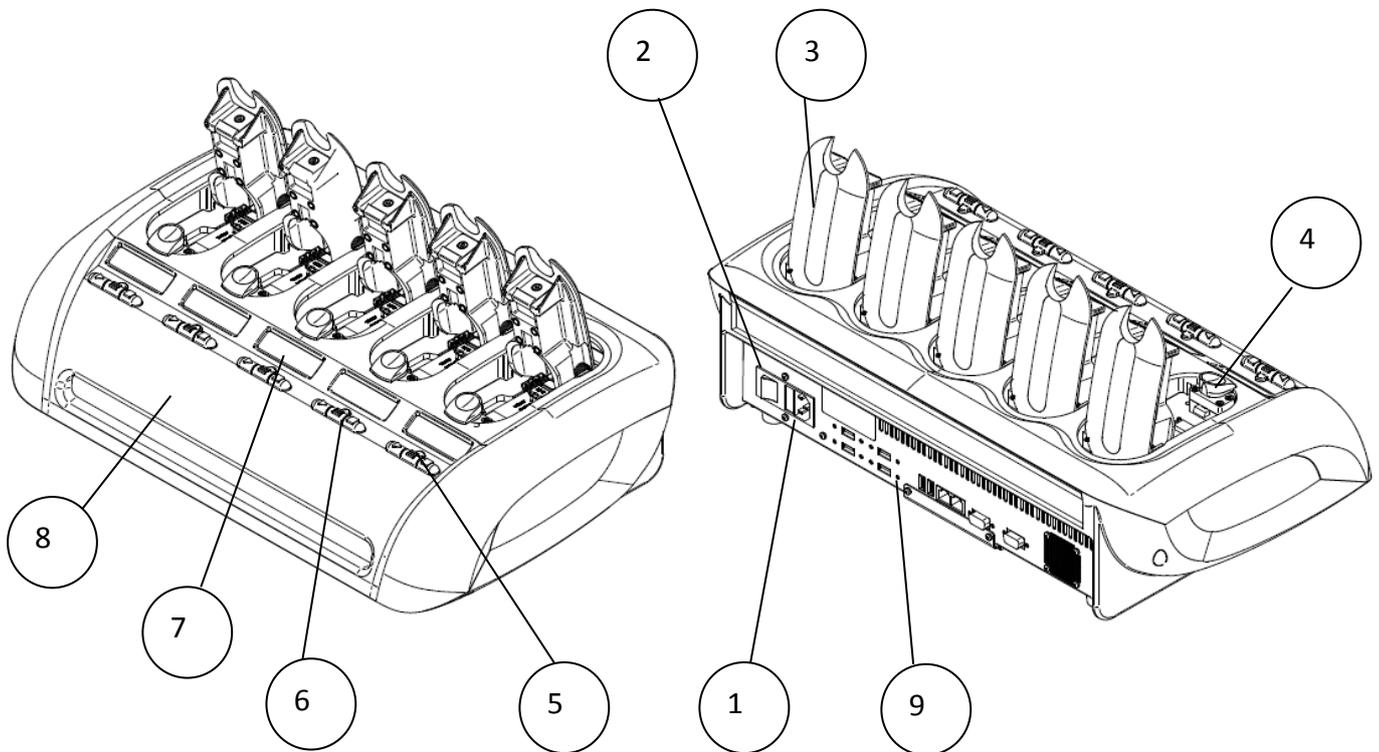
Fig 3: Temperature Control System (TCS)

1. Power Supply plug and Fuses
2. Power switch
3. TCM hatch
4. TCM opening key
5. State led
6. Function keys
7. TCM display
8. Front panel
9. Communication back panel

3.2 OR General Description

The OR is an optical device for acquiring images of the microarray on the chip. It has been tuned in accordance to silicon oxide thickness to provide a limit of detection of 25 fluor/μm^2. The camera offers up to 1392 x 1040 pixels and operates in 8-bit mode. It has two programmable outputs that are used for turning on an excitation system based on two identical illuminators located symmetrically to the sides of the camera and tilted at 45 degrees respect to that. Each illuminator is composed of a 5 mm white LED, a red LED, two aspherical lenses and an excitation filter. A dedicated software, E@syCheck, is used to drive the OR.
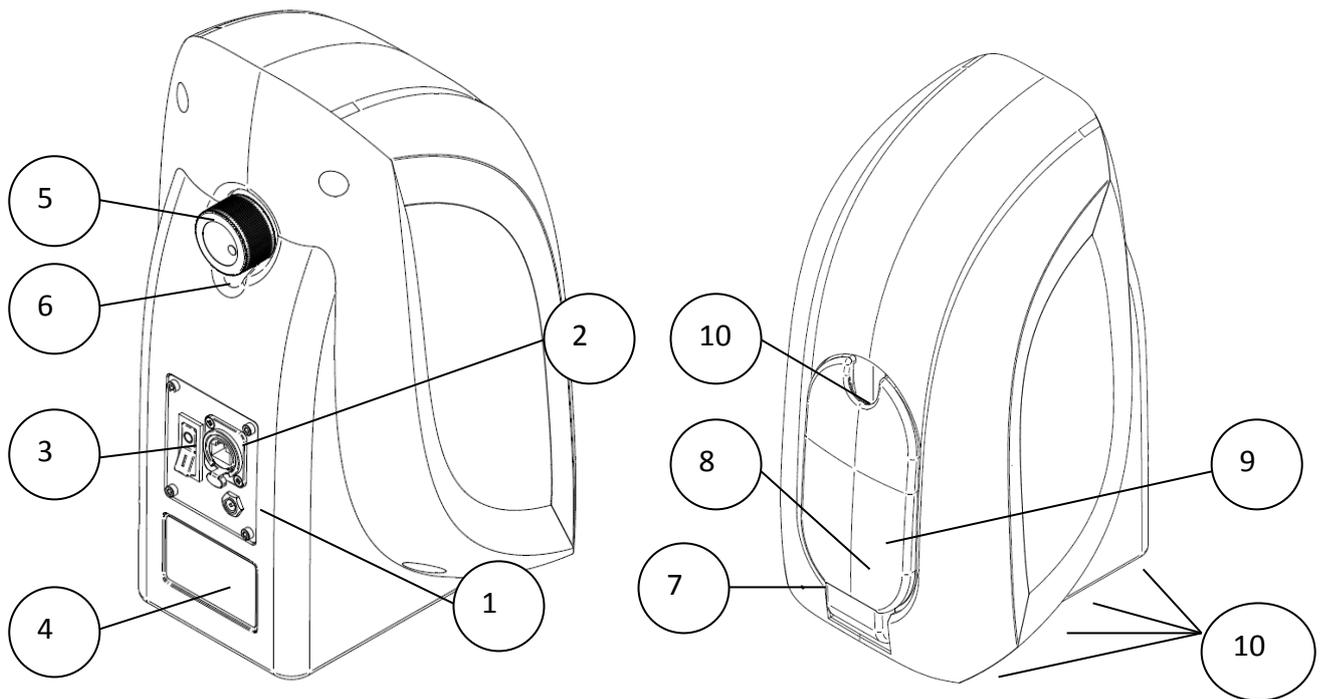
Fig. 444: Optical Reader (OR)

1. Power Supply Jack	2. IEEE 802.3 Ethernet
3. Power Switch (1 = ON; 0 = OFF)	4. Product Identification label
5. Focus Adjustment Knob	6. Focus Adjustment Locking screw
7. Power Status Led	8. Front Hatch
9. Slotted Insertion Plate	10. Rubber feet

3.3   TOM General Description

The TOM is an auxiliary device for the VerePLEX™ Biosystem having the capability to be connected to the Base TCS by USB cable and VGA cable as shown in the following pictures:

Base TCS Rear Panel

USB

VGA
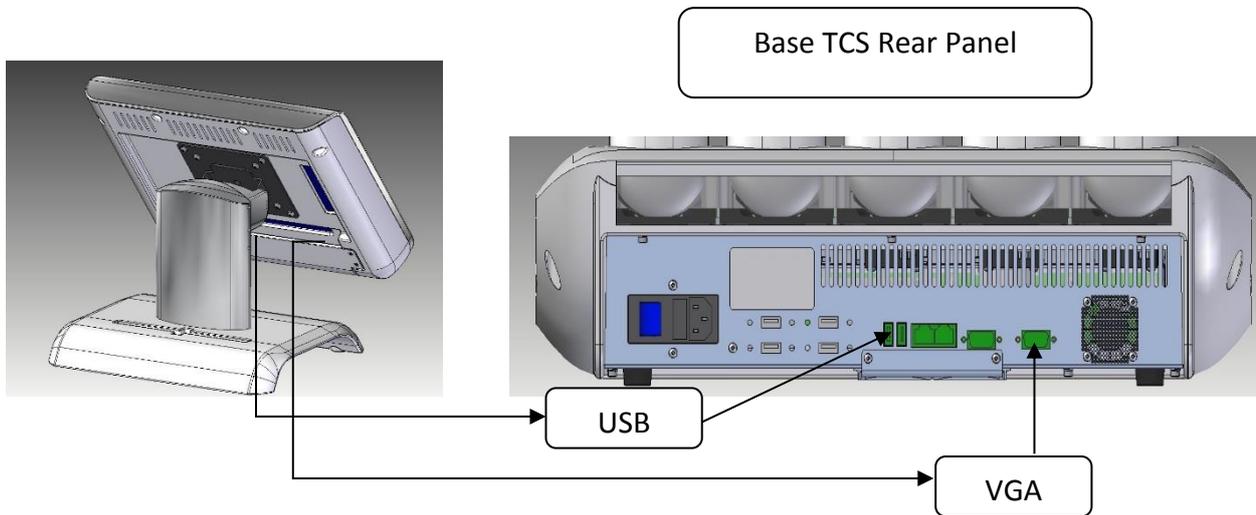
In the same rear panel, the TOM is to be connected to a 12V DC 3A power source.

Chapter 4

4 Installation

4.1 General

The VerePLEX™ Biosystem should be installed on a clean, dry, level surface with sufficient cool airflow to operate properly. The instruments have been factory calibrated and does not require further calibration upon installation.

4.2 Action upon delivery

Before unpacking, check the instrument case for signs of external damage. If the case is broken or damaged, do not use the instrument and immediately notify the shipper of the damage.

Unpack the TCS case and check the list of components:

- TCS unit
- Power cord
- 802.3 IEEE Ethernet STP cable
- Chip holder

Unpack the OR case and check the list of components:

- OR unit
- Power cord with adapter
- IEEE 802.3 Ethernet cable
- 2D barcode reader

4.3 Preparation prior to installation

Site Requirements

The TCS and OR requires a solid bench of dimensions at least 550 mm long and 350 mm deep. Unpack power cord and Ethernet cable; keep them close to installation site in order to take them at the proper time. See Appendix A for a detailed list of requirements for the installation.

4.4 Bringing into operation

Refer to the rear panel of the instruments and connect the cables according to their respective ports.

4.5 TCS Connection

See below for an overall view of the TCS rear panel:
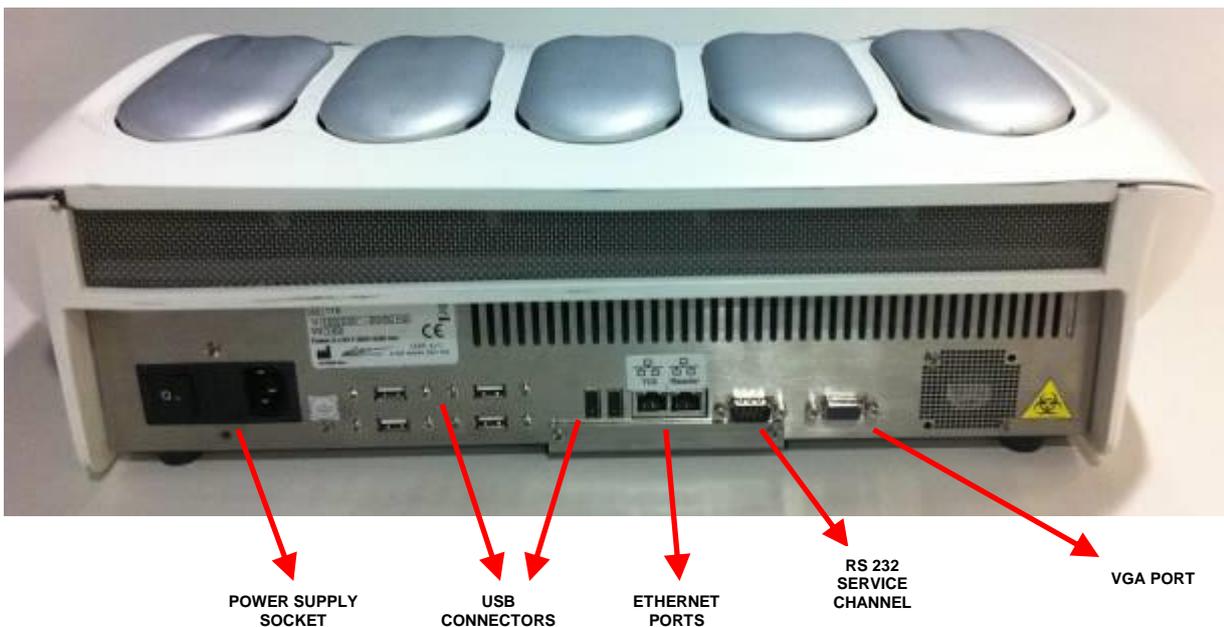
Fig. 557: TCS Back Panel

4.5.1   TCS Power Connection

Connect the provided power cord to the back of the TCS and a power outlet.

> **i**
>
> Power supply
>
> Input Voltage: 100/240 Vac (extended range 90 ¸ 264 Vac)
> Input Frequency: 50 /60 HZ (47/ 63Hz)
> Input power: 140W maximum
>
> Automatic switching

4.5.2   OR Power Connection

Connect the packaged Switching AC adapter output jack to female connector at the back of the OR.

> **i**
>
> Switching AC Adapter input features:
>
> 100-240 Volt AC
> 0.4 Ampere
> 50-60 Hz
>
> Switching AC Adapter output features:
>
> 12 Volt DC
> 1.25 Ampere
> Centre Hole Positive
> Outer metal sleeve connected to Negative

Connect the Switching AC adapter power cord to a power outlet.

4.5.3 TOM Power Connection

The rear panel of the TOM has to be removed before accessing the connection ports. Refer to the illustrations below on the rear panel removal.
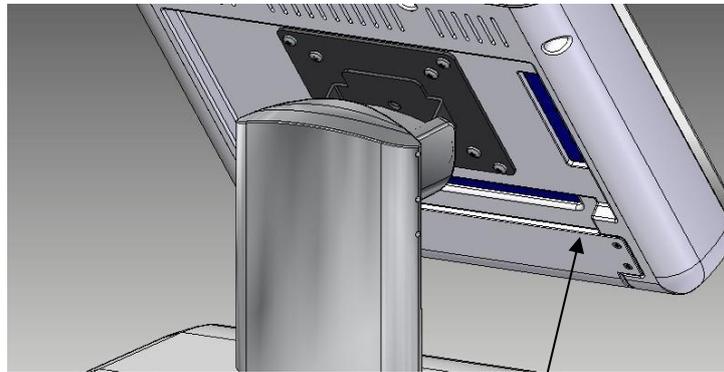
Cover Connector Panel

Unscrew cover connector panel and get the following:
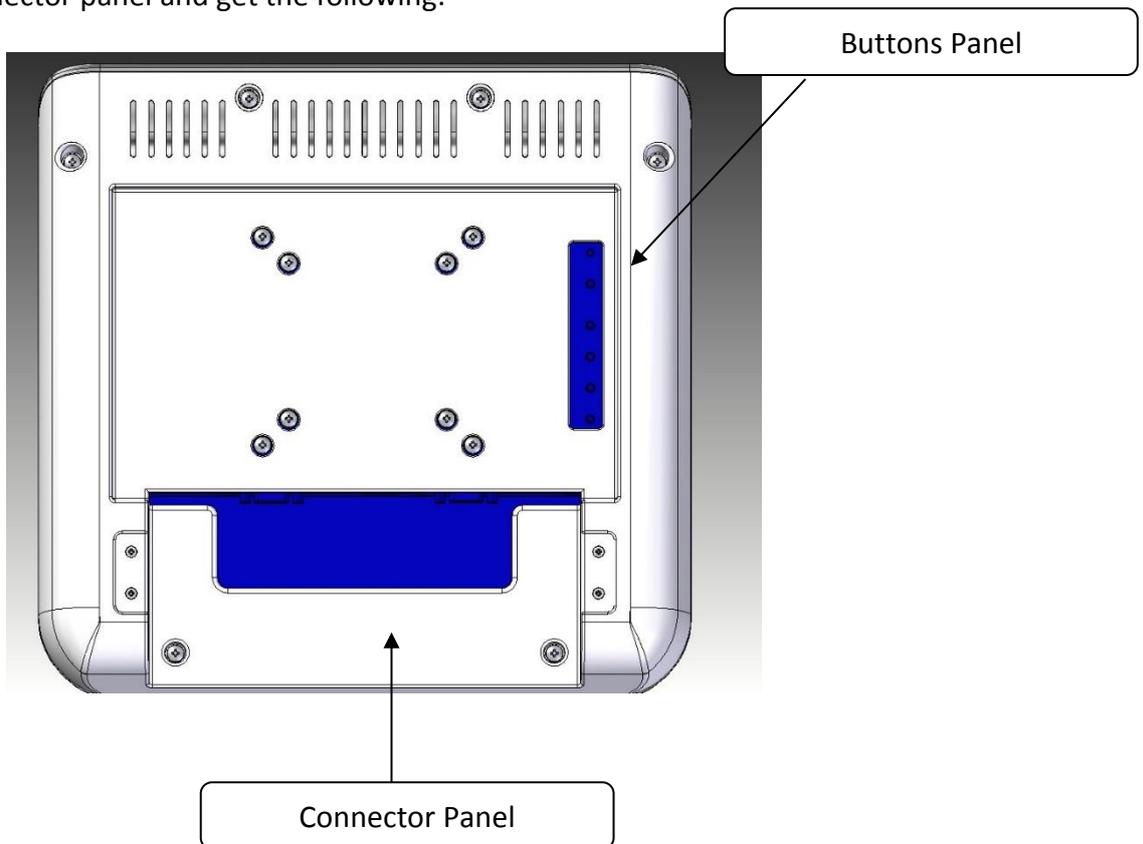
Buttons Panel

Connector Panel

Fig. 8: TOM back panel

Connect the USB and VGA cables from the monitor to the appropriate connectors at the back of the Base TCS.

USB   12 Vdc Power Supply   VGA
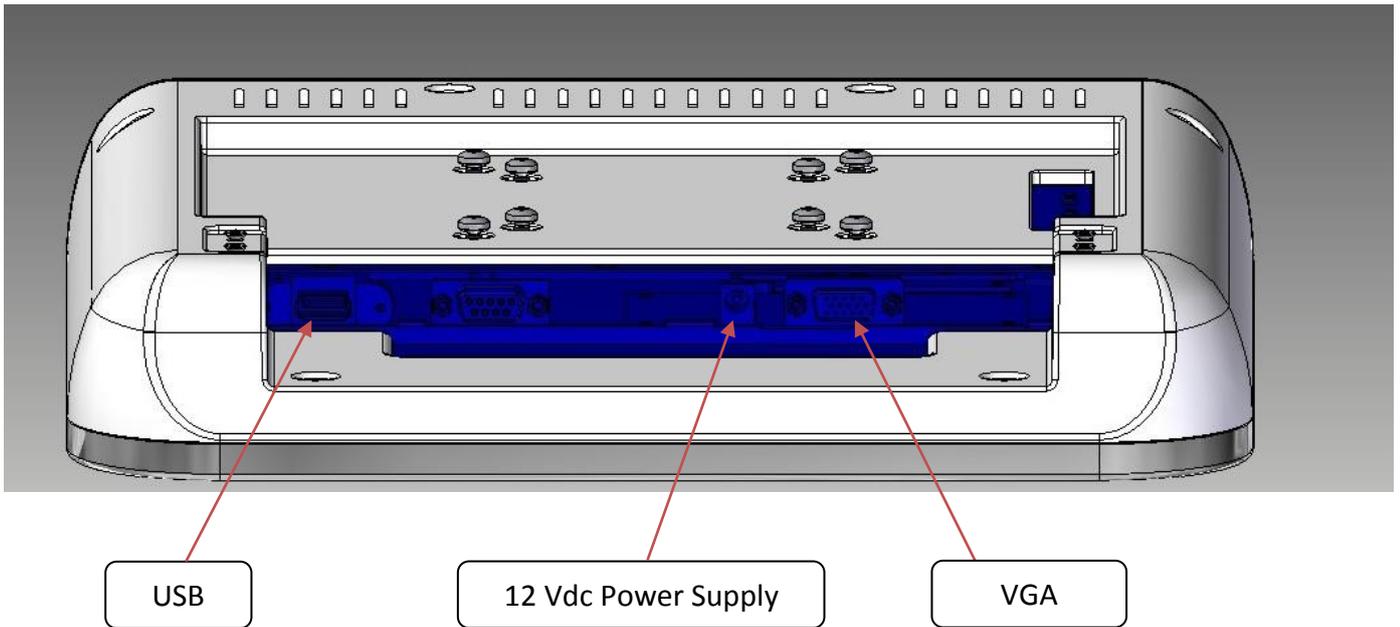
Fig. 9: Base TCS back panel

Connect the packaged Switching AC adapter output jack to female connector at the back of the TOM.

Switching AC Adapter input features:

100-240 Volt AC
1.5 Ampere
50-60 Hz

Switching AC Adapter output features:

12 Volt DC
3 Ampere
Centre Hole Positive
Outer metal sleeve connected to Negative

Connect the Switching AC adapter power cord to a power outlet.

4.6 TCS configurations

In a default configuration, the TCS instruments are connected using Ethernet cables to the supplied laptop via a network switch. The Optical Reader is also connected using Ethernet cable to the same switch. The configuration may be customized to specific site requirements. An network switch is recommended for this configuration.

> It is recommended to use a crossed Ethernet cable when you make a point to point connection.
> The port has auto-switching function.
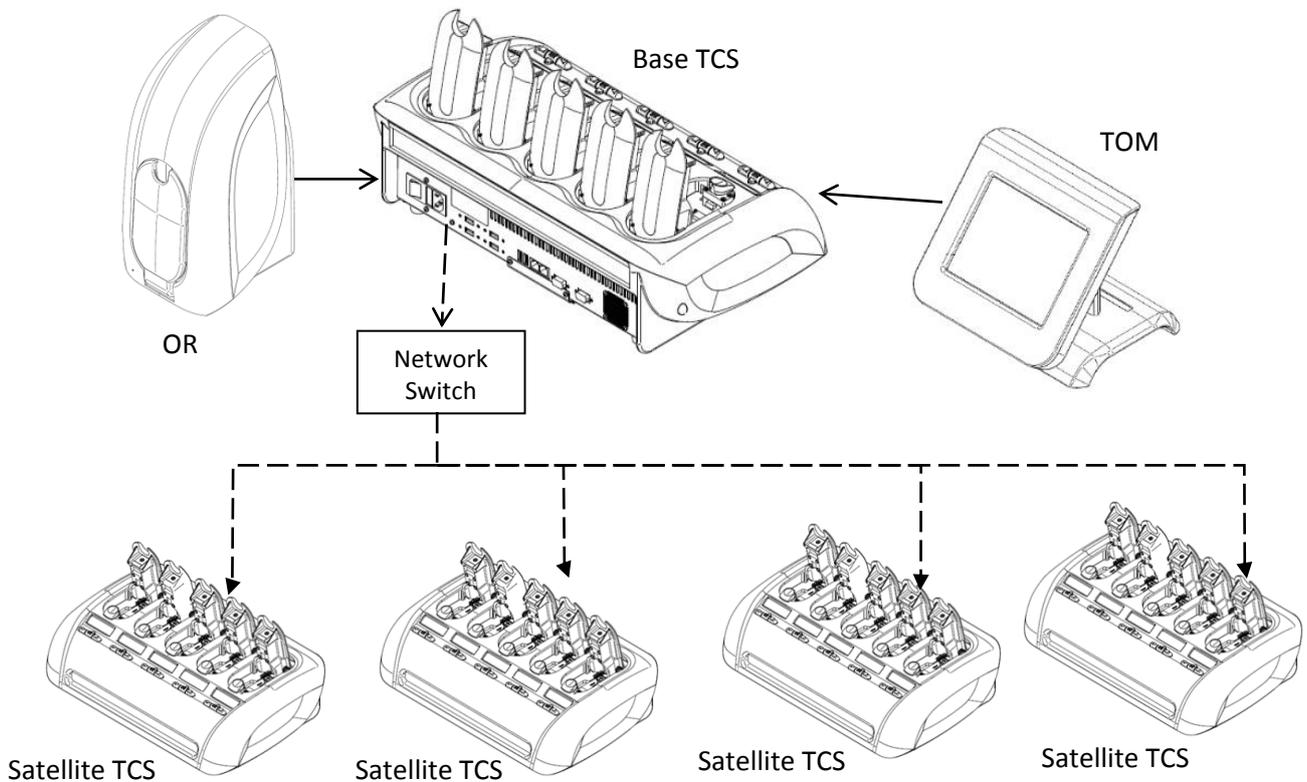
Fig 10: Overview of full LAN setup
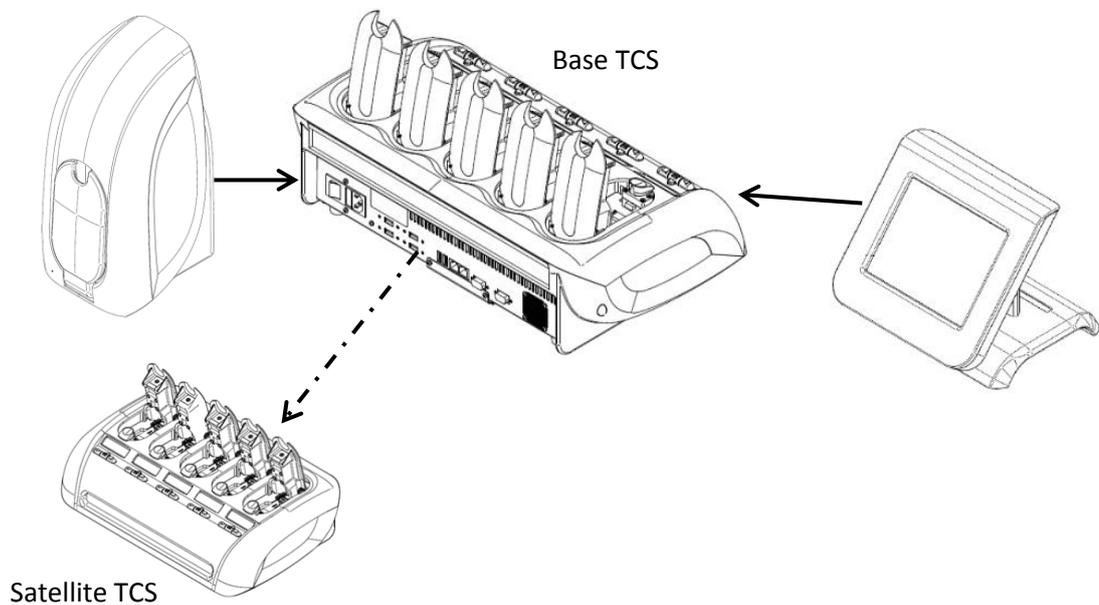
Fig 11: A 2 x TCS setup without switch

The TCS and OR are recognized based on their static IP addresses and have been factory configured. Changing of the IP addresses is not recommended. Please contact your local technical support if there are specific requirements.

4.7 Software installation

The instrument should already have the correct software installed.
Customer should not have to install the software.

> The Software VerePLEX™ 5.3.1 and higher has been validated on Windows 10 Pro. The software should not be used on an older version of Windows operating system.

4.8 BioApplication

Central to running the assay and performing microarray analysis is the BioApplication. Each Targets detection panel is defined by a particular BioApplication. All settings required by the instruments to execute the VereChip run are wrapped in the BioApplication such that user do not need to do any settings or adjustments.

These settings include the thermal protocol, image capture settings, microarray probes layout and diagnostic rules which determines what targets are Detected or Not Detected.

The VerePLEX Biosystem comes preinstalled with certain BioApplications. For newly launched products or new BioAppplications, user should contact their local sales or technical support personal for the relevant BioApplication that they require.

The E@syManager software is where the assigned administrator can manage the BioApplications. The administrator can import and delete BioApplications. Inaddition the Administrator also assigns a default BioApplication to each user. An account with Power User access level can change their assigned default BioApplication while an account with Standard User access level cannot change their assigned default BioApplication. Changes have to be done by the administrator.

Chapter 5

5 Theory

The TCS thermally controls the chip using resistive heating and forced air cooling. Each TCS is equipped with 5 modules (TCM as Temperature Control module) that are able to run 5 separate chips separately for different thermal profiles. Thermal profiles (PCR) are pre-programmed and monitored by E@syControl software.

The OR provides a collimated and monochromatic source of red light that excites the fluorophores that are bounded to the DNA oligos on the microarray surface. The fluorophores then emit light at a slightly longer wavelength with the intensity of the emission proportional to the fluorescent concentration in each microarray spot.

An emission band pass filter separates the fluorescent wavelength from the excitation wavelength, and the resulting image is captured by a high-sensitivity CCD camera. The digitized image is saved as *.tiff* and is analyzed by E@syCheck software. E@syLIMS would interpret the results and provide a final report based on the chip type and BioApplication used and the results can be then exported and archived as CSV or PDF format.

5.1 *Function*

Each TCM consists of electrical contacts with internal sensors and resistor heaters. These contacts are performed by spring-based pins with the capability of moving order to achieve better contact adaptation. Electrical continuity is ensured by the lid. Once the lid is closed, it exerts a force over the chip, compressing the spring-based pins.
In this way, the chip is in full contact with the TCM electronic board. This allows the regulation of thermal energy into the chip. Feedback is returned by a 4-wire sensor reading circuitry.

Upon the instrument start-up, each TCM performs a self-check and will give an error if they do not pass entirely. In this case, the particular TCM will not be usable while the remaining TCMs that pass the self-check will be functional.

Once the self-check is completed, it is ready to receive a chip. If the chip is validated, the TCM is ready to receive a thermal protocol. During the temperature program, it is possible to view the temperature courses as described in the next chapters.

The OR is like a microscope with a dedicated light source. It would capture an image of the whole microarray and the image is interpreted by a defined set of diagnostic rules in the BioApplication.

Annual calibration is recommended for both the TCS and OR and to be carried out by certified service engineer.

5.2 Performance and limitations of use

TCM thermal regulation limits and characteristics:

- Reading sensor accuracy = ± 0.1º C
- Regulating temperature accuracy (during set point maintenance)= ± 0.2 º C

Operative temperature range is 45º C to 100º C.

A log file records each run-time to give end user the possibility to make an offline data analysis. The log file contains information about thermal profile, detected errors etc.

The OR has a detection limit of 25 fluorophores/µm². Each dot in the detection area has a cross section of about 6.7 um per pixels.

A full analysis cycle, from chip introduction, image capture, image analysis to chip removal, takes about 15 seconds. Therefore, approximately 3 chips can be analyzed per minute.

Chapter 6

6 Operation

6.1 Preparation prior to operation

Prepare the chip according to the IFU accompanying the reagent kit.

6.2 E@syControl operation

Below is a summary of steps for thermal control operation of the TCS:

Setup
1) Turn on the TCS
2) Login to E@syControl to use the TCS

Run
For each sample test:
3) Scan 2D barcode of chip to load the calibration data into E@syControl
4) Load the temperature program or BioApplication by E@syControl
5) Start the temperature program or BioApplication by pushing start in the TCM front panel or by clicking start in the E@syControl software

Termination
6) Logout E@syControl

7) Turn off the TCS

6.2.1 Powering up the Temperature Control System (TCS)

Upon turning on the TCS instrument, an initial hardware test will be performed to evaluate the status of the system. In particular, the following components are checked for each of the 5 modules:

- Flash
- Fan
- E2prom
- A to D converter
- Presence of A to D calibration data

Any test failure detected at this point will cause the specific module to stop booting completely with the message of the error displayed on the TCM LCD display. This prevents the user from using a faulty module and please contact Technical Support for repairs.

6.2.2 Run E@syControl and Login to use the TCS

Start the E@syControl. Once loaded, the GUI is displayed. The software will begin to search for available TCS units. The software will check and connect the configured TCS.

- Red TCS icon means that the TCS is disconnected
- Yellow TCS icon means that the TCS is connecting
- Green TCS icon means that the TCS is connected

If the software is not able to connect the TCS, see section 4.5.

The platform offers the capability to use the "Virtual Keyboard". To enable this function, the user has to check the item View -> "Virtual Keyboard" in E@syManager tool. After the item has been checked, the user can use the virtual keyboard for text editing operation.
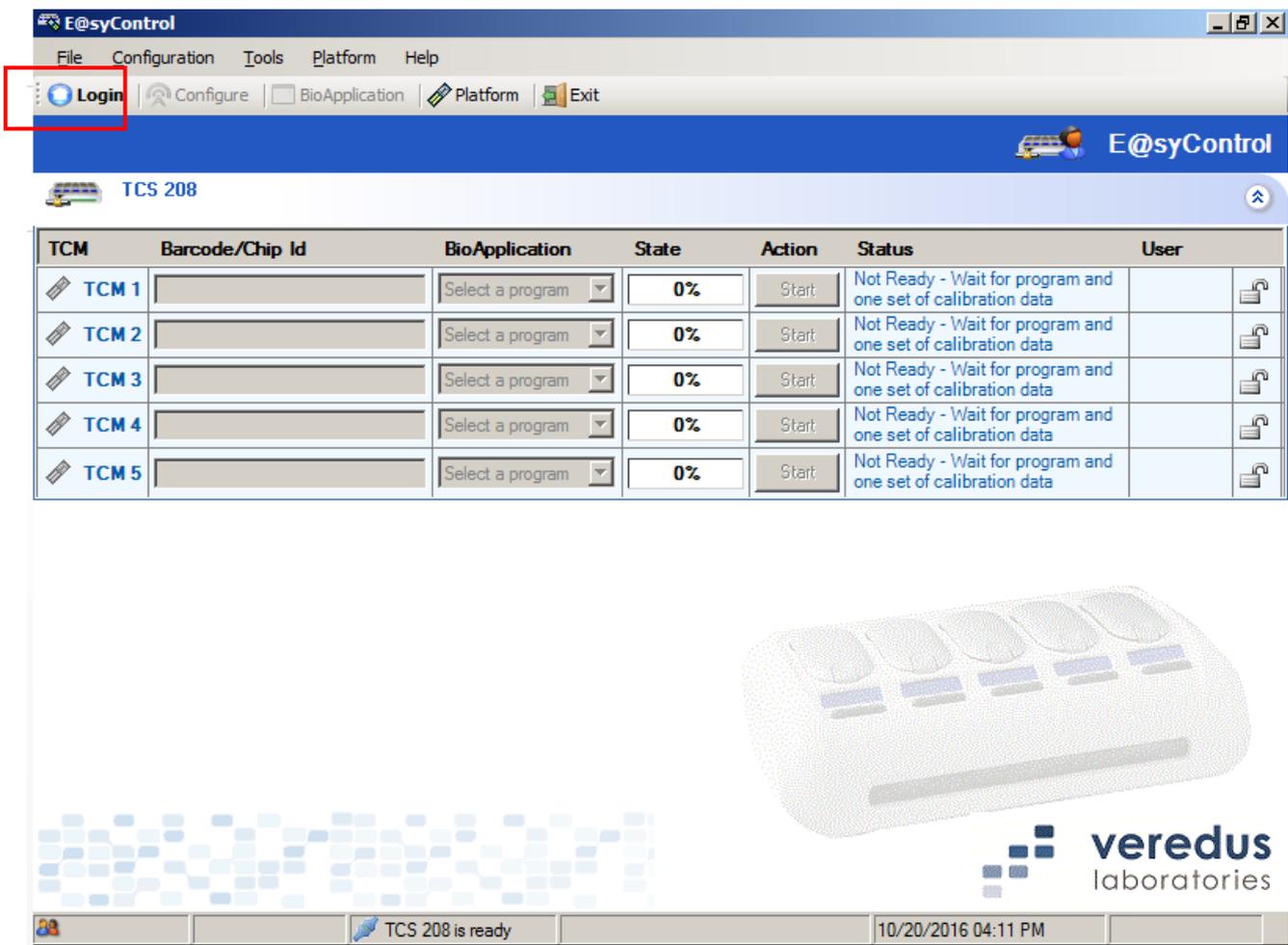
Fig. 12: E@syControl Main window

Once a TCS is connected, the TCS button is highlighted and can be selected. It is mandatory to press the "Login" button in the toolbar for user authentication. (Fig. 12).
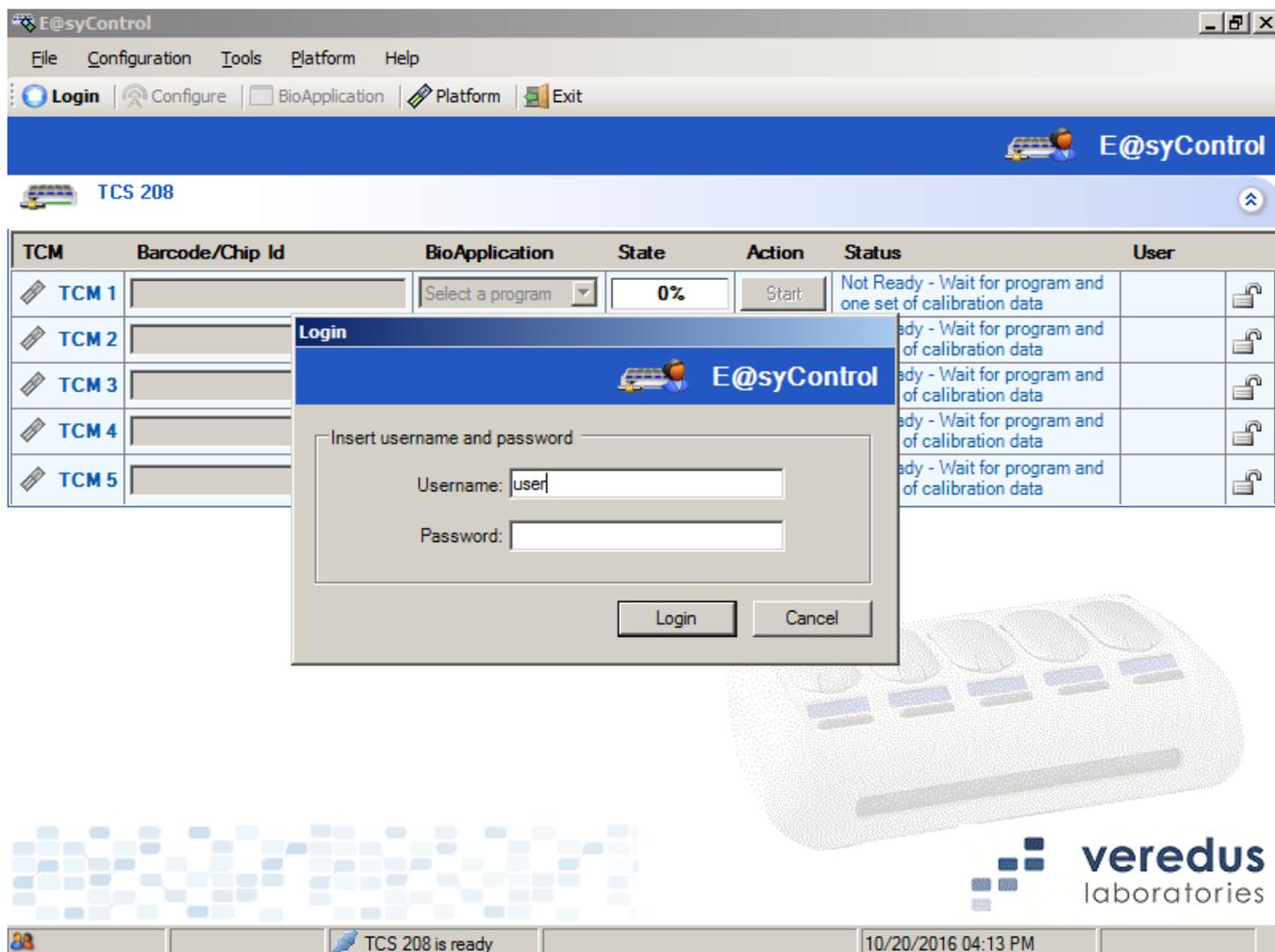
Fig. 13: User authentication

After the login authentication, the user is enabled to use the TCMs of all connected TCS. E@syControl will provide different features according to the group permission:

- Standard User
- Power User
- Administrator

Every operation (start, send, lock, view log, reset, etc.) can be performed by user selecting the related TCM option from context menu as showed in the figure below. To access this context menu, right click on the TCM section using the laptop keypad or mouse.

Fig. 14: TCM option context menu

6.2.3 Calibration data verification and TCM calibration

The user needs to scan the 2D Data Matrix Barcode printed on the chip using the supplied barcode reader and the application will display the barcode. The 2D barcode contains the chip ID and the calibration data.

The software can give out the following error messages:

"Calibration data not found" means that the calibration file is missing.

"Delta TC out of specs" means that the Delta TC value is greater than 0.00041389.

"Sensor Spread @ 60 out of specs" means that the value is greater than 7.85.

"**Sensor Spread @ 90 out of specs**" means that the value is greater than 8.45.

The last three messages are related to wrong calibration data. In this case, the user should discard the chip and notify the problem to the Manufacturer.

If there is no error message and "Not Ready" is displayed in the Status message box, the calibration data is sent to the TCM correctly and the chip ID becomes green color (Fig. 15).

Fig. 15: Chip validation and calibration data loading

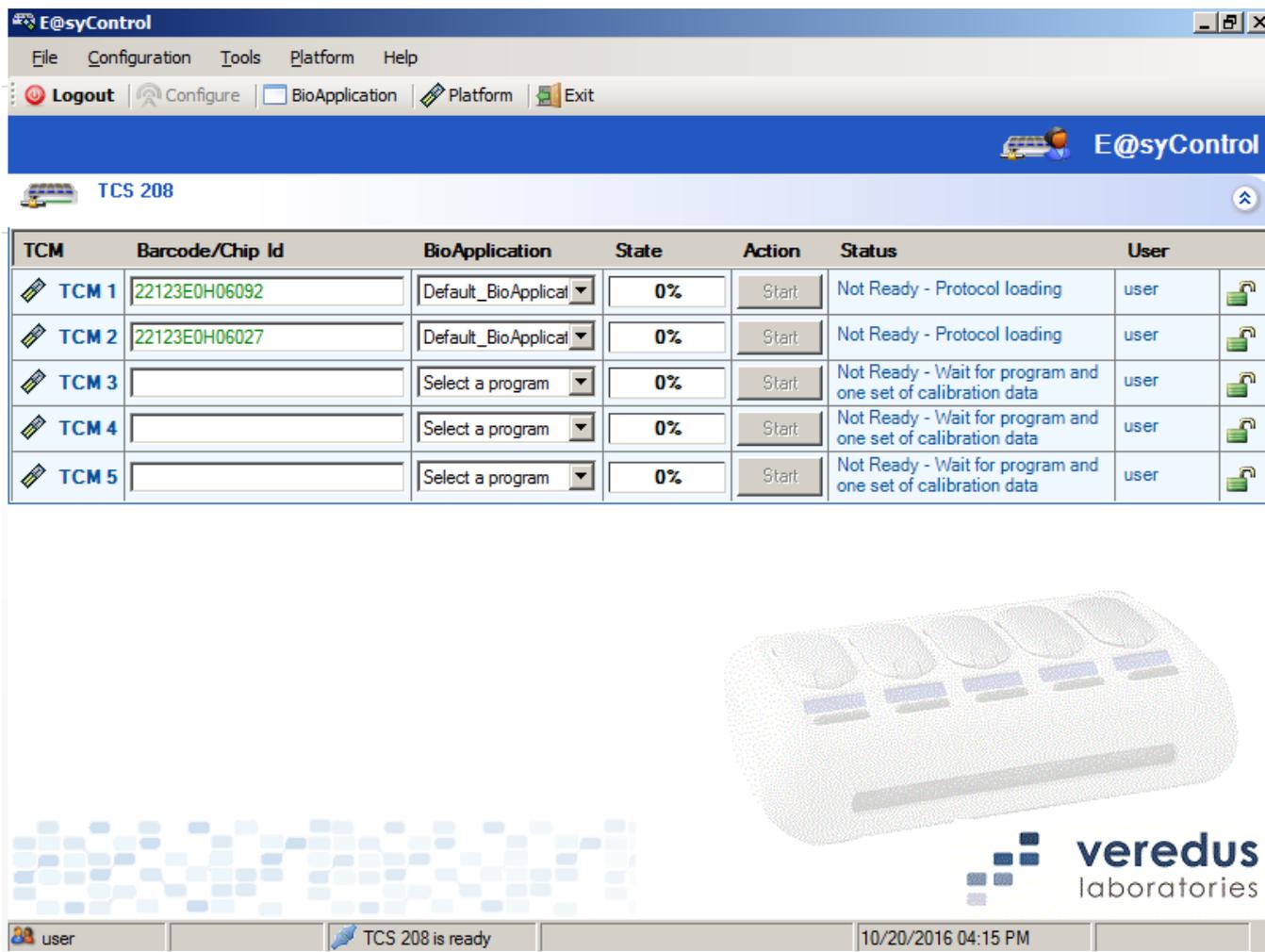The user can insert the chip into the TCM and close the lid. The heaters and sensors embedded in the chip are checked. During validation, "Chip Validation" will be displayed in the TCM display.

After validation, if "CHIP IS NOT VALID" error message is displayed in the TCM display and the software, the user has to follow the procedure described below:

    (a) Open the lid,
    (b) Close the lid for a new validation

If the error message "CHIP IS NOT VALID" is still displayed, it means that the chip is not usable and has to be discarded.

Once the chip is validated, the user has to select the Temperature Program or BioApplication. The user can either select the Temperature Program or BioApplication before or after the chip validation phase. When the message "CHIP INSIDE PRESS START" is displayed on the TCM display, the user can begin the operation.

6.2.4 Chip traceability

In order to trace each single chip from the start to the end of an experiment and to avoid reusing the chip more than once, it is necessary to store all the relevant information and steps performed in the central database.

After a run is completed, E@syControl stores in the database all the information to trace the operations related to the used chip.
When the user inserts the barcode of a used chip, the application shows the following warning message:
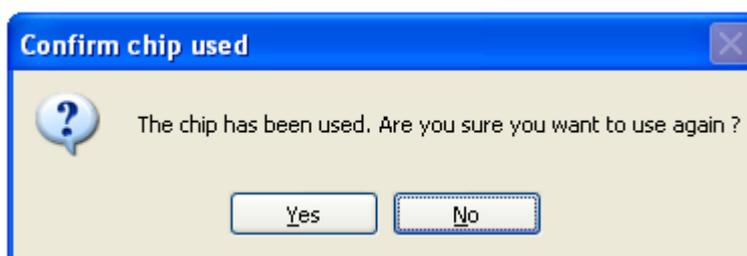

Fig. 16: Chip traceability

The recommended action to press the "No" button which will remove the chip ID from E@syControl. This stop the user from thermal cycling a used chip. Pressing the "Yes" button will allow the user to proceed with the run. Only perform this step if the user is sure that they want to thermal cycle a used chip a temperature program or BioApplication. Pressing the "No" button, all the info related to the chip ID are deleted in the software GUI.

6.2.5 Temperature program run

Before running a temperature program the user can check the program by pressing the middle button in the TCM:

1) Chip ID and calibration data
2) Temperature program loaded
3) Chip has been loaded and recognized inside the TCM

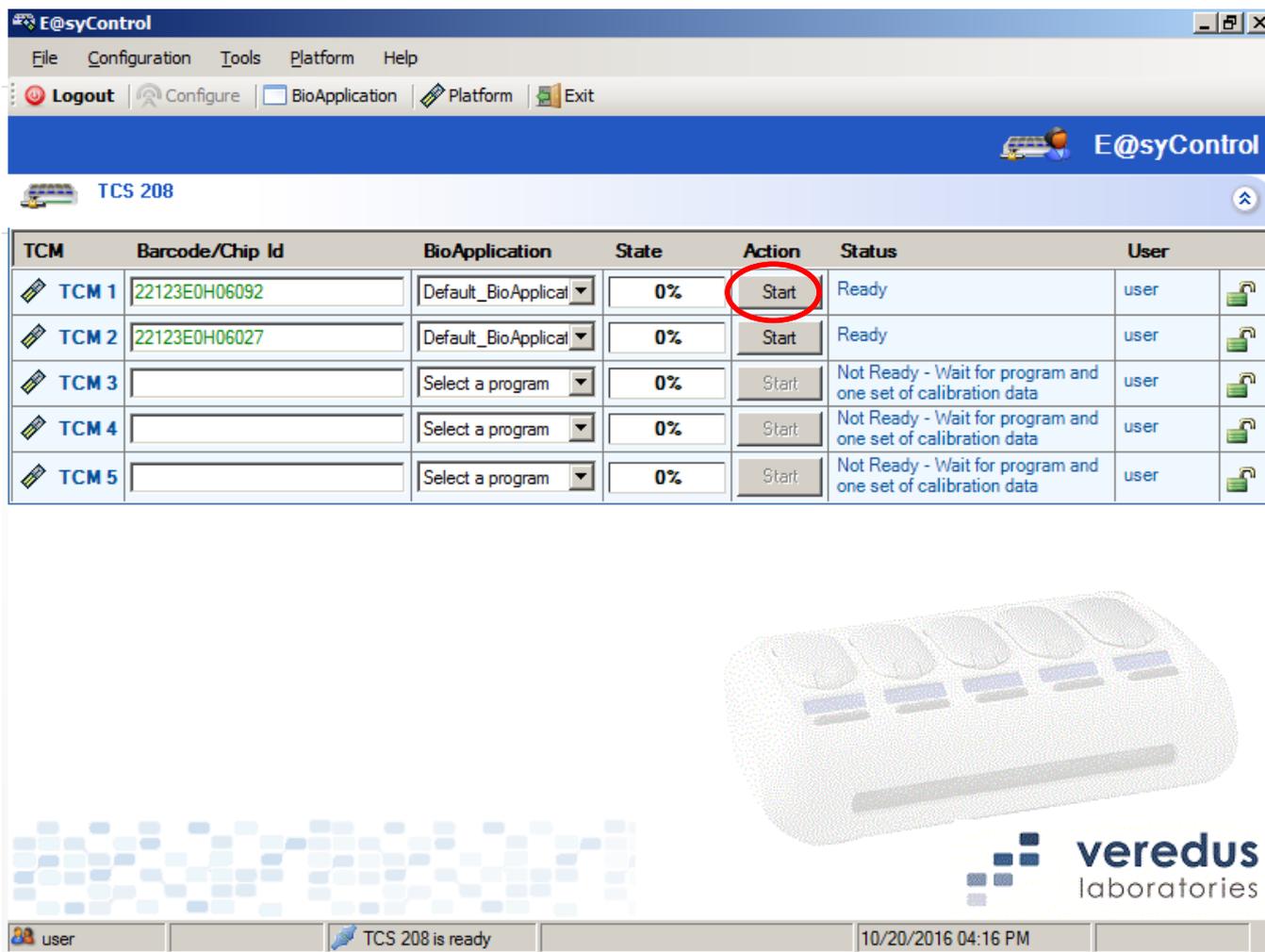Fig. 17: Ready to start

Pressing the   button   [Start]   in the software in the TCM line or the physical TCM left button starts the PCR process and the progress bar will start to count the percentage of elapsed time (Fig. 18 & 19).
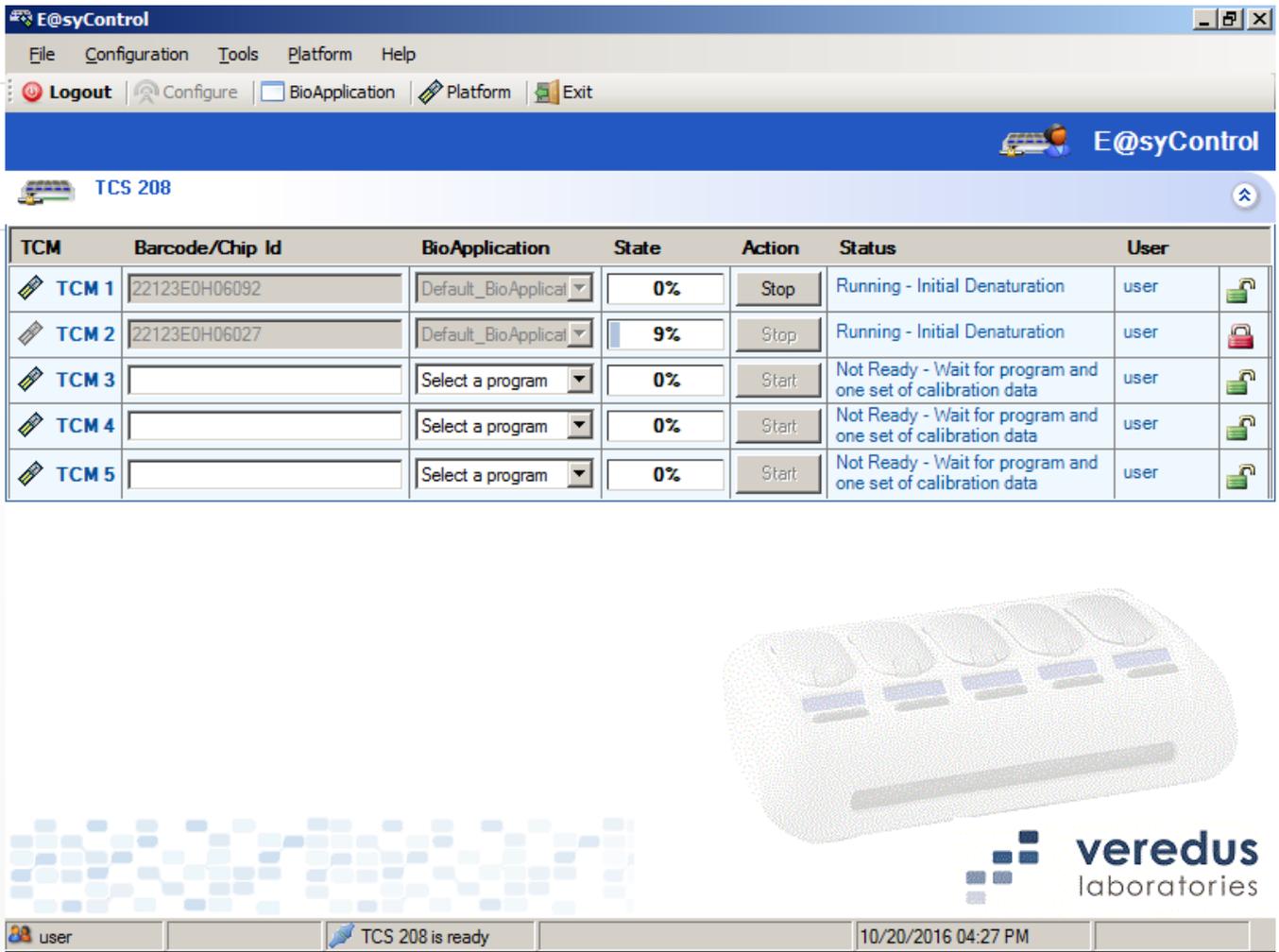
Fig. 18: Progress bar counting

Before the hybridization step, the TCM pauses and waits for the user to extract the chip for further operations. The following message will be displayed on the TCM:

WAITING FLUIDIC
OPERATION

When the chip is ready to complete the fluidic operation, the user can insert the chip into the TCM inside the module and press the [Start] button to proceed.

At the end of the temperature program, the TCM will display the following message:

Protocol
COMPLETED

The chip can be extracted and the TCM module can be prepared for a new chip run. The last temperature program set will be kept.

6.2.5.1 Software Lock TCM

E@syControl provides the *lock/unlock single TCM* feature to minimize the risk of accidental errors due to multiple users on the same instrument.

The TCM will lock when:

      a. User signs out of E@syControl

      b. Auto lock after a preset time

The red lock icon indicates that the particular TCM is in used and can only be unlocked by the same user or the administrator. A locked TCM will not respond when the physical buttons on the TCS is pressed. But the TCM lid itself is not locked and can be opened.

> Do not open the TCM lid while the thermal protocol is still in progress. Doing so will pause the run and may render the results invalid. The thermal protocol will resume after the lid is closed and chip verified.

6.2.6 BioApplication Management

For ease of use, all the settings and parameters are contained in the BioApplication and this is specific to the chip and reagents used.

A BioApplication is defined as a set of input data/files:

- Layout of the Microarray
- Temperature Program
- Reader parameters
- Settings for the microarray image analysis.
- Diagnostic rule

To check and view the temperature program associated to the default BioApplication, the user can select the "BioApplication" item in the toolbar or in the menu under "Tools". The "Default BioApplication" will be highlighted in red as shown in the image below:

Fig. 19: BioApplication Management

The BioApplication Management window contains the list of all BioApplication records in the database.

The BioApplication cannot be edited or managed by user inside the E@syControl tool. Only the Admin can manage the BioApplication package by the E@syManager tool.

The Power User can select their own default BioApplication in the BioApplication Management window. The Standard User, however, cannot change the default BioApplication as it is pre-defined by the Admin. Only the Admin can change the assigned default BioApplication for the Standard User.

Through the toolbar and menu, the Power User can launch the BioApplication Management window to select the default BioApplication. The default BioApplication selected will be automatically sent to the TCM once the chip 2D barcode is scanned. If there are chip runs which require a different BioApplication, it can be selected from the dropdown list after the chip 2D barcode is entered.
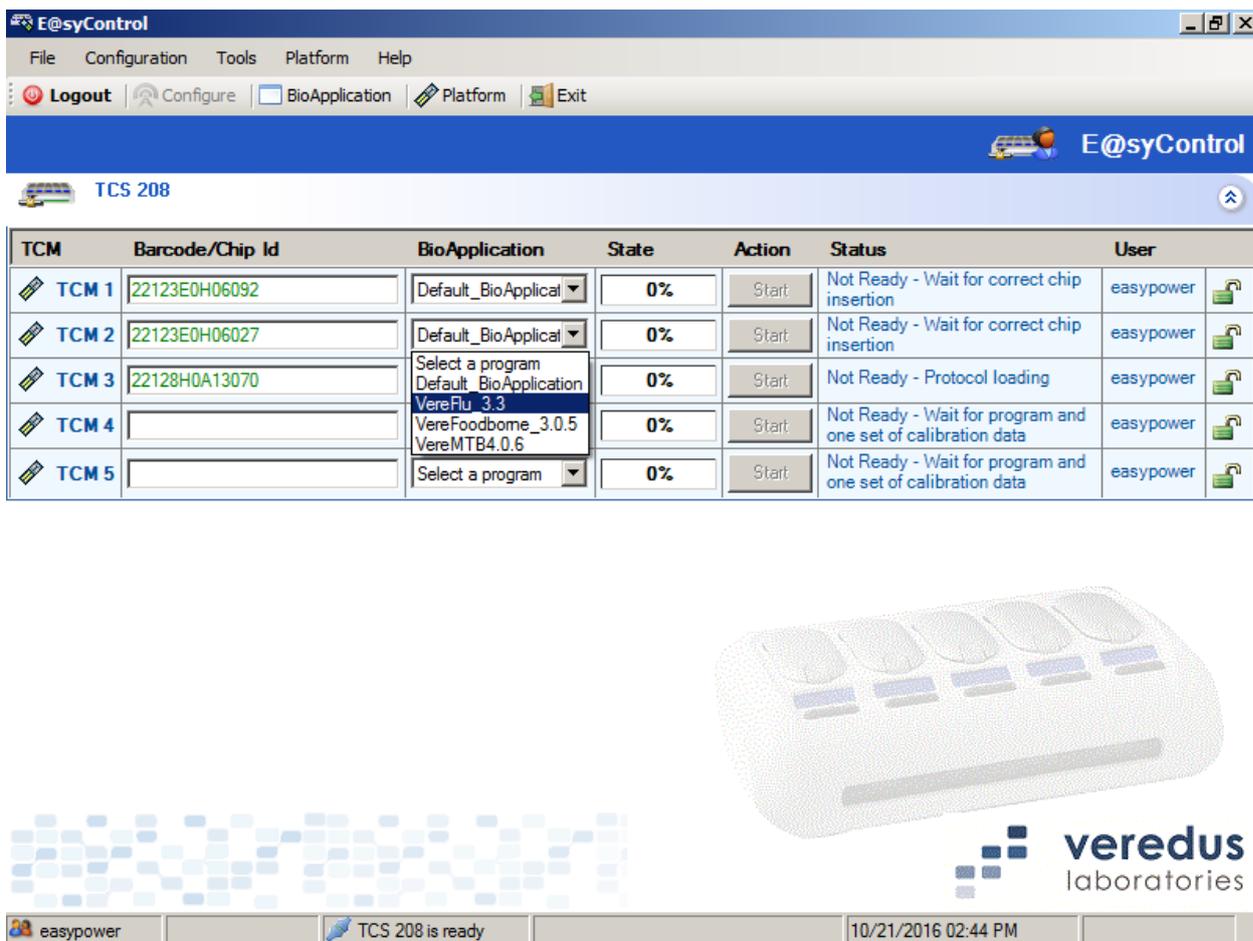
Fig. 20: Selecting a different BioApplication

Once the BioApplication is changed in the dropdown list, the new thermal protocol will be automatically sent to the particular TCM and overwrite the previous default protocol.

> ⚠️ Note: After selecting the different BioApplication, depending on the length of the new protocol, it may take a few seconds for the complete protocol to be sent over and overwrite the previous default protocol.

In the event that there is a need to change the protocol by sending the same protocol to multiple TCMs, instead of changing it 1-by-1 using the dropdown list, user can also send the same protocol to multiple TCMs using the "Send Group" function shown below. To access this menu for the particular TCM, right click on the Status column.

Note: After selecting the different BioApplication, the thermal protocol has to be sent to the TCM to overwrite the previous default protocol.

Fig. 21: Selecting a different BioApplication

In this example, TCM 2 has been changed to VereFlu_3.3 and TCMs 1 and 3 are to be changed to VereFlu_3.3 too. After having selected send group, another window would appear enabling the user to send the same protocol that TCM 2 currently has to multiple TCMS (i.e. TCM1 and TCM 3).
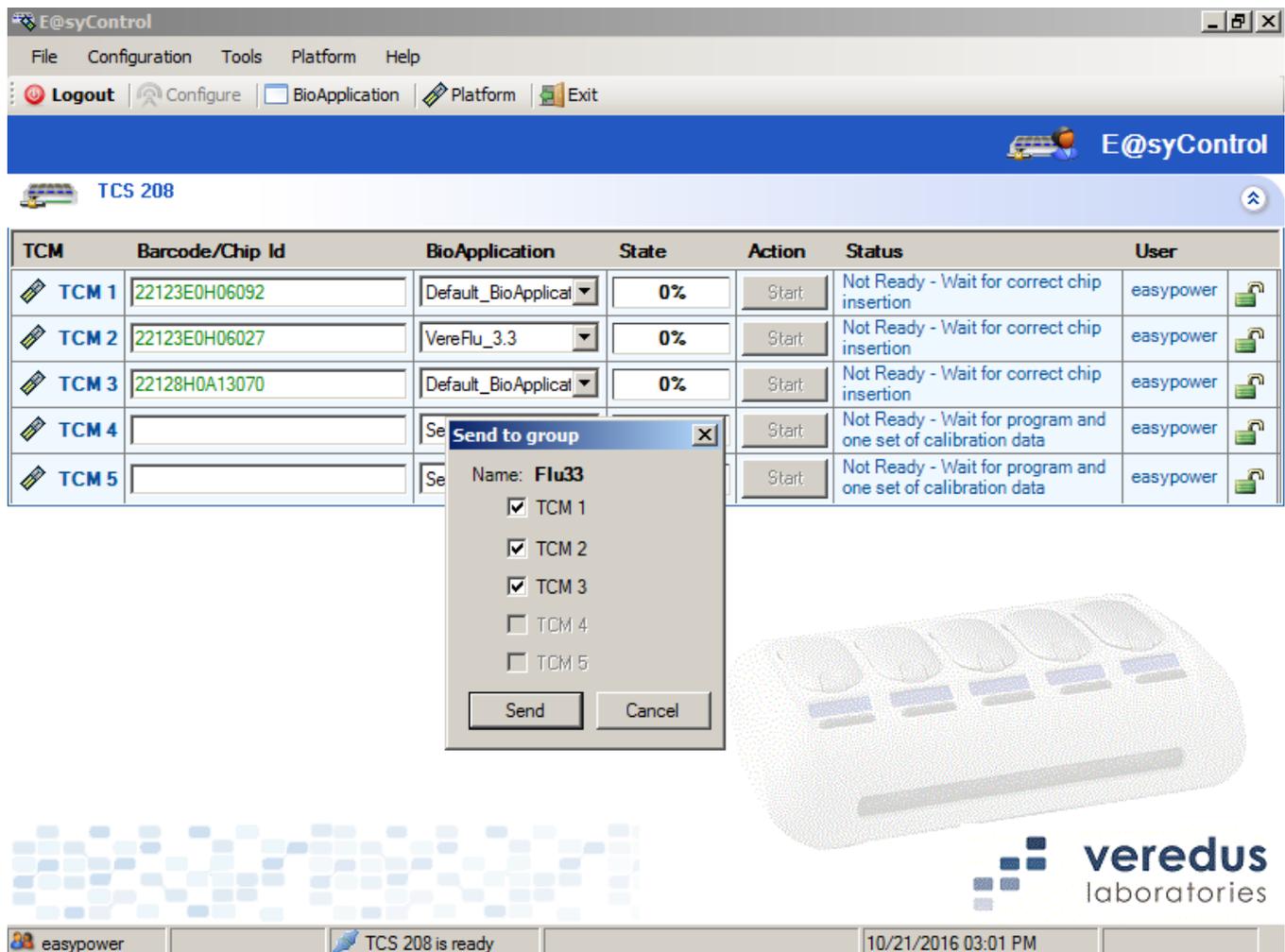

Fig. 22: Sending BioApplication

6.2.7 Warning run time lamps visualization

The service engineer is able to enable or disable warning run time visualization. A warning will be present when the TCS is unable to reach a set temperature within a specified amount of time. This will not cause the TCS to terminate the thermal protocol run but would log this event as a temperature timeout and indicate in this warning lamp. The temperature time-out would usually occur if the set cooling temperature is below the ambient temperature of the instrument.

If the temperature warning item in the Configuration->Options menu is enabled, a colored lamp is shown for each temperature course to show (real time) if it is correct or wrong (green, orange or red). If temperature stays into $\pm$ 0.5C° set-point range, the green lamp is on, otherwise the orange lamp is shown. The red lamp is shown only if the Temperature Program is stopped for an over-temperature error in the TCM.
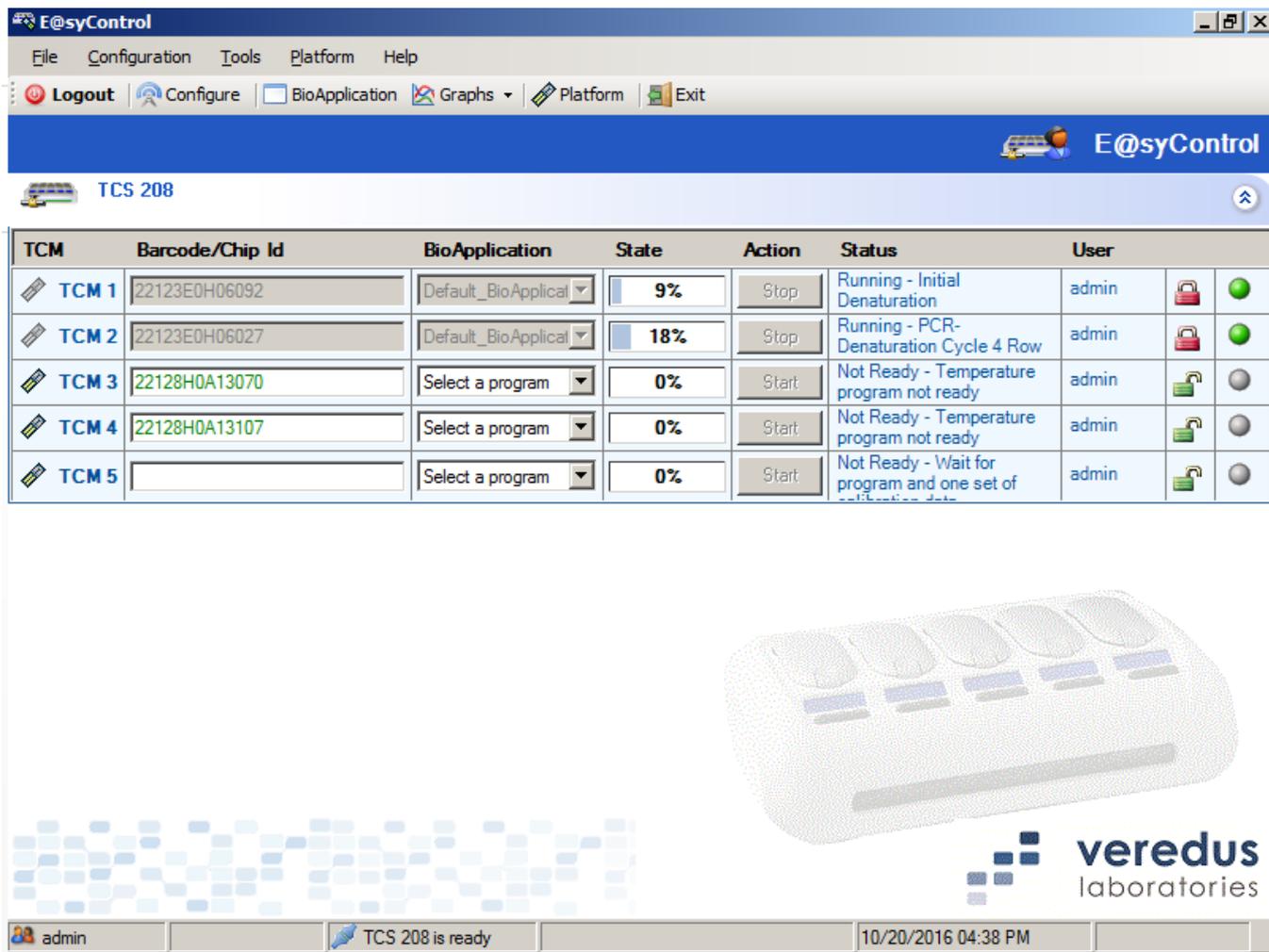
Fig. 23: Warning lamp

It is possible to show the error log smart window by clicking on the red/orange lamp in the main window as shown below:
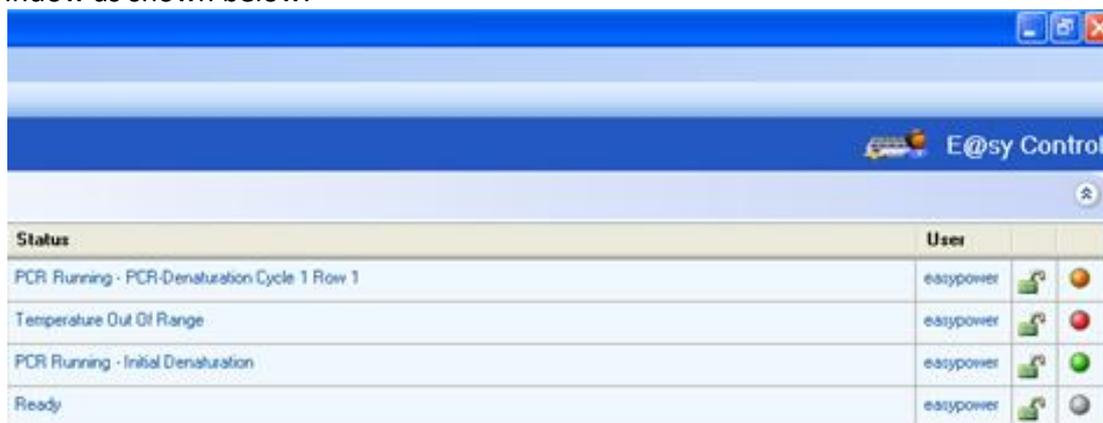
Fig. 24: Clicking on red/orange lamp

Clicking in the red/orange lamp it is shown an error log as shown below:
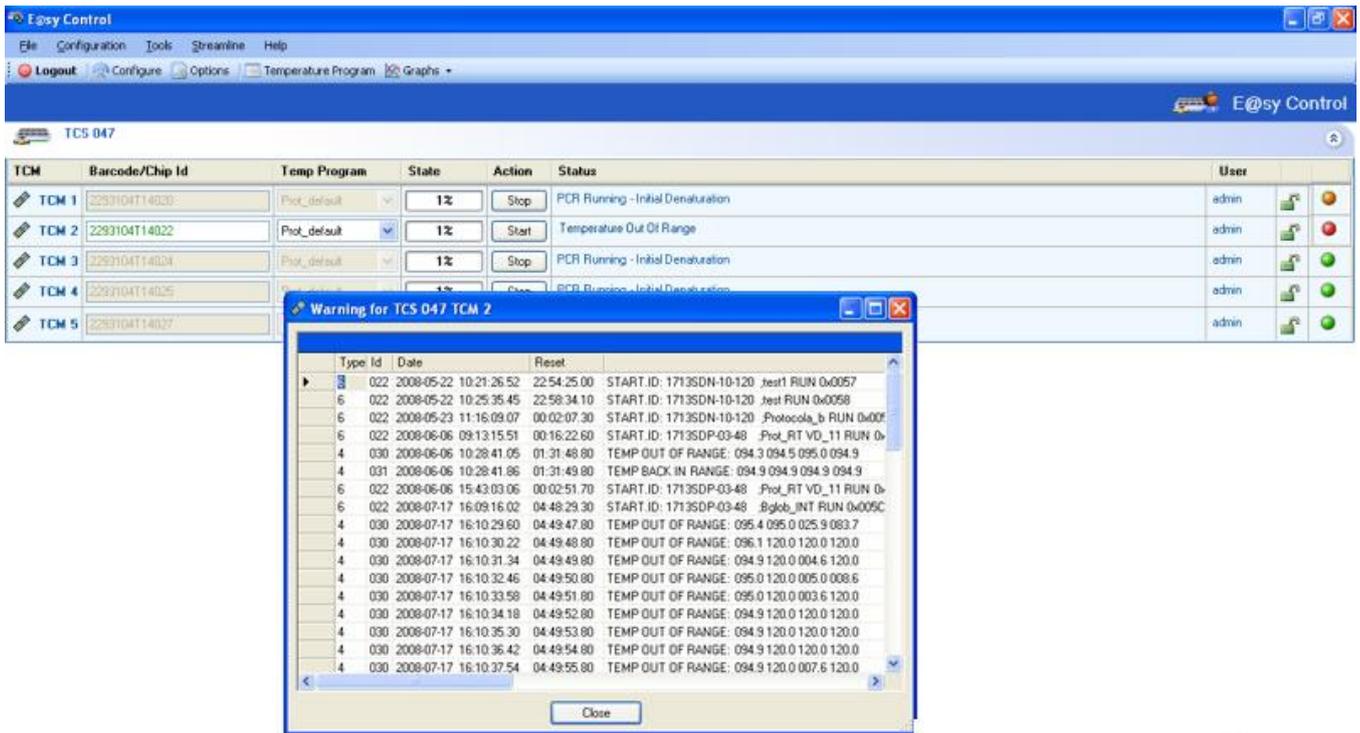
Fig. 25: Warning log window

6.2.8 Log View for TCM (administrator only)

Only the administrator can view the TCM log. This tool can show Logs files with all its data fields that can filter visualization, save as *.txt* file and load for background analysis.

To retrieve the log, the user has to select "View Log…" by clicking on the TCM option context menu. A window will be displayed as the following figure:
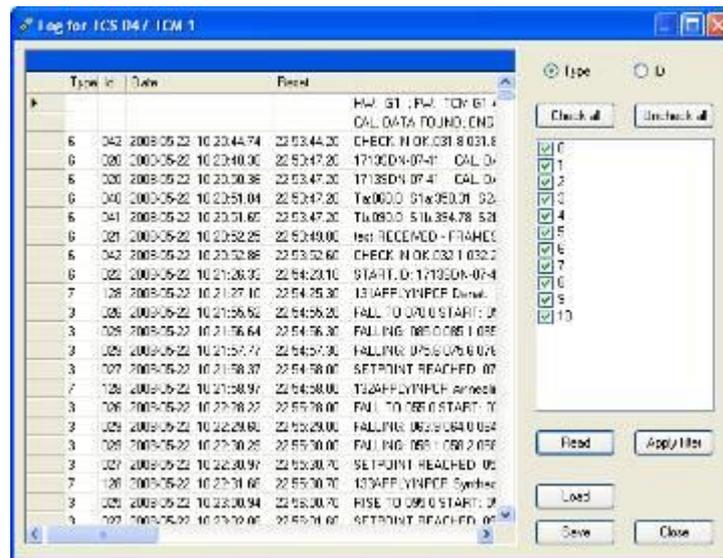
Fig. 26: Log view

This log file can then be saved and sent to service engineer for troubleshooting.

6.2.9   TCS configuration

Only the service engineer can configure the TCS IP addresses from the Configuration menu or from the Configure button on the toolbar. The window is shown in Fig. 27 below:
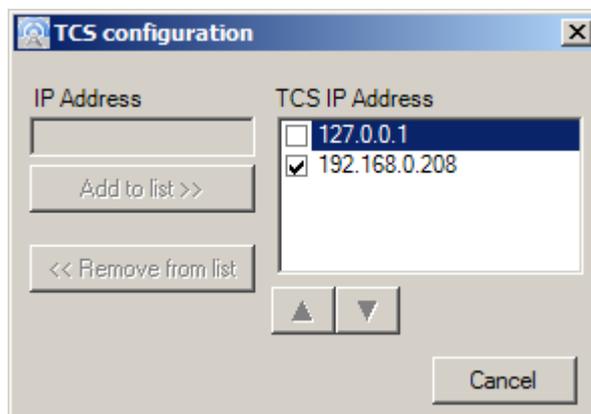
Fig. 27: TCS configurations

## 6.3   *TCM Reset function (Power and Administrators)*

It is possible to reset a single TCM by clicking on the "Reset" item in the TCM option menu. This operation can be performed only by Power and Admin users.

This reset function is not usually used during normal operation. In the event that the TCS status does not match the status in E@syControl software, the whole TCS instrument may be rebooted to resolve the sync issue. But if there are chips running, specific TCM can be rebooted using this function.
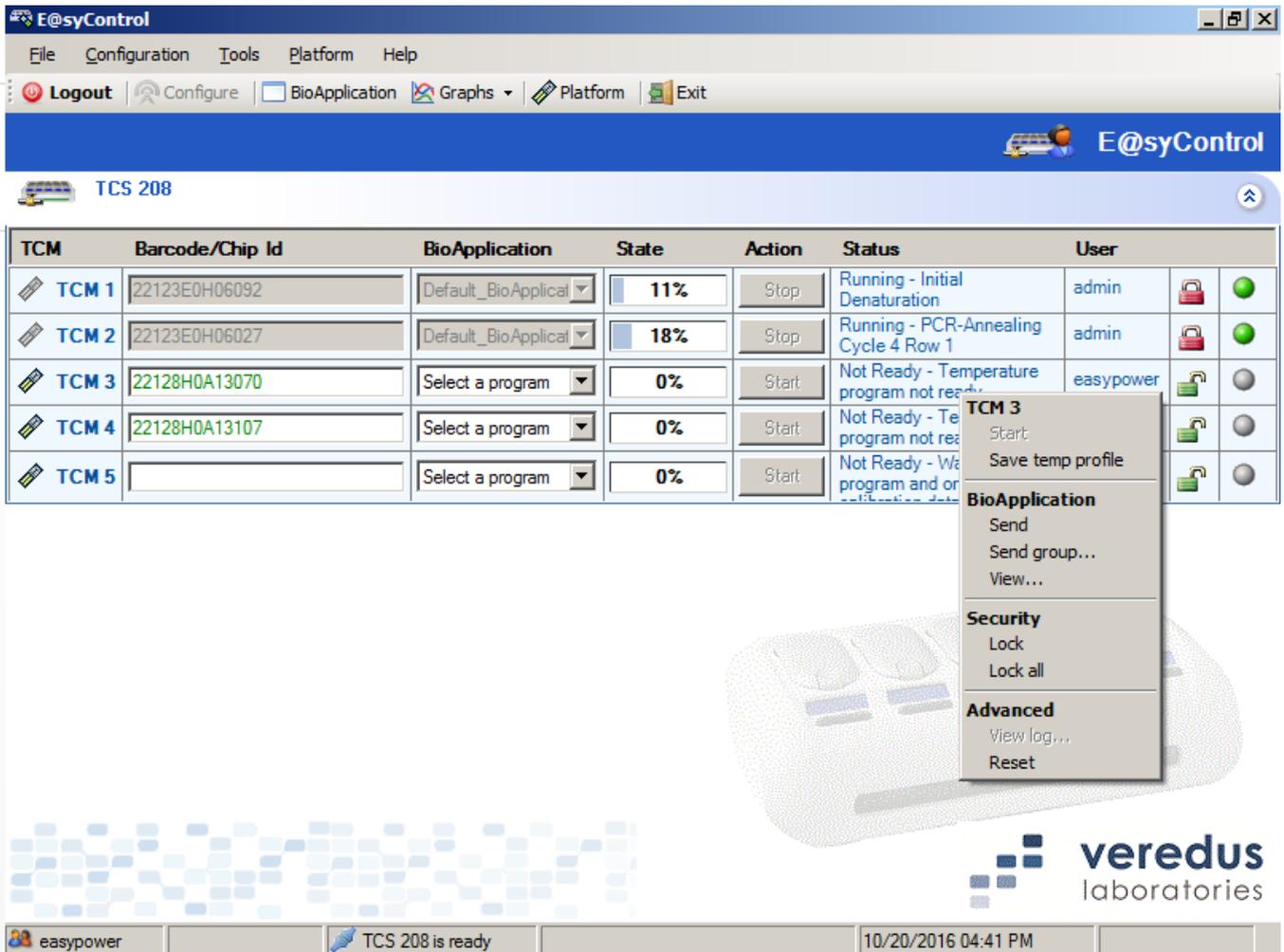
Fig. 28: TCM Reset function

- AC-DC converter
- Presence of AC-DC calibration data

Any boot-up test failure will cause a hardware error and a TCM stop with the message of the error displayed on the TCM LCD display.

6.3.1   Message and sound events (Power and Administrators)

Power and admin users can set messages and sounds by selecting them from the Configuration menu:
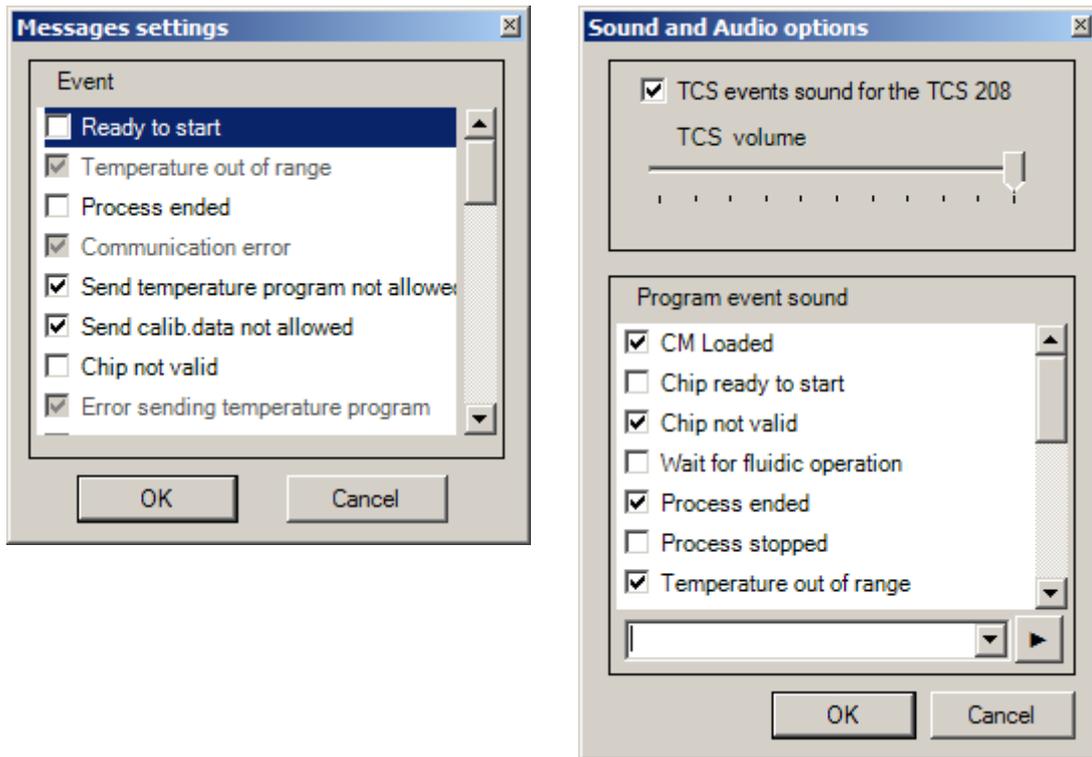
Fig. 29: Message and sound events

6.3.2   Shut-down procedure

The TCS does not require any particular shut-down procedure. It can be switched off directly without damages.

6.4 E@syCheck and Optical Reader Operation

6.4.1 Preparation prior to operation

The chip should have undergone thermal cycling, hybridization, washing and drying steps before imaging the microarray using E@syCheck.

To acquire and analyze an image of the microarray by an OR, use the E@syCheck tool. When the user launches E@syCheck tool, the following GUI is displayed:
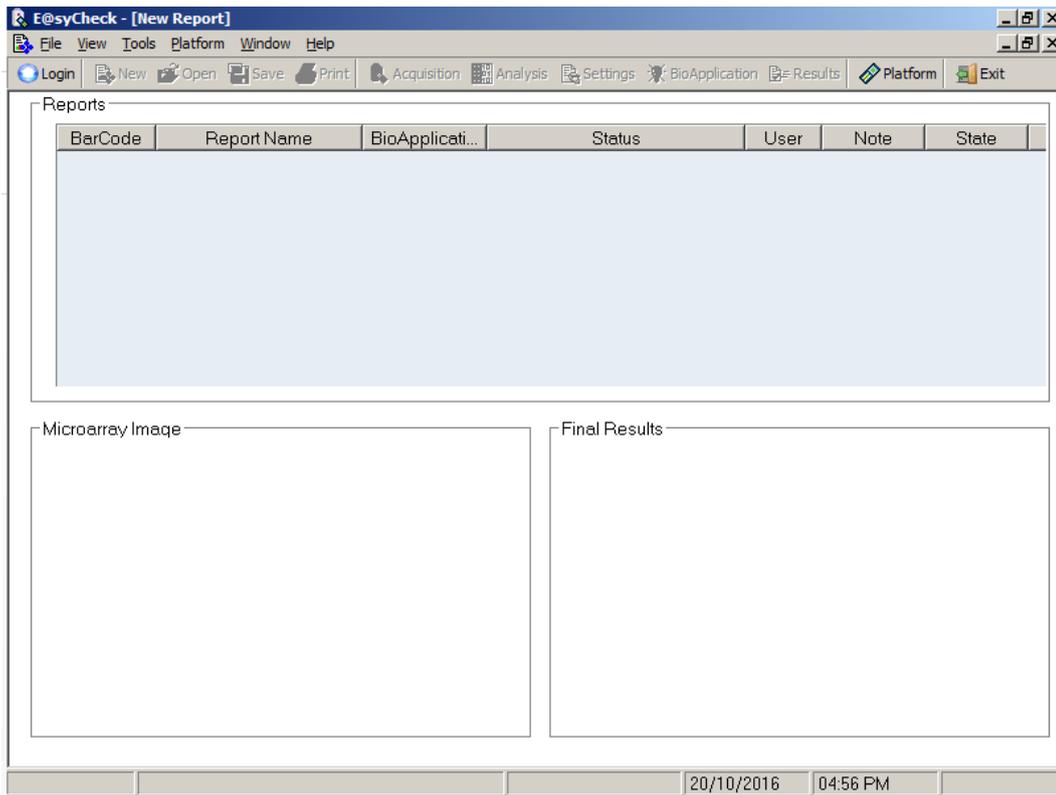
Fig. 30: E@syCheck main window

It is mandatory to press the "Login" button in the toolbar for user authentication.
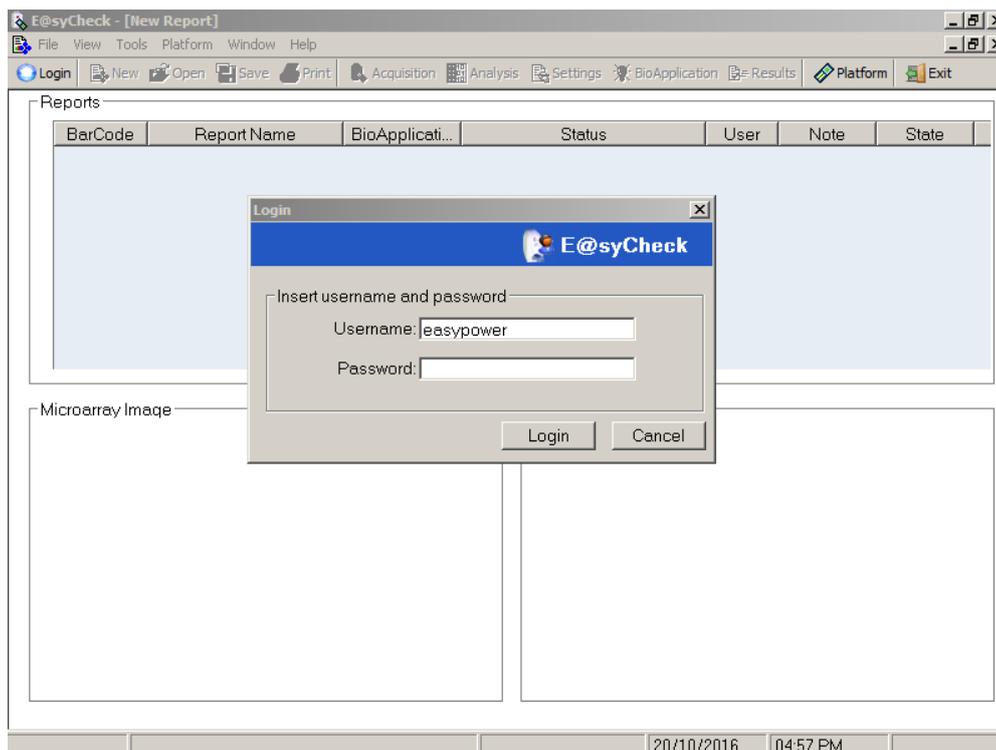
Fig. 31: User authentication

After login authentication, the user is enabled to use the E@syCheck tool and the OR. E@syCheck will provide different features according to the group permission: Standard User, Power User and Administrator.

6.4.2 Scanning Microarray and Reports creation

When a user logs in to the E@syCheck tool, a "New Report" window will be shown. This window is used to create a new chip analysis and report.
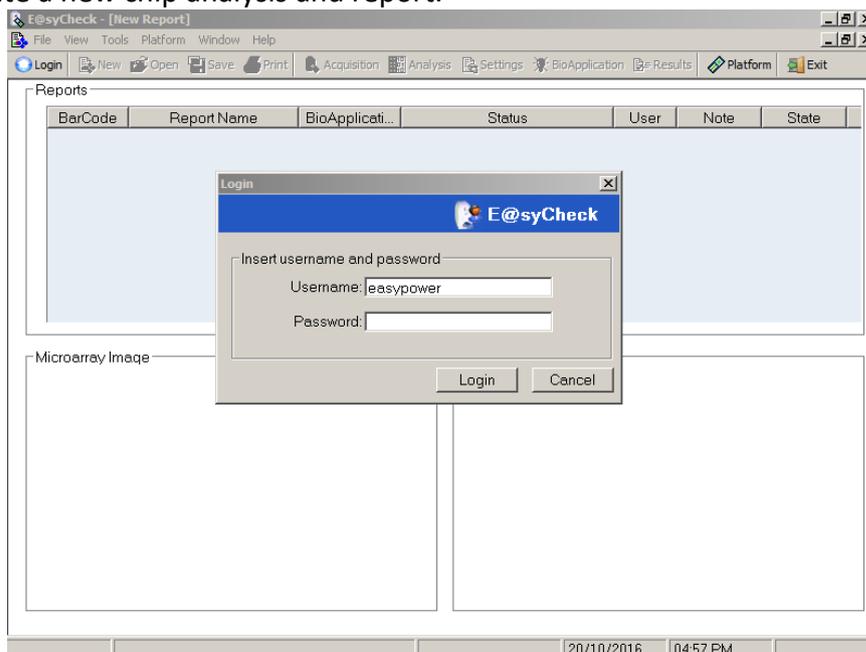
Fig. 32: New Report window

A cursor is positioned in the text area under the "BarCode" column field. Using a barcode reader, the chip ID can be scanned and will be entered into the text area. The chip ID can also be manually entered followed by the "Enter" key.
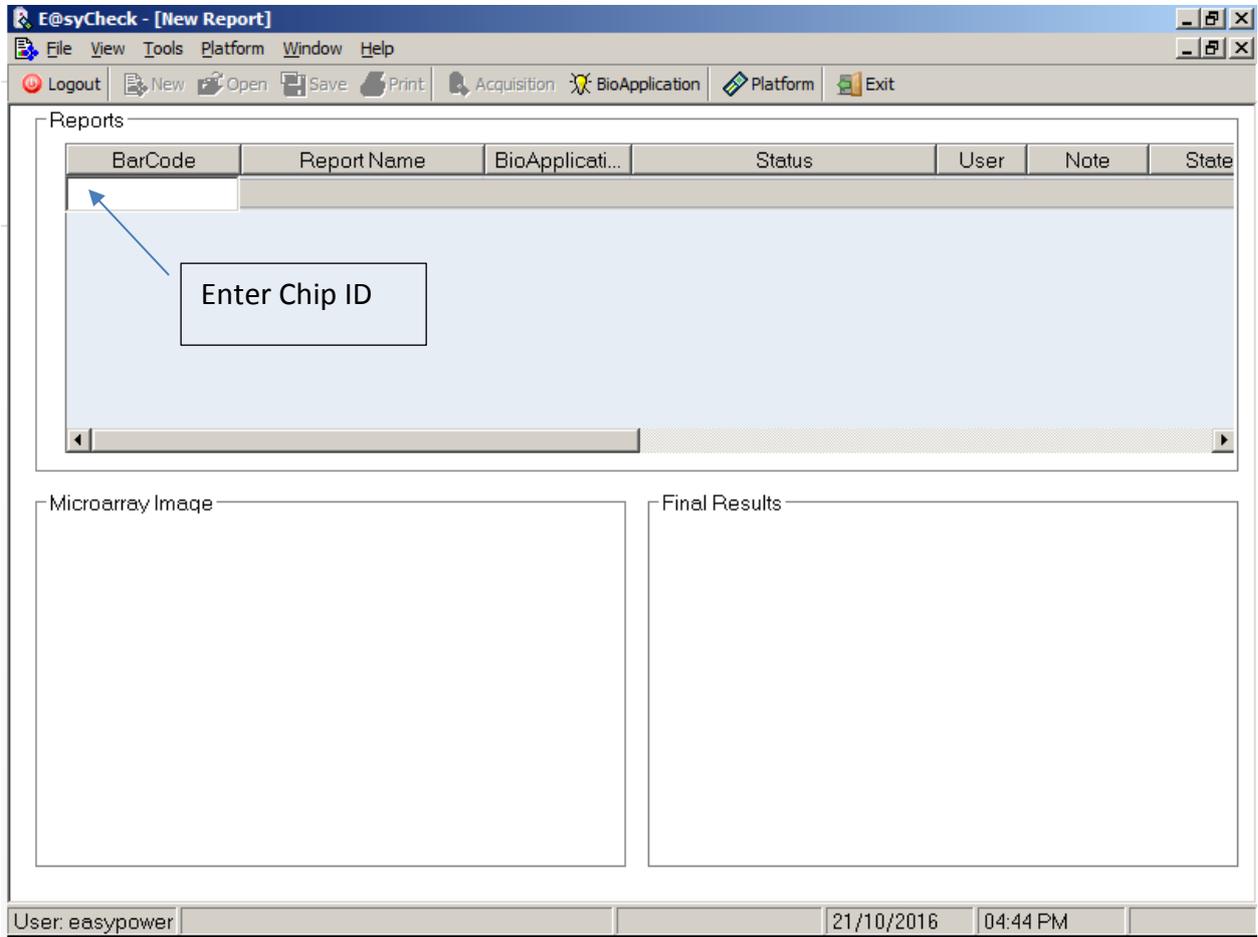
Fig. 33: BarCode insertion

Before the chip scan and data analysis, the user should ensure that the correct BioApplication is selected. To select the appropriate BioApplication, the user should click on "BioApplications Management" button under the "Tools" menu. (Fig. 34)
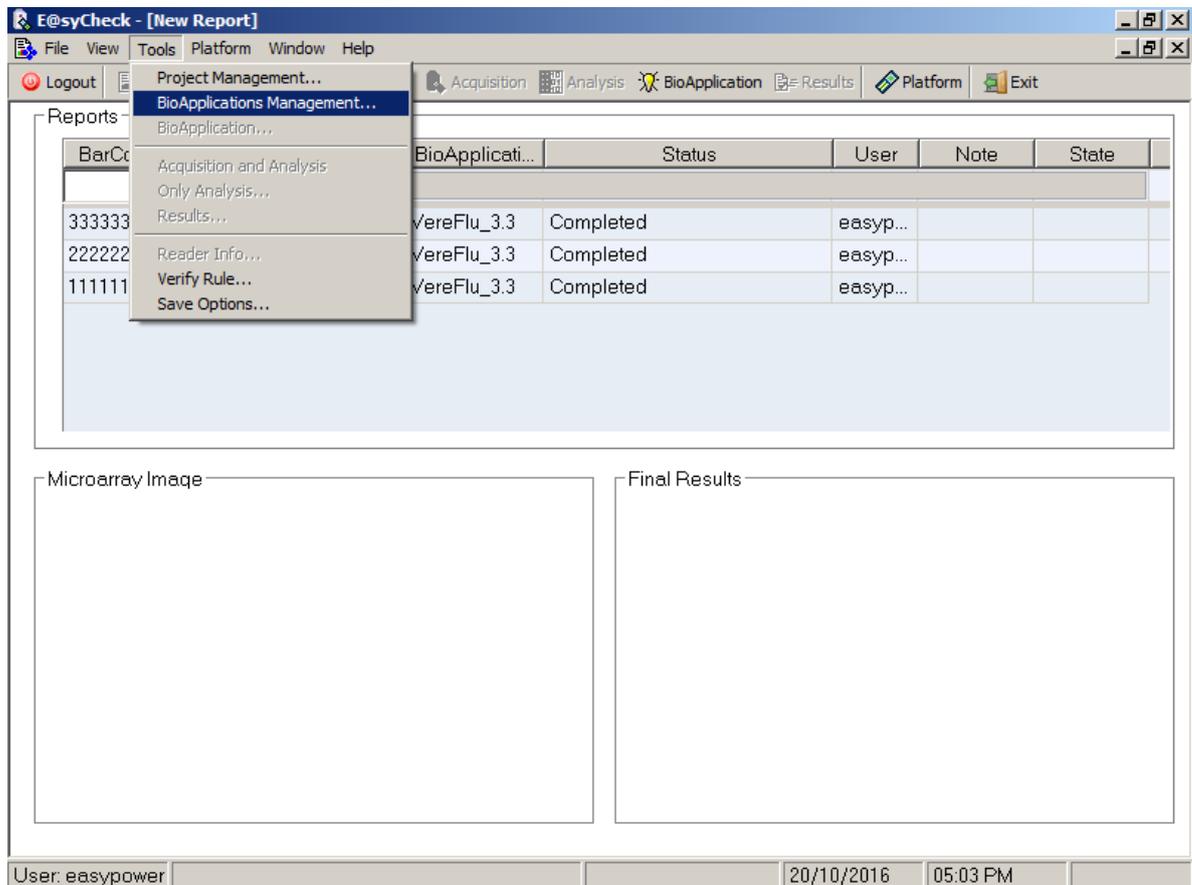
Fig. 34: Open BioApplications Management window

Select the correct BioApplication by clicking in the check box. Refer to the back of the chip label or the chip IFU for details on which BioApplication to use. (Fig. 35)
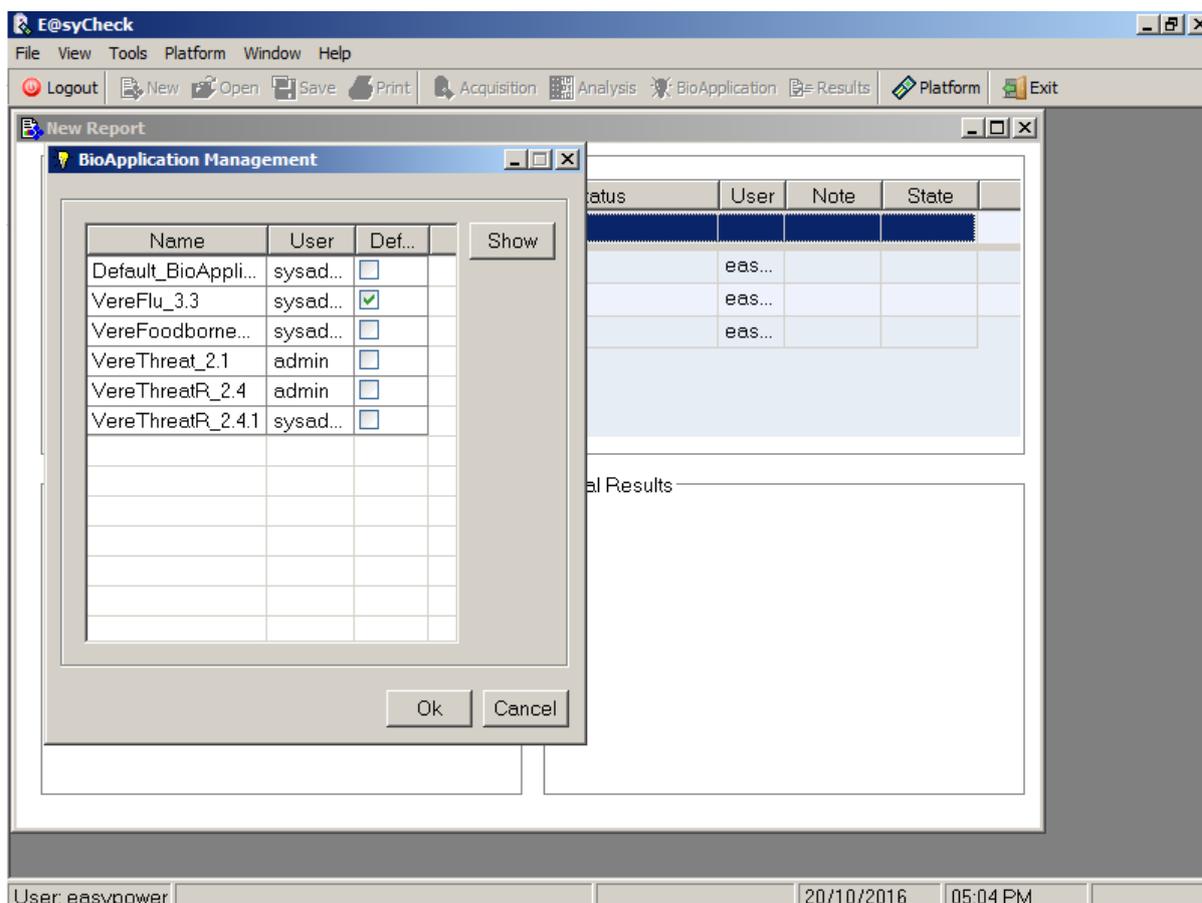
Fig. 35: Check the correct BioApplication

Selecting the wrong BioApplication may result in analysis error or incorrect final result.
If the wrong BioApplication is used, select the correct BioApplication and re-analyze the same chip.

By selecting the BioApplication this way, it becomes the default BioApplication for every chip analysis after the chip ID is entered. If a different BioApplication is required, it has to be changed in the BioApplication Management Window.

6.4.3 Acquisition and analysis operation

To perform an "Acquisition" operation, it is necessary that the OR is turned on and connected to the Base TCS or laptop.
To begin chip scan and data analysis, the user clicks on the "Acquisition" button on the toolbar or selects the menu "Tools-> Acquisition and Analysis" item.
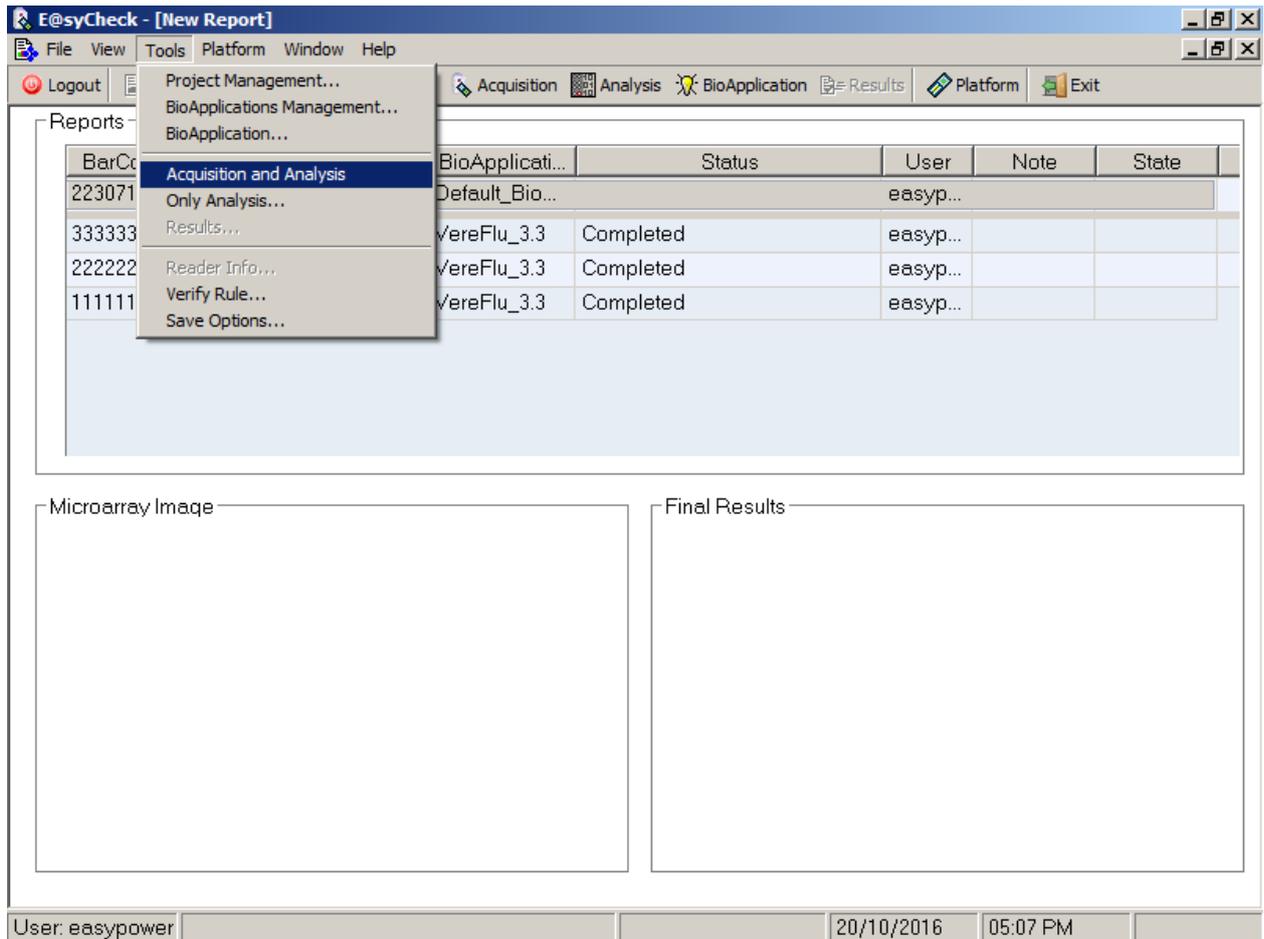
Fig. 36: Acquisition and Analysis selection

If the OR is turned off, an error message will be displayed. Ensure that the power of the OR is turned on before clicking on the "Acquisition" button. If message persist, ensure that all connections are connected securely.
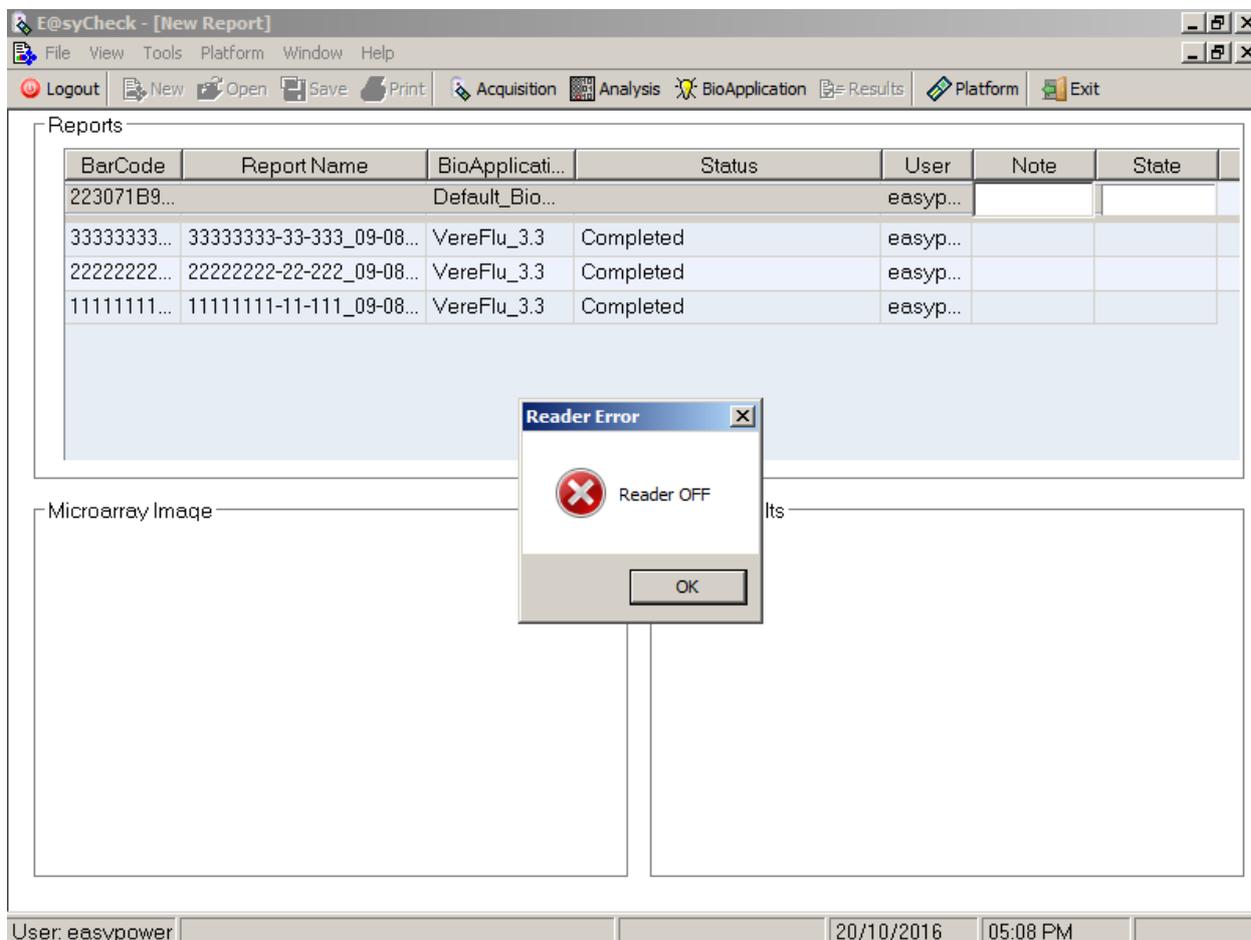
Fig. 37: Reader off message

When "Acquisition" operation begins, the progress bar in the "State" column will advance. The following operations are performed:

- If no error occurs during the image acquisition of the chip, the obtained image is automatically saved in the hard disk. And the *.tiff* image would be the same name as the chip ID. If a *.tiff* image with the same name already exists in the database, a time-stamp is automatically added to the image file name.

- The image is analyzed using the image analysis settings and the microarray layout files associated to the BioApplication.

- The analysis generates an intensity levels file that is saved.

- The intensity levels file is required to generate the final report that consists in the creation of the E@syCheck project to obtain:
  - *final check*, a report indicating the list of targets turned on/off (as it is explained in Appendix B Project management);
  - *test result*, a detailed list of targets in the panel and the "Detected / Not Detected" result for each target.

- To generate the report, the application uses the personal default rule.
- The final analysis (Final Check and Test Result) is saved in a project file and linked in the local database. If a project file with the same name already exists, a time-stamp is automatically added to the project file name.
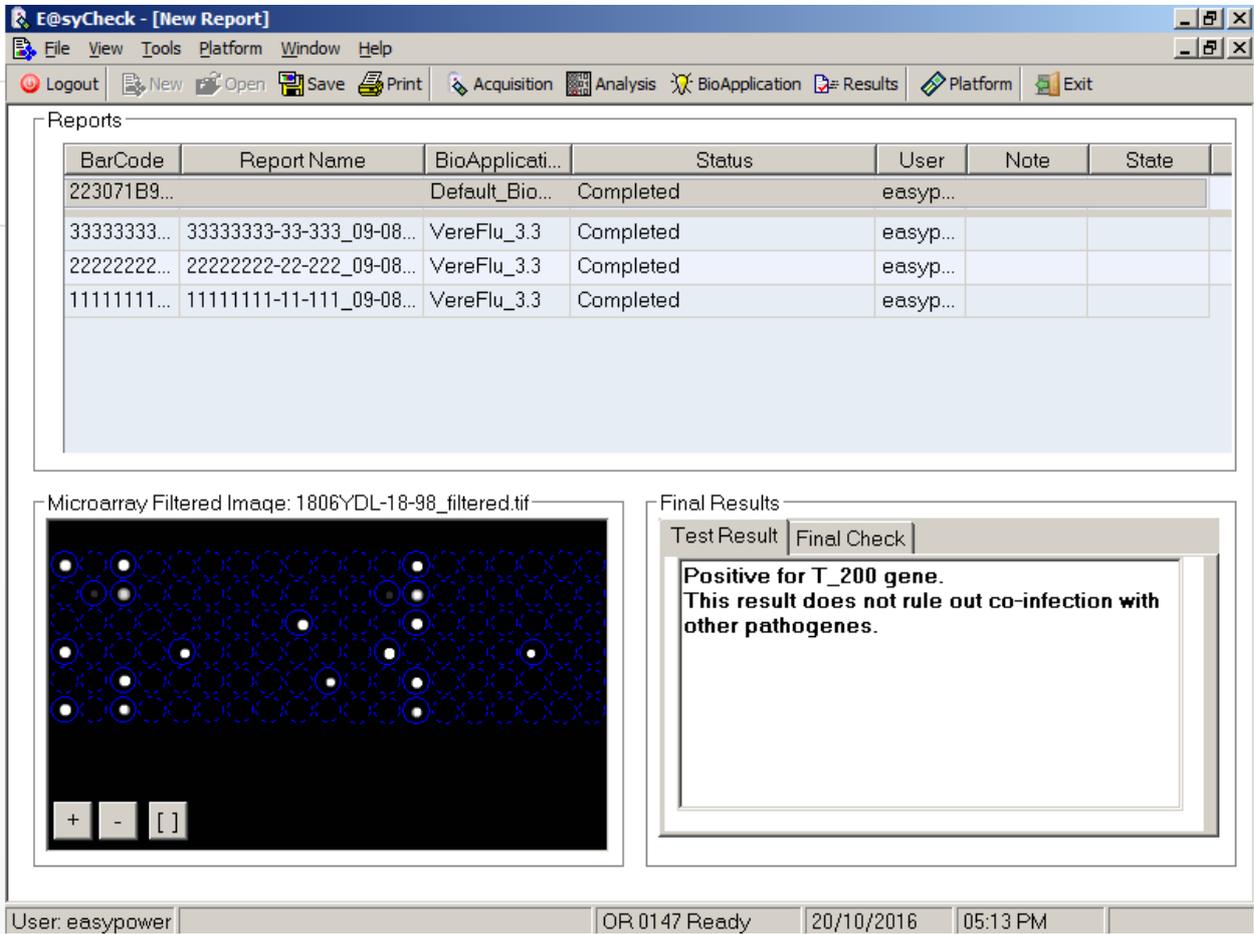
Fig. 38: Acquisition and analysis completed with success.

On the bottom left of the window, the Microarray Equivalent Image (MEI) is displayed instead of the original microarray image (MOI) obtained by the image analysis. This image is saved and never displayed by the E@syCheck tool. The MEI removes all the artifacts and gives a good perception of the microarray quality.

On the bottom right, the results of the analysis are displayed. The default view is the Test Result (Fig. 38). The Final Check view can be displayed by clicking on the second tab and it indicates the list of targets and controls with their relative results (Fig. 39).
The "Note" field is an editable text area for the user to input any information. For instance, it could be used for linking sample ID with chip ID.
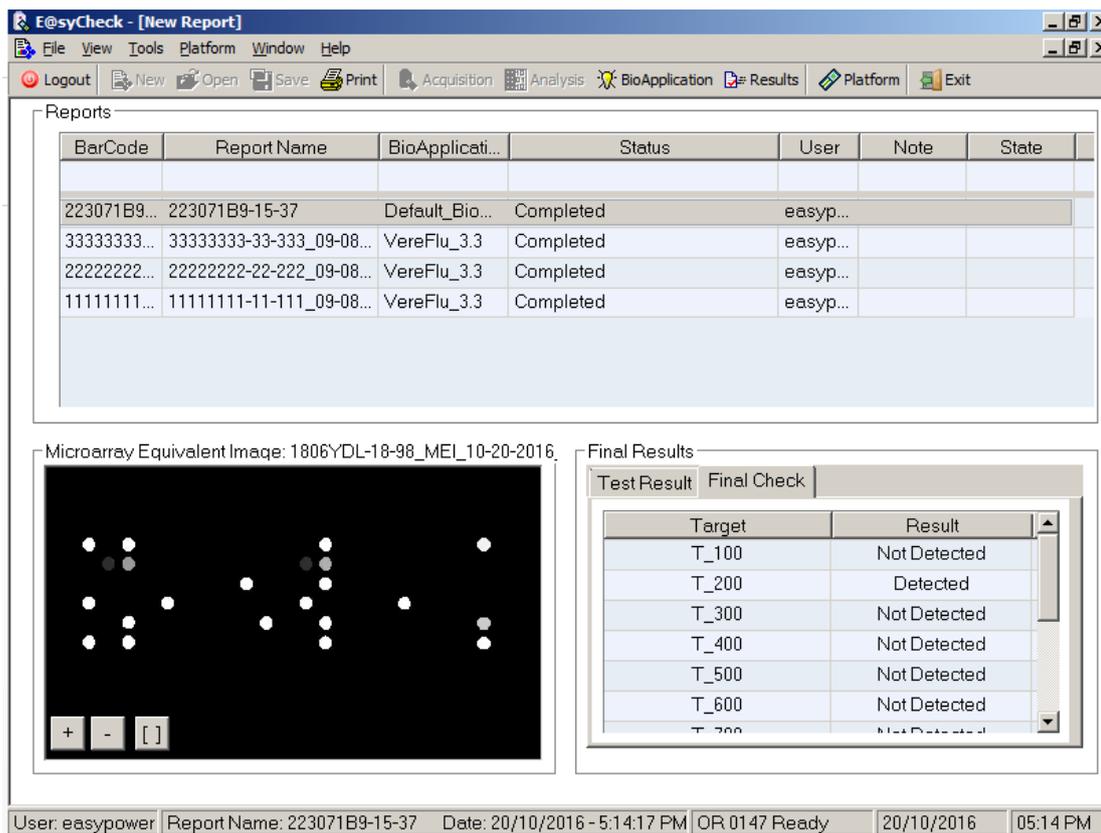
Fig. 39: Final Check view.

The user can maximize the MEI image by clicking on "Full Screen" button ([ ]) of the image (Fig. 40).
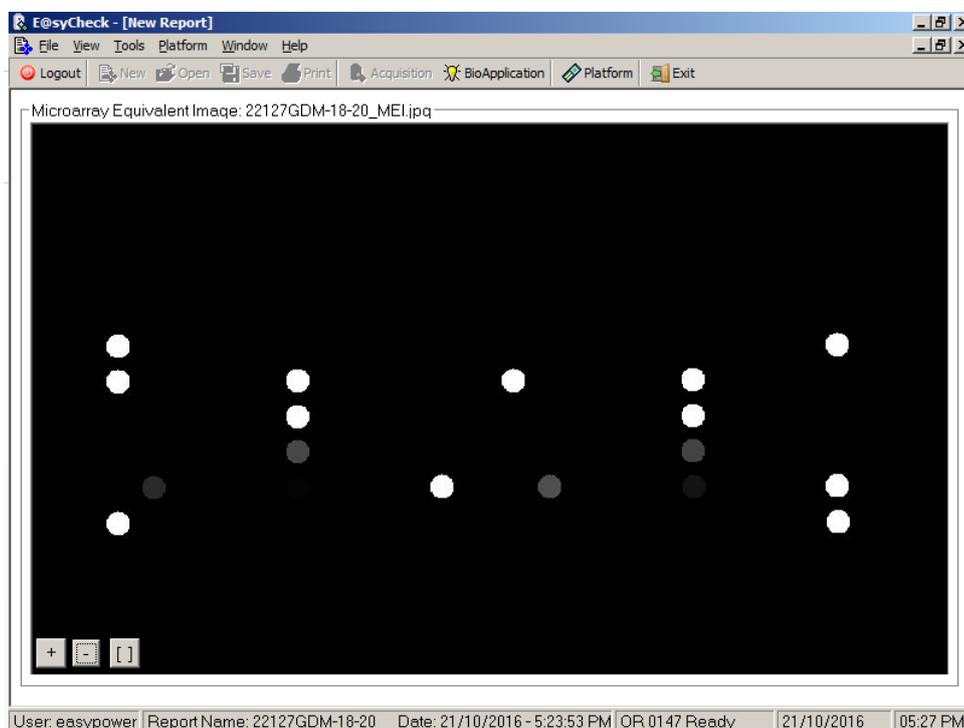
Fig. 40: MEI maximized

To return to the previous view, the user clicks on the same button of the image.

The information shown in the "New Report" window can be translated into a PDF format by clicking the "Print Report" button on the toolbar or selecting the menu "File -> Print Report…" item.
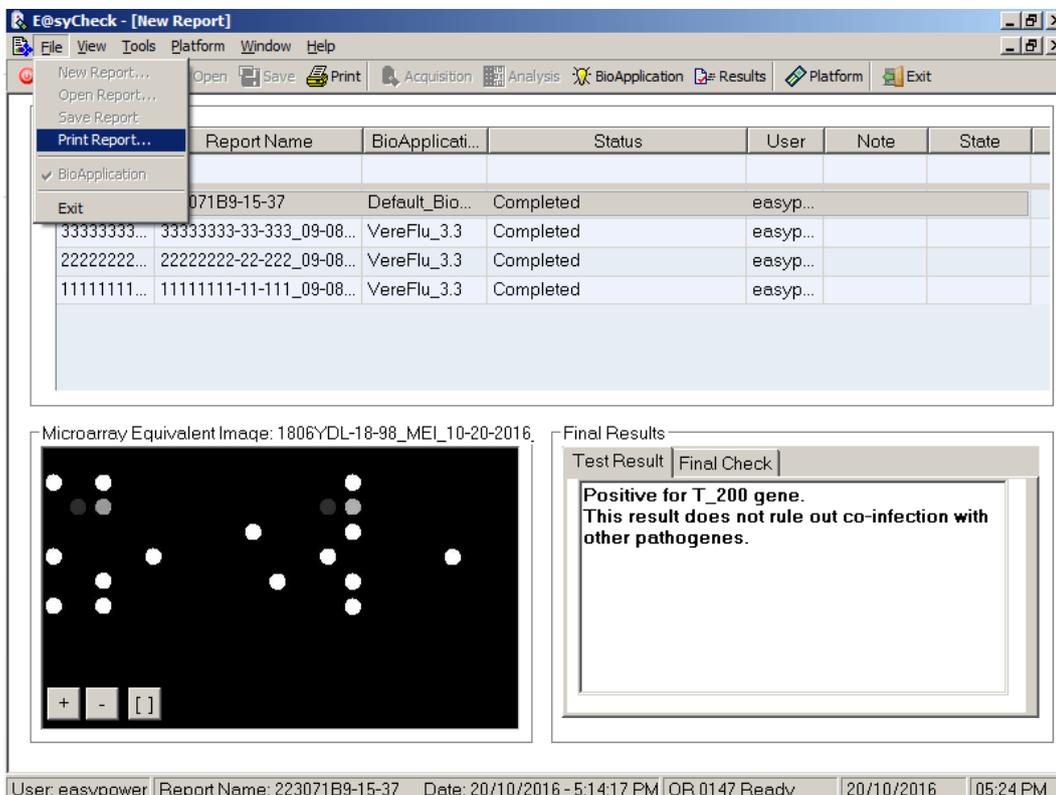
Fig. 41: Print Report selection.

The "Print Report" section has a few options. The page layout can be changed between Portrait and Landscape. Also, there is an option to include the microarray image. The user can also add their own company logo to the report.
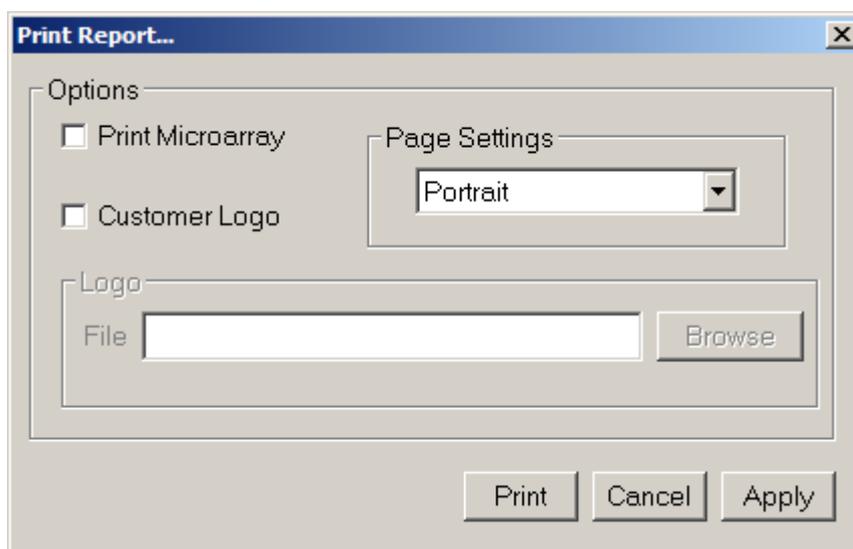
Fig. 42: Print Report options.

After selecting the options, the user can click on the "Print" button to bring up the navigation window shown below. This allows the user to define the location of where the PDF report will be saved.
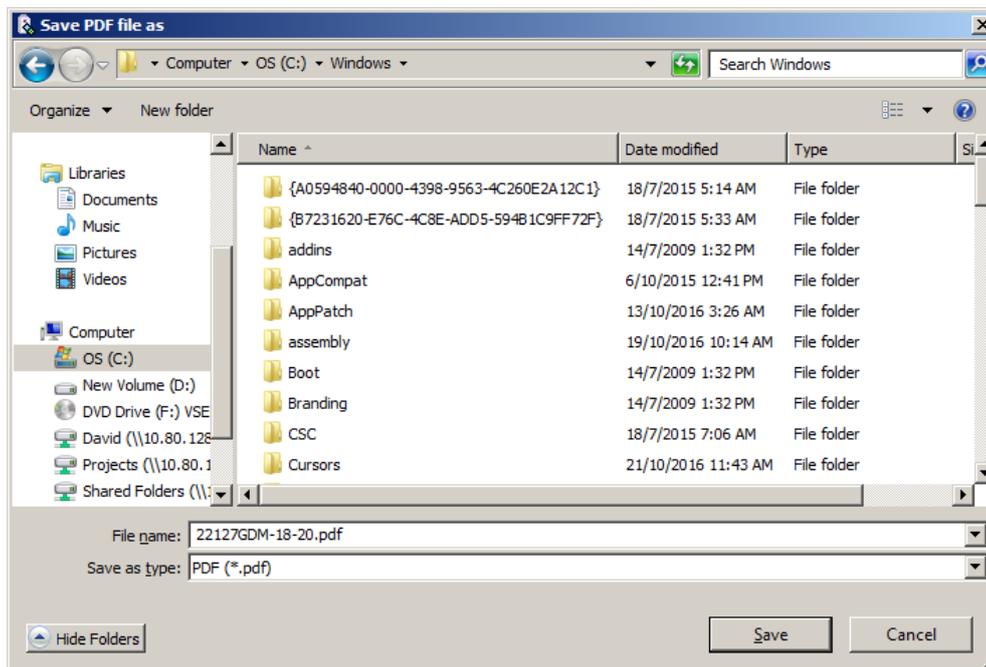
Fig. 43: PDF Report location.

The PDF report is shown in the following window (Fig. 44):
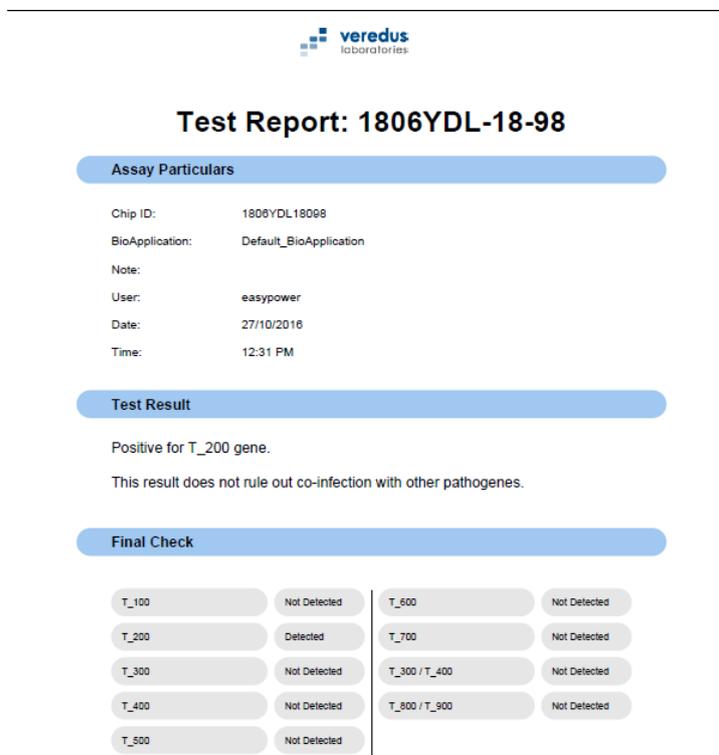
Fig. 44: Print Report window

This PDF file contains all the info for each sample and is compressed in 1-2 page. The information includes:

- Name of the chip, the user ID, the date and time and the test result,
- Microarray image if selected,
- Final Check results which has the full list of targets and detection status.

In case of artifacts and noise on the microarray, it is possible that some spots are not perfect according to algorithms in the software (applied during the image analysis) that determinate good, bad and empty spot. The E@syCheck tool manages, in terms of microarray interpretation results, the presence of 'bad spot' flags among the capture and controls probes. This 'bad spot' management is described in the diagnostic rules.

In the MEI, the 'bad spot' are displayed in red. The color is proportional to their "Signal Median – Background Median" value.
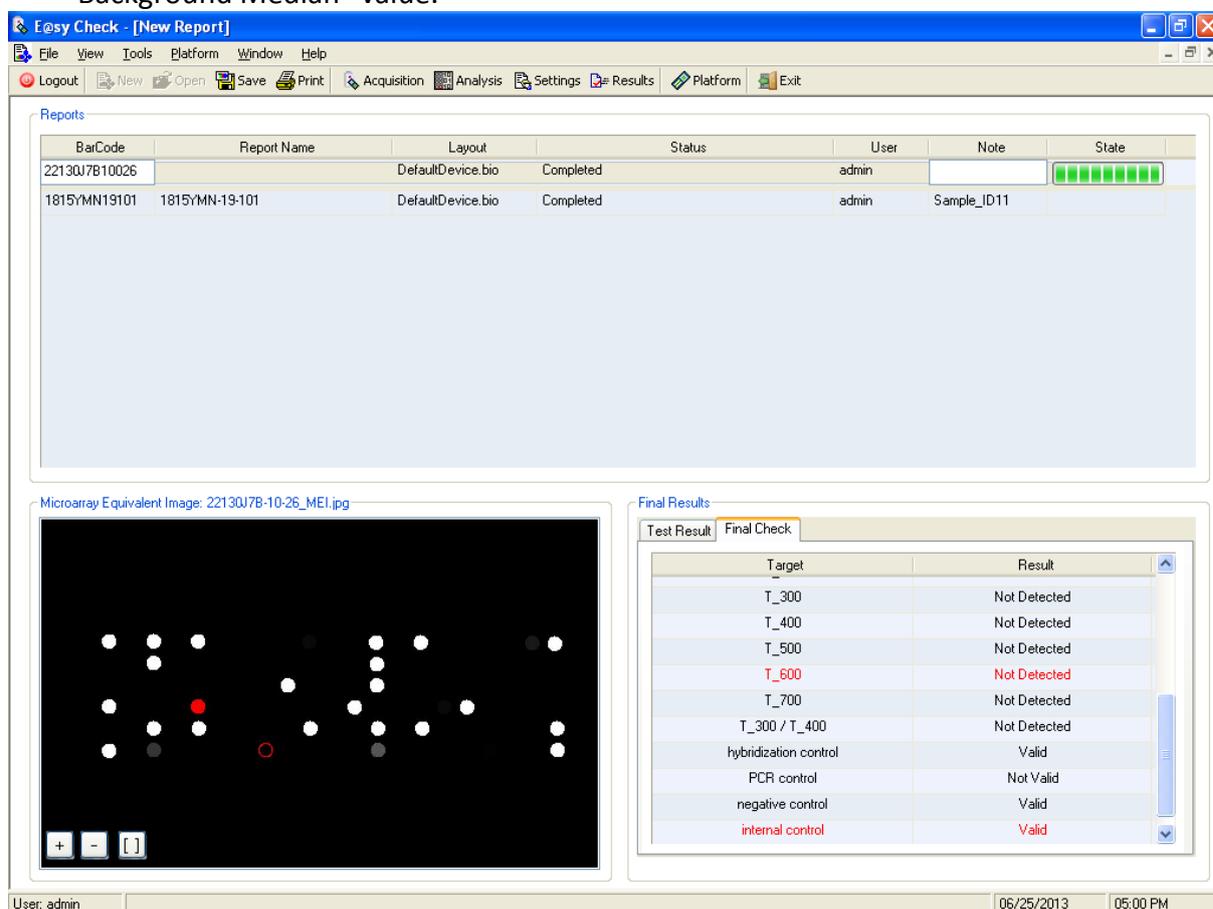
Fig. 45: Bad Spot in MEI

In the Final Check list, the user can see some target or control in red color. These contain the probes that are identified as bad spots. If the user clicks on one of these red targets, the user can view the list of bad spots belonging to the selected target or control.
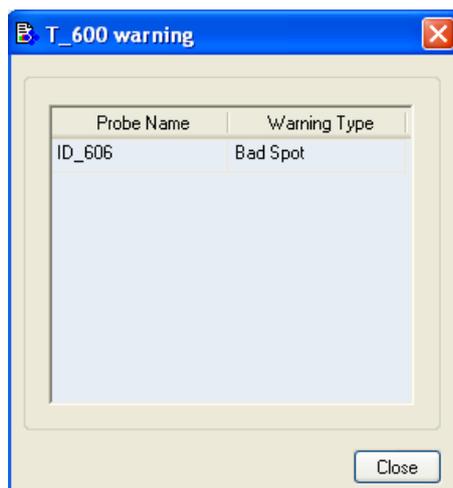
Fig. 46: List of warning for a target

6.4.4 Error during Acquisition operation

The Optical Reader should be turned on before launching E@syCheck software as the software initializes the camera upon starting.

During the "Acquisition" operation, If there is a power trip or if the Optical reader is turned off and on, the software will detect when the Optical Reader is power cycled.
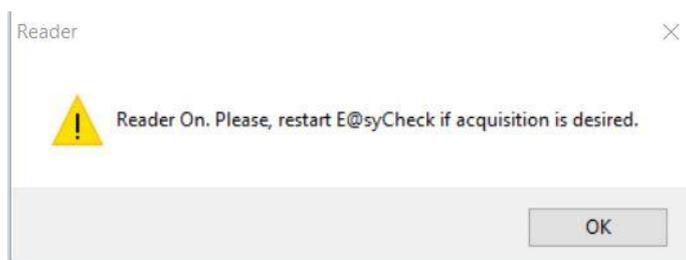
Fig. 47: E@syCheck error

The reader messages can be dismissed. To resolve this error, close E@syCheck and restarting it will re-initialize the camera.

In case of bad alignment due to artifacts and noise on microarray, a Microarray Filtered Image (MFI) is displayed with the relative grid alignment. The MFI is obtained by the original acquired image, removing some artifacts and giving a good representation of the microarray quality. In this case, the E@syCheck tool allows the following choices:

- *Ignore the warning*, if the shown grid alignment is correct.
- *Manual analysis*, if the grid alignment is not exact and the user wants to start a manual analysis.
- *Abort*, if the user wants to stop the analysis.
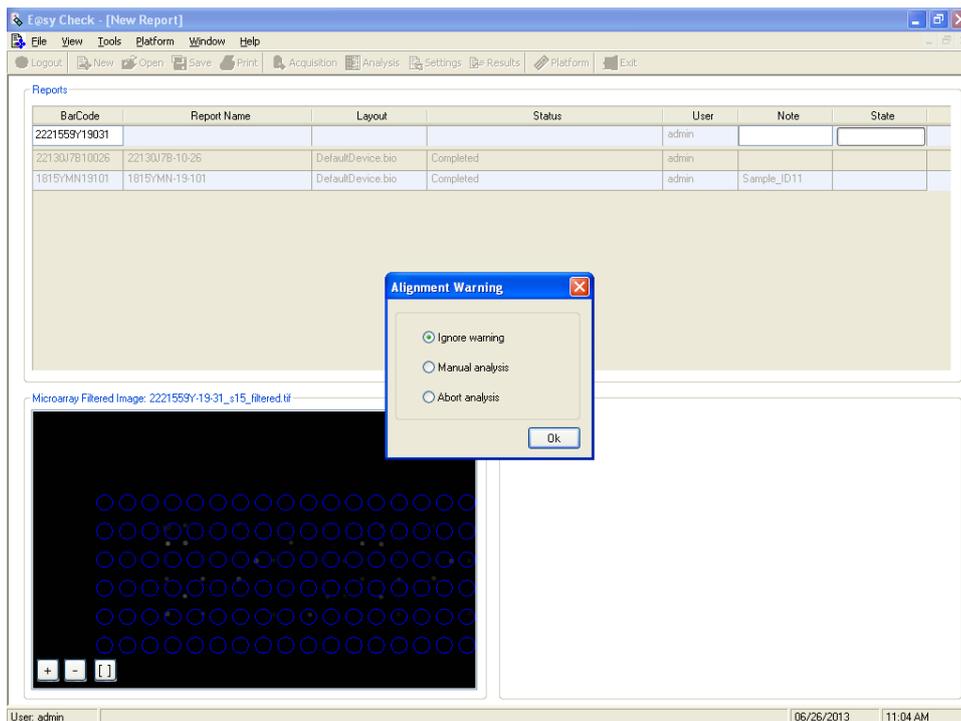
Fig. 48: Alignment warning and MFI

If the user selects the "Ignore warning" option (Fig. 48), the analysis continues as explained above. If the selected option is "Manual analysis", then H-MAT tool is launched and E@syCheck application is minimized. H-MAT shows a microarray filtered image (MFI) and the original grid with the purpose to help user in the alignment.
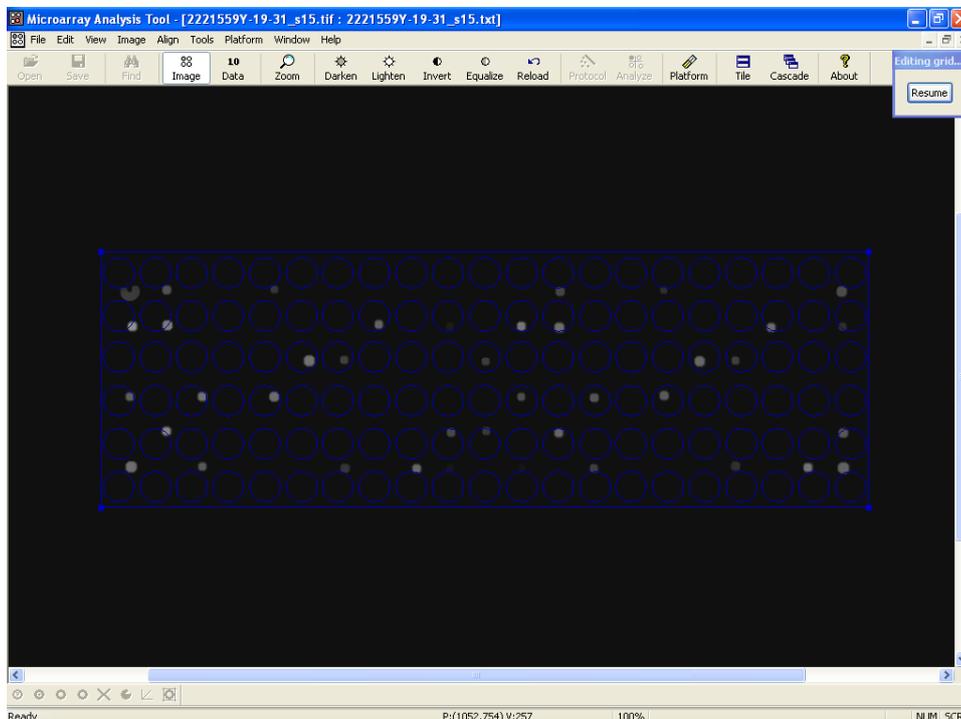
Fig. 49: H-MAT grid alignment

The user has to align the grid manually and then click on "Resume" button to start the image analysis (Fig. 50).
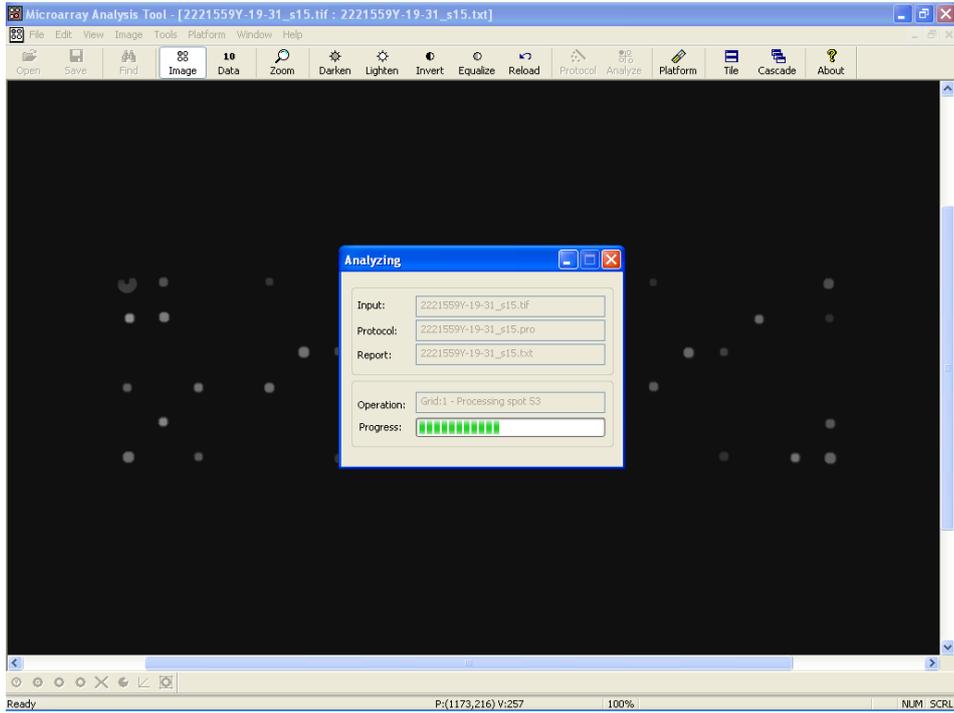
Fig. 50: H-MAT

When the progress is completed, the image analysis is finished and H-MAT will be closed automatically. E@syCheck will continue the processing up to the diagnostic analysis.
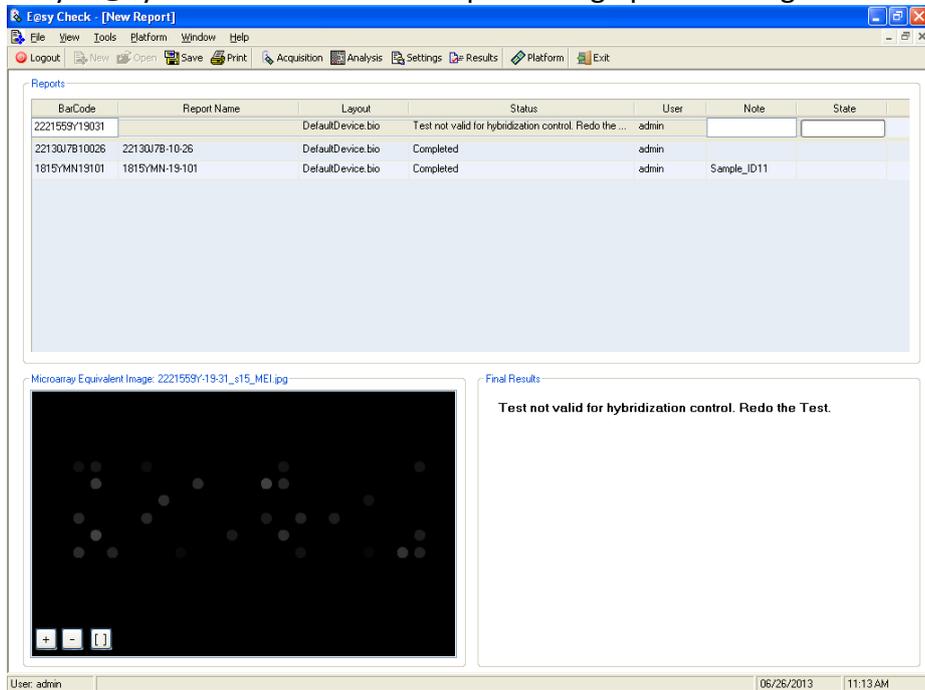
Fig. 51: Manual analysis result

If the selected option is "Abort analysis", then the analysis is stopped and an error message is displayed in the Final Result frame.

6.4.5 Chip traceability

In order to trace the single chip from the start to the end of an experiment and to avoid reusing the same chip, it is necessary to store in the database the steps performed.

In particular, after an "Acquisition" operation is performed for a chip, E@syCheck tool saves in the database all the information necessary to trace a chip. When the user inserts the barcode of a used chip, the application shows the following warning message:
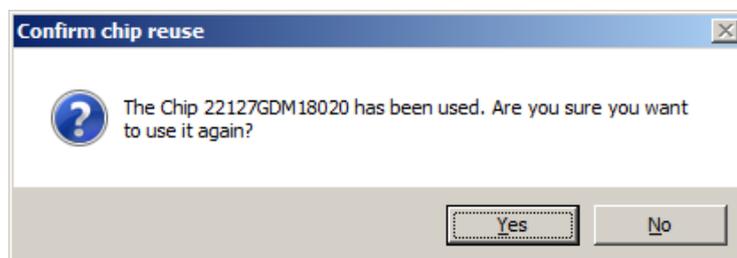
Fig. 52: Confirm Chip reuse

The usual steps for a chip acquisition will be followed if the user selects "Yes". If the user selects "No", all the information related to the chip ID is deleted in the software.

6.4.6 Report option (administrator only)

The user can view the chip and analysis information of all reports saved in the local database. As a default, those displayed are the last ten reports saved in the database. The display shows the latest report on top. If the user wants to show more or less than ten reports, the user can select the menu "View -> Report Option…" to set the number of the last reports to visualize.
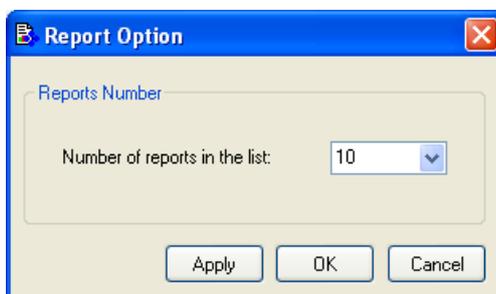
Fig. 53: Report Option Window

If the user clicks on a report row, the relative image and the final results will be displayed in the bottom of the window.
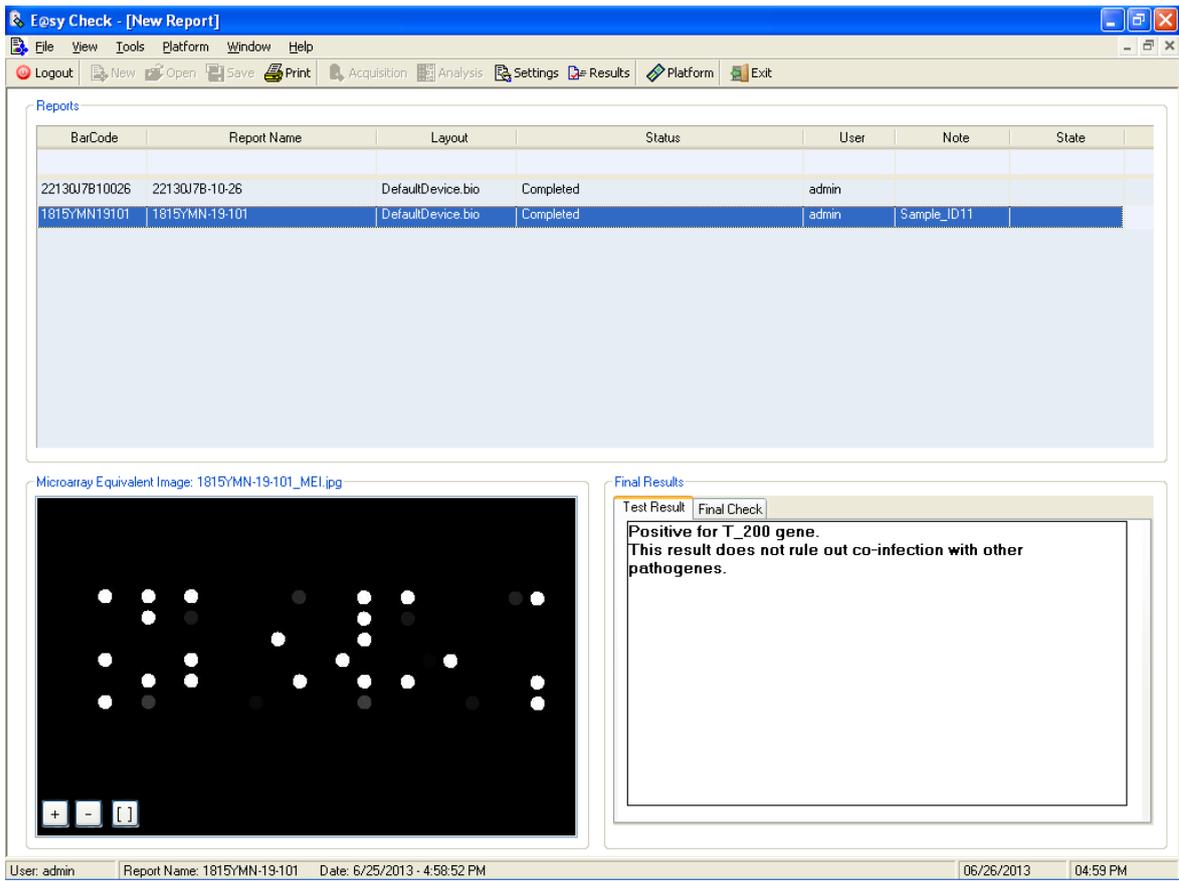
Fig 54: Saved report view

6.4.7 Switching Between Applications

The "Platform" menu provides a quick access to switching between E@syCheck, E@syControl and E@syManager. User can also use the "Platform" button in the toolbar (Fig. 55).
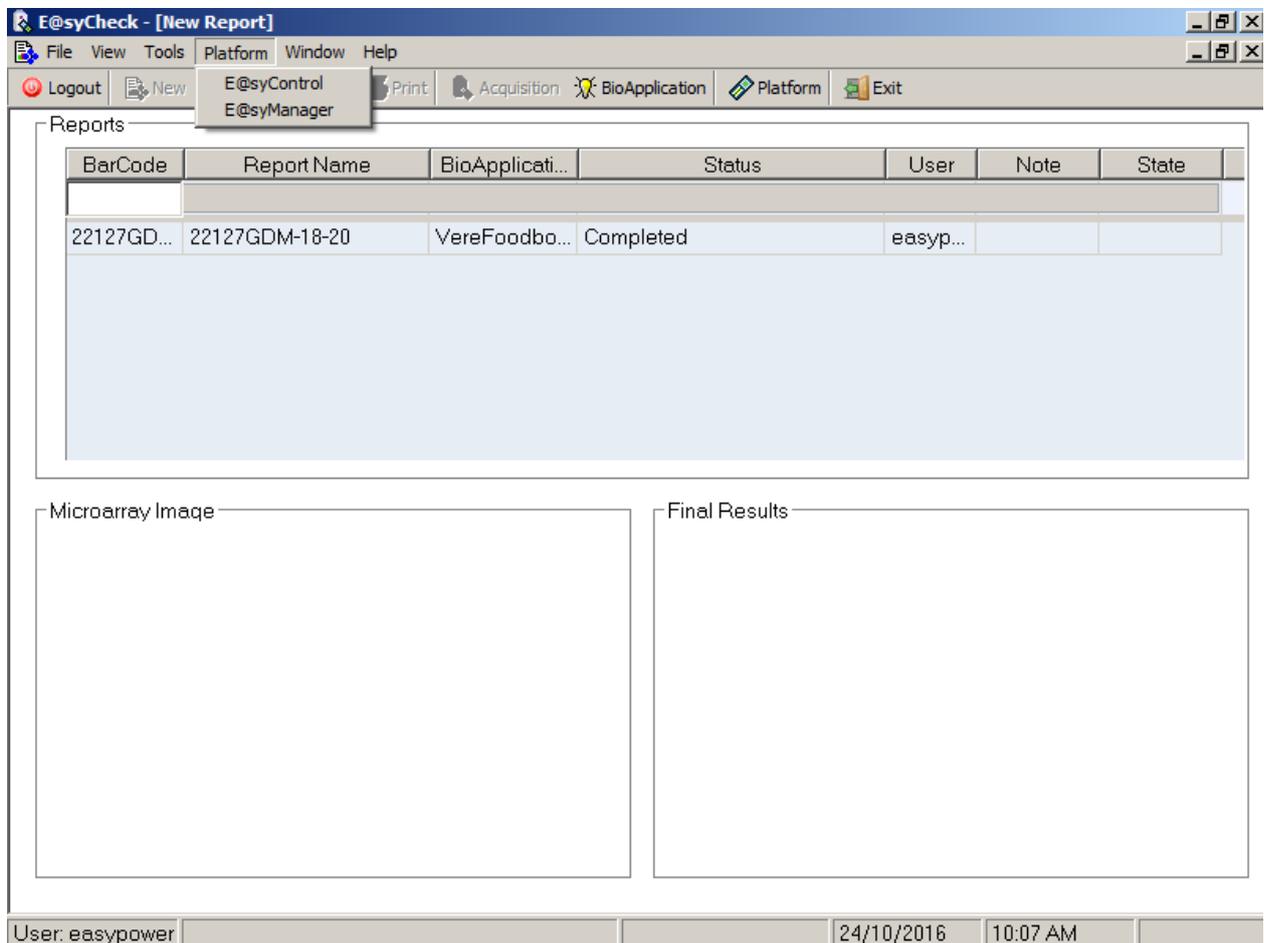
Fig. 55: Platform menu

The menu "Help -> Contents…" item will launch the VerePLEX™ IFU (Fig. 56).
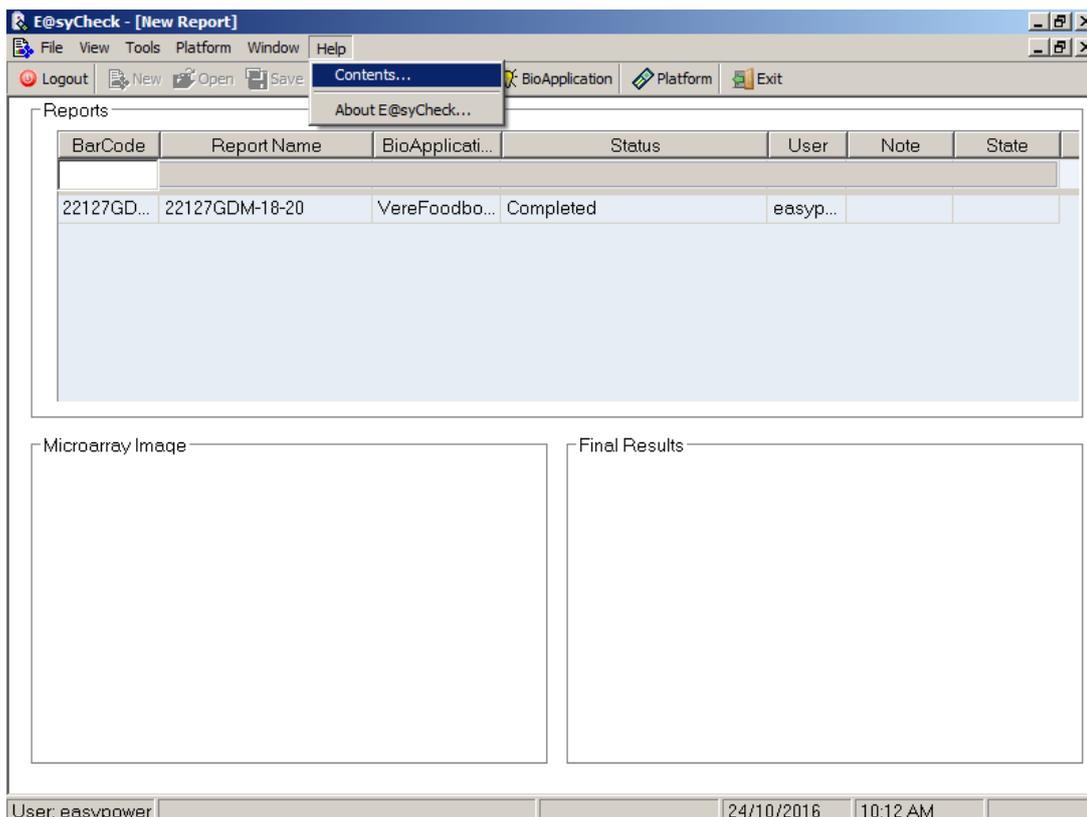
Fig. 56: Help menu

The menu "Help -> About E@syCheck" item shows the general information about E@syCheck tool (Fig. 57).
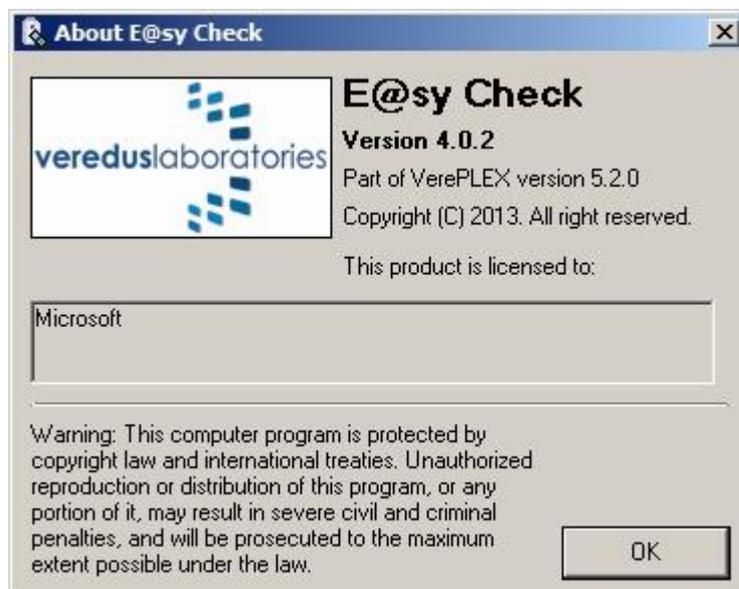
Fig. 57: About E@syCheck window

If the user checks the menu "Virtual Keyboard" item in E@syManager tool before the E@syCheck launch, a virtual keyboard will be shown every time that the user clicks on a text area.

6.5   E@syManager Operation

This application allows the user to manage the security of the VerePLEX™ Biosystem Software. This tool includes the features to create and manage user accounts and groups. The Administrator can make workgroups and define the permissions and privileges related to every VerePLEX™ Biosystem Software application. The Standard User can only view the account data.

Upon launching E@syManager, the user is required to log in (Fig. 58).
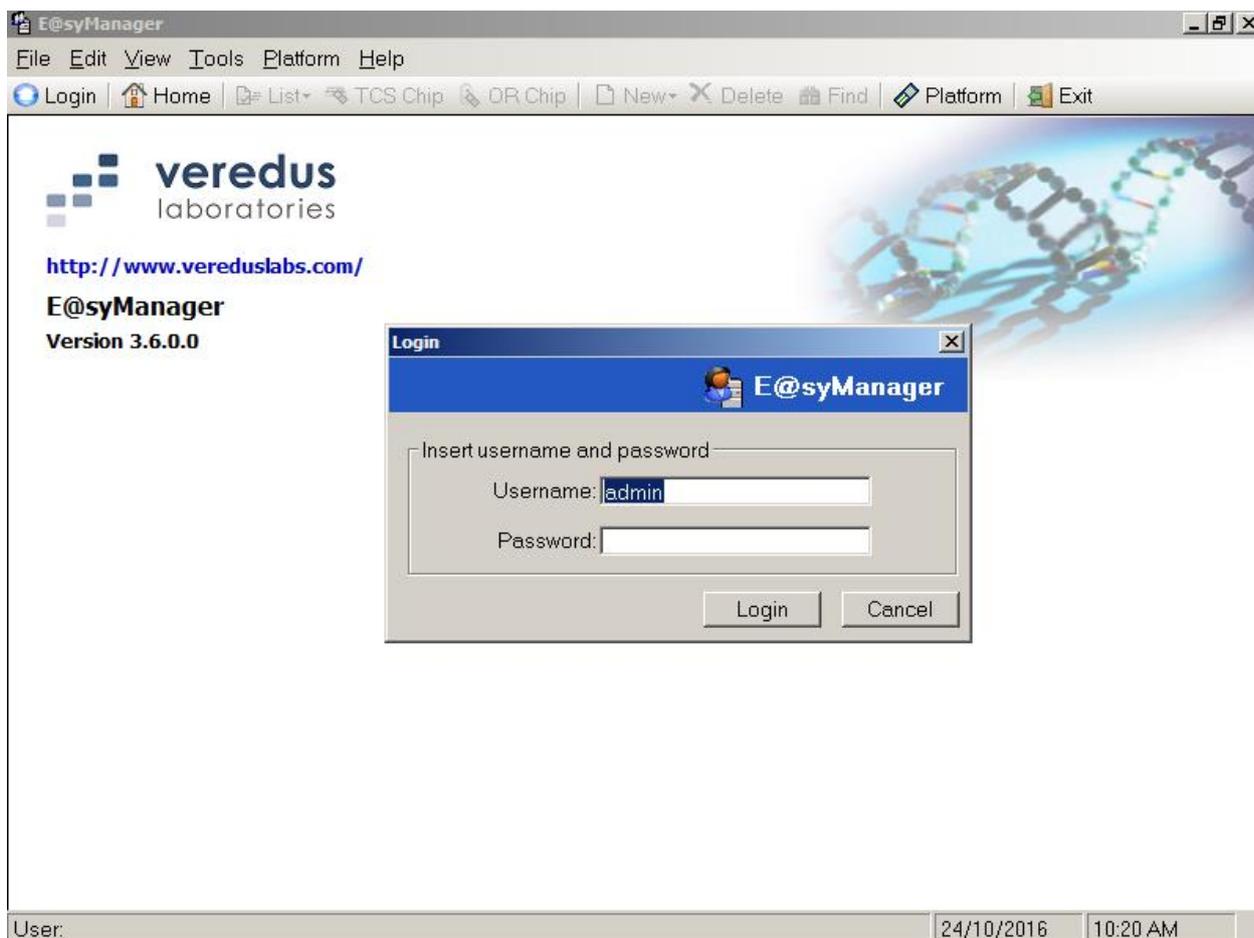
Fig. 58: Login

6.5.1   List Toolbar

The "List" toolbar provides access to the list of items that is used globally in the software:

- Group → Provides group level access control. The levels are UserAdmin, PowerUser, User. The SysAdmin is for Service Engineer access control.
- User → List of users with their assigned default BioApplication. Users are linked to group level.
- Lock → List of applications currently in used and is locked. The lock is removed when the application is closed. In the event there is a sync error and an application is locked, the admin can delete this record from this list.
- BioApplication → List of BioApplications that are installed in the system. The BioApplications contains all the settings required for a particular chip run and microarray image analysis.

- TCS ➔ List the status of the connected TCMs and if they are in used by any user.
- View ➔ List the different type of views which can be created in the E@syManager.
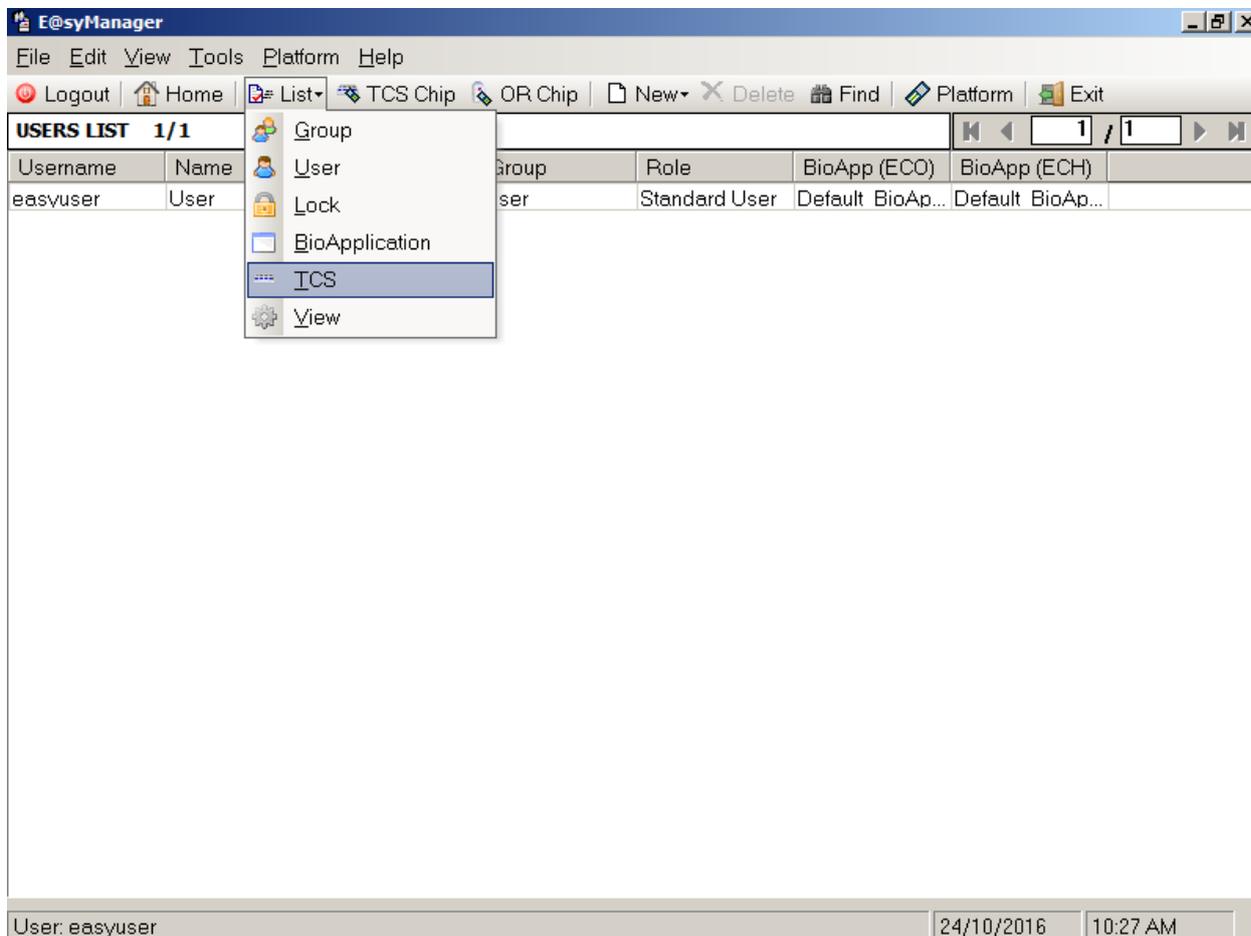
Fig. 59: List function

6.5.2 Creating New Group (admin only)

There are three default groups with defined access controls. The admin can create more groups and the access controls will be linked to either Power User or Standard User. The admin cannot create more admin access level groups.

To create a new group to allow users to have the permission to access to the applications of VerePLEX™ Biosystem and to configure some customizable features, the admin has to click "New ➔ Group" in the toolbar of the main window or select the menu "File ➔ New ➔ Group".
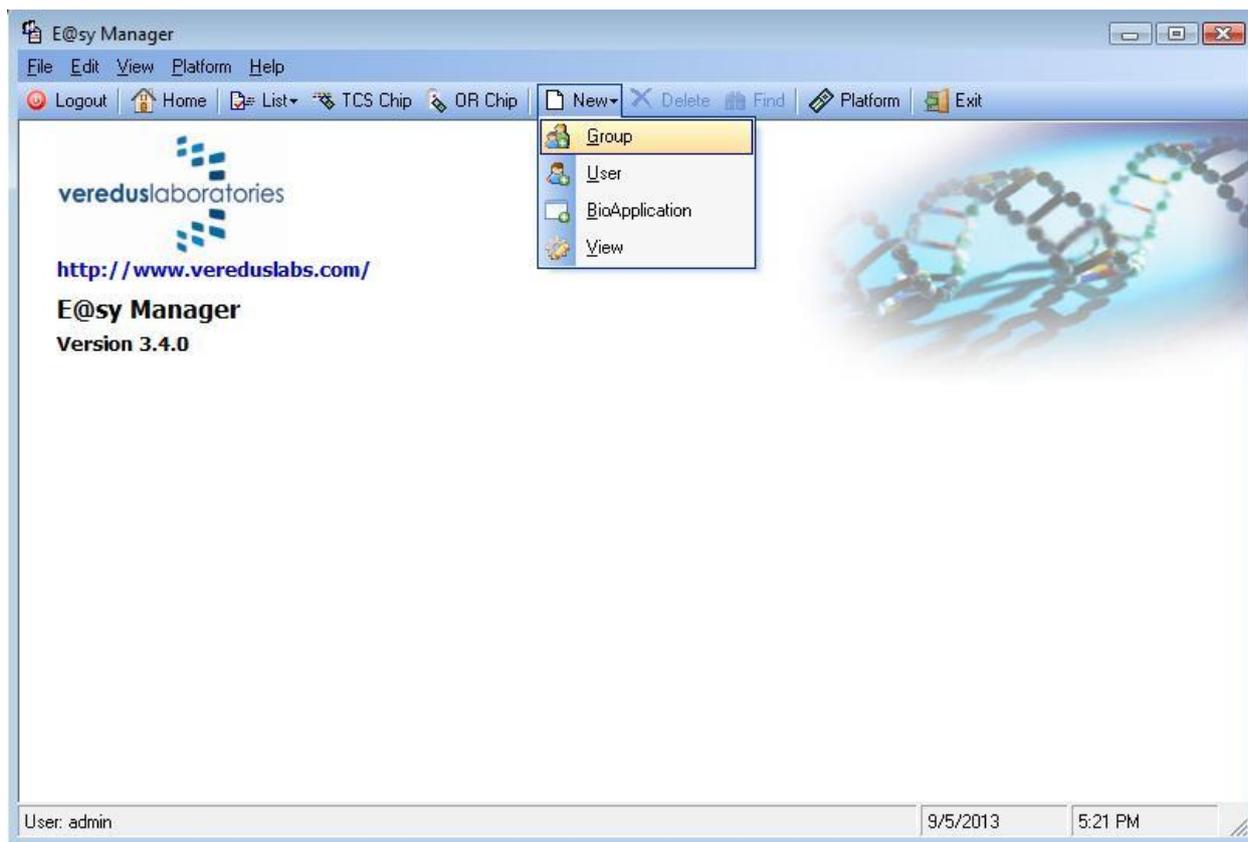
Fig. 60: New Group

The application will show the "New Group" window with several parameters. The admin can create different groups. Each one will be characterized by a sub-set of VerePLEX™ Biosystem application that users can use.

A Default BioApplication should be assigned to each group. When a new user is assigned to this group, their default BioApplication would follow what is assigned in the group.

The admin and Power Users would also be able to assign their own BioApplication in the E@syControl and E@syCheck applications and it would overwrite the current setting. Standard Users would not be able to assign their own BioApplication in the E@syControl and E@syCheck. Also, when a user who is assigned a BioApplication is deactivated or removed, it would revert to the default Group BioApplication.

It is possible to create an account to login in E@syControl as standard user and another account to login as power user, as showed in the following picture:
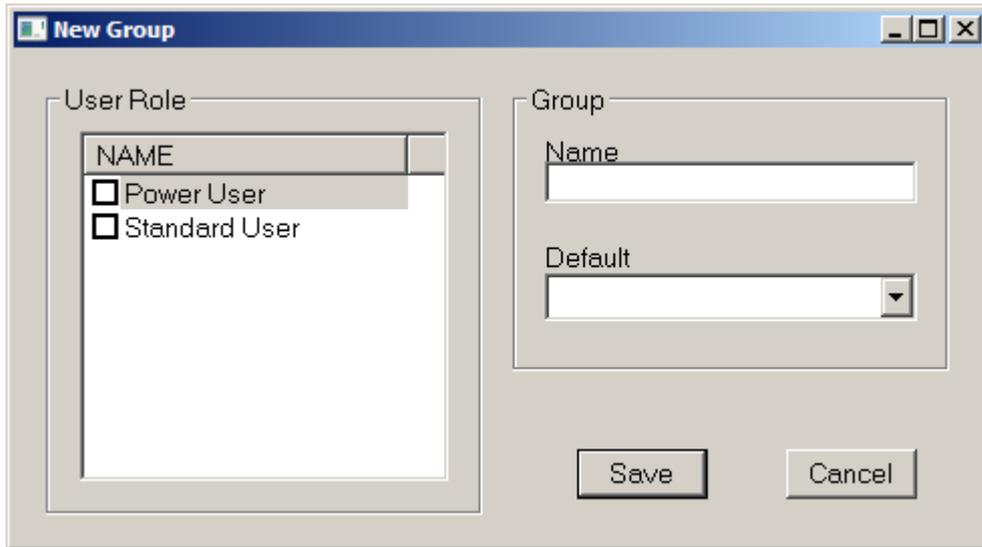
Fig. 61: New group account

The admin can save the group and the list of the groups stored in the database will be shown in the Groups List window.

Only the Service Engineer can create multiple admin groups.

6.5.3 Creating New User (admin only)

To create a new user and to allow users to have the permission to access to the applications of VerePLEX™ Biosystem, the admin has to press "New → User" in the toolbar of the main window or select the menu "File → New → User".
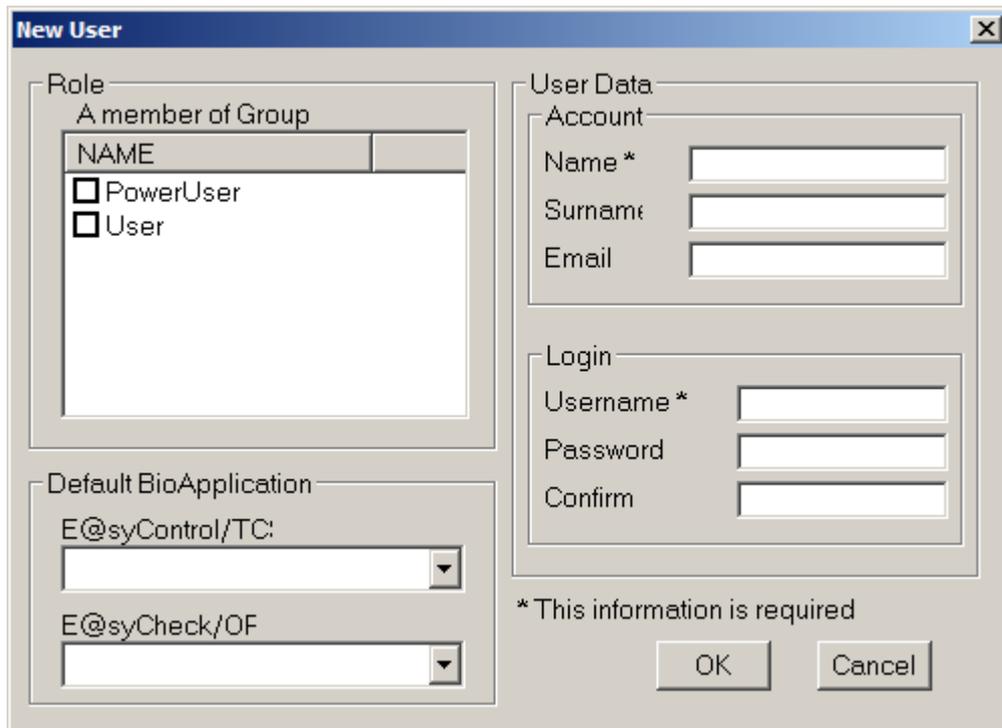
Fig. 62: New user

To create a new user, it is necessary to insert data in the text area of the "New User" window. The Administrator has to insert: (* indicates compulsory fields)
o   Name of the user *
o   Surname of the user
o   Email
o   Username *
o   Password *
o   Confirmation of password*

Next, the admin has to select the group to which the user belong to and also assign the Default BioApplication. Finally the admin can save the group and the list of the users stored in the database will be showed in the main window.

Only the Service Engineer can create multiple administrators.

6.5.4 New View (All user access levels)

To create a new view to visualize data in accordance to parameters set by user, the admin has to press "New → View" in the toolbar of the main window or select the menu "File → New → View".
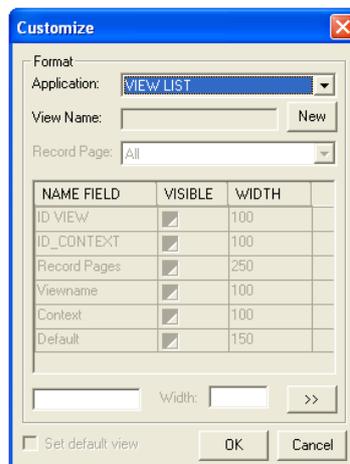
Fig. 63: New view

To set the fields that the user wants to show, the width and other parameters, the admin has to press the "New View" button and insert and select:

o   The entity in which to apply the settings
o   The name of the new customizable view of the data
o   The number of record for page that he wants to show
o   The fields to show and the width for each.

The user has to check the "Set default view" if the view is to be the default view when user log in the application the next time. The admin can save the view and the list of the views stored in the database will be shown in the main window.

6.5.5 BioApplication

The BioApplication is provided with each chip application and provides all pre-defined settings required for chip run and microarray image analysis. These settings cannot be modified. If there is any update or customization, it has to be done by the service personnel.

A BioApplication is defined as a set of input data/files:
- Layout of the Microarray
- Temperature Program
- Settings for the microarray image analysis.
- Diagnostic rule
- Reader parameters

The selection of the BioApplication allows the software to load automatically the data in the related tools and instruments avoiding/reducing the human errors. The BioApplication selection allows all users to load input data in a simple and unambiguous way. All BioApplications will be stored in the Central Database.

6.5.6 TCS Chip Traceability

The Administrator has to click on "TCS Chip" button in the list bar of the main window or the "TCS Chip" button in the toolbar (Fig. 64).
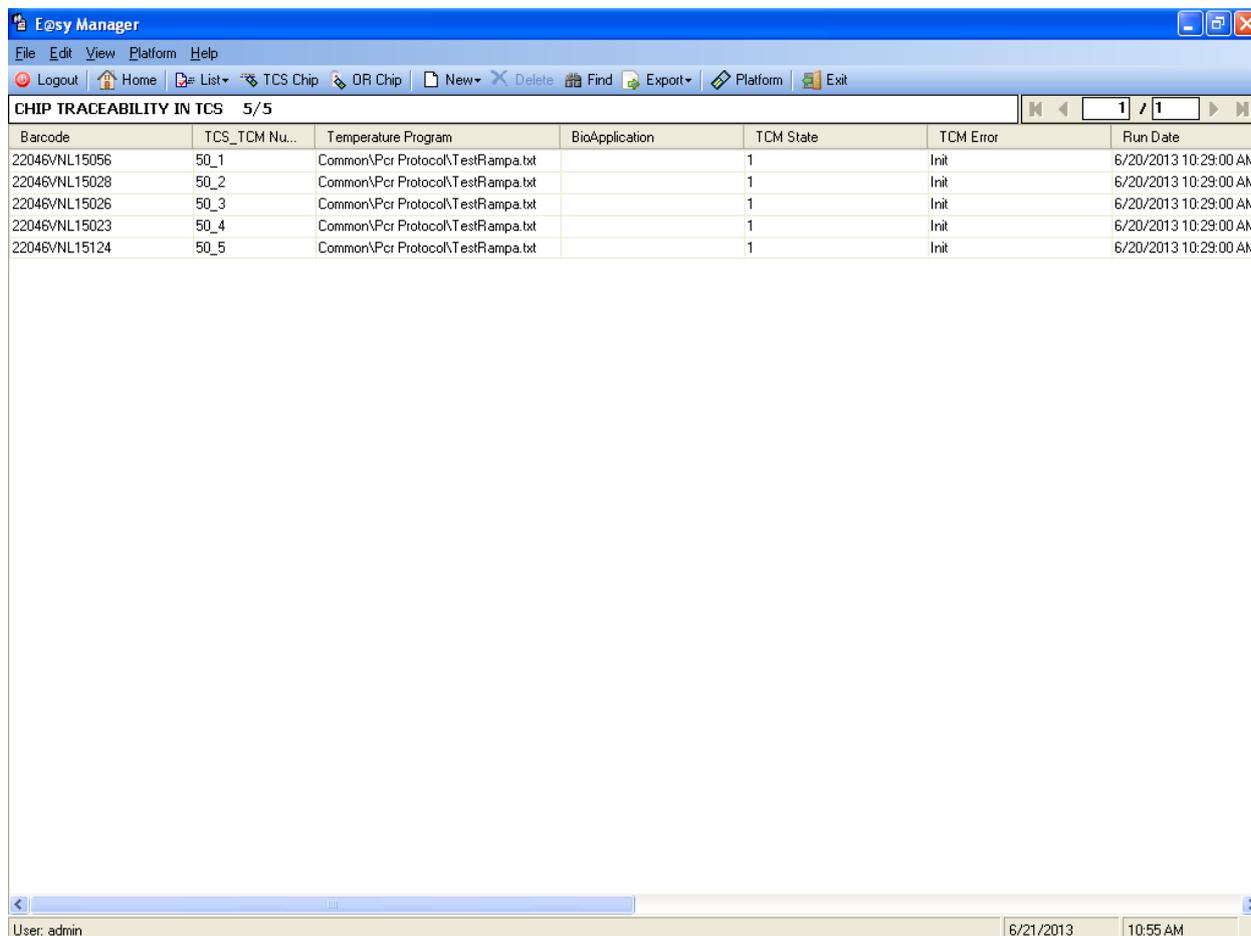
Fig. 64: TCS Chip traceability

The information listed is:
- Barcode number
- TCS serial number and TCM number
- Temperature program file
- BioApplication name
- TCM state (0 = init phase not runned, 1 = run completed)
- TCM error (errors code: 0=Init, 1=completed, 100=Over temperature, 101=Temperature out of range, 102=Lid open, 103=TCM stopped, 104=Reset, 105=Not completed)
- Date of completed or interrupted temperature program run
- PC name
- User name

6.5.7   OR Chip Traceability

It is possible to list the all the information related the chip ID management in the OR. The admin can click on the "OR Chip" button in the toolbar to display this information.

Fig. 65: OR Chip traceability

The information listed is:
- Barcode number

- BioApplication name
- Layout Microarray file
- Image analysis Settings file
- OR serial number
- Optical Reade error status (see the table below)
- Number of acquisitions for LOC
- Date of completed or interrupted image analysis
- PC name
- User name

Chapter 7

7   Maintenance

7.1   Cleaning

DO NOT perform any cleaning operation with the system turned on. Before starting these kind of action always switch OFF the system by placing rear panel button in 0 position and detaching power cord from AC high power socket. The instrument external cases may be cleaned with a soft cloth soaked with isopropanol or ethanol.

For further maintenance, it has to be performed by qualified service engineer.

7.1.1   Technical service

If you require technical service or replacement parts, please contact your local sales representative or dealer who sold the product.

Please provide the following information:
• Model name and serial number of the instrument.
• Location of the instrument and name of the person to contact.
• Reason for the service call.
• Date of delivery.

7.1.2   Disposal

The instruments contain electrical or electrical materials and should be disposed of as unsorted waste. It must be collected separately, according to European Union Directive 2202/96/CE on waste and electronic equipment – WEEE Directive. Before disposal, contact your local Veredus representative for country specific instructions.

7.2   Calibration

Calibration is recommended once every 12 months or in case of any serious problem, the TCS and OR must undergo calibration maintenance and the calibration have to be carried out by certified personnel or trained personnel appointed by Veredus. To schedule a calibration, contact your local distributor or Veredus Laboratories.

7.3 TCS Troubleshooting

A standard operator or user shall not open the equipment in case of any repairs or actions that have to be taken. This operation shall be executed only by authorized technical personnel after the equipment is isolated or disconnected from the hazardous live voltage.

Possible failure modes and troubleshooting actions are listed in the table below:

SN	Failure description	Cause	Actions to be taken
1	TCS does not turn ON	Power switch is turned OFF	Place the switch in ON position
		TCS power cord is not connected to TCS or to mains AC	Check connections
		Fuses are damaged or missing	Check fuses and replaces the defective ones
		Internal short circuits	Disconnect the machine from AC main and call service.
		Power AC/DC converter is damaged, or burned out	Disconnect the machine from AC main and call service.
2	Embedded PC resets	PC reset key has been touched	Turn the TCS OFF, then restart
		Power supply voltage drop	Check fuses and replace the burned ones
		Bad insertion of CF card	Turn the TCS OFF. Check CF card insertion
3	TCS does not give any response to mouse and keyboard	Connecting cable is disconnected or badly connected to PC	Check cable and/or replace it
		Mouse or keyboard are disconnected or badly connected to PC	Check cable and/or replace it
4	TCM's display is ON but Led does not light	LED is damaged	TCM can be used and monitored by E@syControl
5	TCM's status led lights but display is OFF	Display is damaged	TCM can be used and monitored by E@syControl
6	Temperature control is out of specifications	Chip is defective or damaged	Substitute the chip
		Equipment is damaged	If damage is only pertaining to a particular TCM, do not use it. If system damage seems to be present, disconnect the machine from AC main and call service.
7	System does not reach or keep the set temperature	Defective TCM module	Rerun the chip in another TCM module
		Defective chip	Confirm by running the chip in another TCM module. If the same error occurs, it is Chip related.
		Ambient temperature too high	Check that the ambient temperature does not exceed 30°C
8	High power consumption	Sealing are damaged or leaking, fluid is evaporated	Check the chip.
		Internal TCM short circuit	Disconnect the machine from AC main and call service.

SN	Failure description	Cause	Actions to be taken
		Internal power supply is defective	Disconnect the machine from AC main and call service.
9	TCM hatch does not close	Chip badly positioned	Reposition the chip
		External bodies inside the TCM	Check that there are no foreign items in the TCM
		Lock is damaged	TCM functionalities are compromised. To resume it contact service personnel
10	Opening key is blocked	TCM opening mechanism is blocked	Apply a slightly pressure on the hatch and press the opening key again
11	TCM hatch does not open	Chip badly positioned	Reposition the chip
		Lock is damaged	TCM functionalities are compromised. To resume it contact service personnel
		TCM opening mechanism is blocked	Apply pressure on the hatch and press the opening key again
12	Chip does not fit in the TCM	External bodies inside the TCM	Check that there are no foreign items in the TCM
		Contact holder or positioning pins are damaged	TCM functionalities are compromised. To resume it contact service personnel
		Defective chip	Repeat experiment with another chip
13a	TCS icon does not become active in the E@syControl	Ethernet wire is not connected	Connect Ethernet wire
		TCS IP address is not configured in the E@syControl Configuration *Menu*	Contact Veredus or local representative to configure IP address in the E@syControl
		TCS has a LAN forbidden IP address	Contact Veredus or local representative to configure IP address in the E@syControl
		TCS has wrong IP address	Contact Veredus or local representative to configure IP address in the E@syControl
		A firewall could be active in the laptop/PC, that forbids the connection	Check if the Firewall is deactivated
		Some overcrowding in the TCP/IP communication from PC and TCS.	Perform the following steps: 1) Close the SW 2) Re-launch the SW. If the problem persists: 1) Reboot the TCS
13b	TCS icon does not become active in the E@syControl	Control Module problem.	Reboot the TCS
		TCS IP address is not configured in the E@syControl Configuration *Menu*	Contact Veredus or local representative to configure IP address in the E@syControl
14	TCM LCD stops on status "TCM No xx CONNECTING"	Bad connection between TCS (Embedded PC) and that TCM	Check internal cables and backplane
15	TCM LCD stops on status "E2P ADC FAN" "FAIL PASS PASS" with red blinking light	PC board TCM hardware error	Need to replace TCM. Contact service personnel.
16	TCM LCD stops on status "E2P ADC FAN" "PASS FAIL PASS" with red blinking light	PC board TCM hardware error	Need to replace TCM. Contact service personnel.

SN	Failure description	Cause	Actions to be taken
17	TCM LCD stops on status "E2P ADC FAN" "PASS PASS FAIL" with red blinking light	FAN error	Service is needed to check fan cable. Contact service personnel.
18	More TCS with same IP address	No connection with any TCSs	Contact Veredus or local representative to configure IP address in the E@syControl
19	E@syControl has wrong IP address	No connection	Contact Veredus or local representative to configure IP address in the E@syControl
20	Missing calibration data	It is not possible to send calibration data to TCM because calibration files are not installed or corrupted	Need calibration data files. Contact service personnel
21	2D barcode unreadable	It is not possible to send the Chip ID and calibration data to TCM	User can change the settings of 2D barcode to read the linear barcode present upon the Chip. Need calibration data files. Contact service personnel
22	Temperature Program stopped	It is possible that user has opened the lid	Close the lid and Press the START button from TCM or SW GUI
		It is possible that user has stopped the TCM unawares	The SW has to allow to the user to create a temperature program to complete the run
		It is possible that user has stopped the TCM unawares in the fluidic phase	The SW has to allow to the user to send a temperature program to complete the run
23	Automatic protocol sending unavailable	BioApplication files not found or corrupted	Need BioApplication files. Contact service personnel
	User sends a wrong temperature program to TCS	Wrong BioApplication selected as default	Select the correct BioApplication by BioApplication management window.
24	The E@syControl GUI is not refreshed properly	TCM Progress bar does not start or it is not correctly updated	Close the E@syControl and re-launch it. After the connection is established the SW will be able to synchronize the data

7.4 OR Troubleshooting

SN	Failure description	Cause	Actions to be taken
1	The OR does not turn on	Power Switch (5) is turned OFF	Turn the Power Switch (5) ON
		Power Supply Jack (3) is disconnected	Connect the Power Supply Jack to the OR (3)
		Power supply cables are damaged or broken	Contact service personnel.
		AC Power Supply Cord (1) is not connected	Check that the power supply cord is securely connected.
		External Power Supply (2) over current protection has tripped	Check the Low Voltage Cable for shorts - Check the OR control board
		External Power Supply defective	Contact service personnel to replace the Power Supply
2	The OR is switched on and working, but the Power Status Led (9) remains off	Power Status Led (9) defective	The Power Status Led (9) is to be replaced
		Power Status Led (9) wiring interrupted or disconnected	Check Power Status Led (9) wiring and reconnect or replace if defective
3	Chip insertion difficult or impossible	Vertical / horizontal misalignment	Reduce the insertion angle in order to better align the chip perpendicularly to the Slotted Insertion Plate (11)
		Presence of foreign materials in the inlet slot of Insertion Plate (11)	Check the Insertion Plate (11) cleanliness
		Insertion Plate (11) out of alignment	Re-align the Insertion Plate
4	The Chip gets stuck before reaching the reading position (end of travel)	Presence of foreign materials (e.g. glass chips) in the internal guide	Remove any foreign material from the internal guide
5	No image from the OR camera	The Ethernet cable is disconnected	Check the Ethernet cable
6	Fluorescent spots are visible outside the detection area (after acquisition)	The anti-glare mask is dirty or stained	The instrument needs technical service
7	Glass chips in detection area	A chip has been damaged in the loading/unloading phase	The instrument needs technical service
		One or more optical interference filters have been broken	The instrument needs technical service

SN	Failure description	Cause	Actions to be taken
8	Alignment fail for all Chips	Wrong crop setup	Close E@syCheck Insert a good Chip inside Reader Open H-EA Open crop window in the menu Option Press on "Search Crop button" Press Save and close H-EA Restart E@syCheck
9	Acquired image is blurred	Chip is not in the correct focus position	Extract and reload the Chip. Try a new acquisition.
		CCD camera is off the focus position	unscrew the Focus Adjustment Lock (7) and go through the focus adjustment procedure
10	Acquired image has low contrast	Moisture has condensed over the optical components	Let the OR in a warm and dry place until moisture evaporates
		One red LED light source has failed	The instrument needs technical service
		Internal optical parts are dusty	The instrument needs technical service
		CCD camera defective	The instrument needs technical service
11	No image is acquired	Both light sources failed	The instrument needs technical service
		The main control board has failed	The instrument needs technical service

7.5 TOM Troubleshooting

SN	Failure description	Cause	Actions to be taken
1	TOM does not turn on	Power Switch is turned OFF	Turn the Power Switch on the back panel of the screen
		Power Supply Jack is disconnected	Connect the Power Supply Jack and check that the power supply is turned on
		Power supply cables are damaged or broken	Contact service personnel
2	Power turned on but no display	Display cable not connected properly	Check that the VGA cable is securely connected to the TCS and also the Monitor
		TCS not turned on	Check that the Base TCS is turned on. Try rebooting the TCS.
3	Touch functionality not working	USB cable not connected	Ensure that that the USB able is connected securely to the TCS and also the Monitor
		Touch driver corrupted	Contact service personnel for driver installation

Chapter 8

8   Technical specifications

TCS dimensions:

Length (mm)	Width(mm)	Height(mm)
500	300	145

OR dimensions:

Length (mm)	Width(mm)	Height(mm)
190	180	320

TOM dimensions:

Length (mm)	Width(mm)	Height(mm)
280	310	300

TCS mass: 10 Kg
OR mass: 3.8 Kg
TOM mass: 5.5 Kg

TCS Technical Specifications		
*Temperature control range	Tenv=26 °C T 40 °C - 100 ºC Tenv=30°C T 43 °C - 100 ºC Tenv=35 °C T 48 °C - 100 ºC	
Temperature Control Accuracy	±0.2 ºC	
Heating rate	25 ºC/sec	
Cooling rate	4 ºC/sec	
Falling and rising ramp thresholds in dry conditions at 26°C	Rising ramp 50-95 °C	33 °C/sec ±20%
	Falling ramp 95-72 °C	10 °C/sec ±20%
	Falling ramp 72 -50 °C	6 °C/sec ±20%
Size	500mm x 300mm x 145mm	
Weight	10 Kg	

Power supply	110/220 VAC, 50/60Hz
Communication ports	2 LAN 6 USB
I/O ports	1 VGA, 1 serial RS-232
TCM Display	LCD 16x2 blue back lighted
Consumption	140W Maximum
Over voltage category	Category I
Safety class	Class 1
Noise level	< 68.9 dBA
Storage conditions	-10°C-50°C, Humidity 20%-80%
Operating conditions	10°C-30°C, Humidity 20%-80%
Preconditioning time	2 hours at ambient temperature, mandatory before use
Firmware SW	Version 5.01
Control Module	Version 5.00
SW Library version	Version 5.20
OS x SW Library	Windows XP Embedded

VerePLEX Biosystem Software minimum requirements	
Processor	1.5 Ghz or more
RAM memory	512MB
Mass storage	250 MB of HDD 40GB, CDROM (for installation)
Communication	2 x Ethernet ports (10/100 Tbase), 2 USB port
External accessory	2D Barcode reader
Operating system	Windows 10, Windows XP embedded
SW application	VerePLEX Biosystem Software 5.3.0 or later

OR Technical Specifications

Sample size	Single slide: Length 74.9 mm – 75.1 mm Width 24.9 mm – 25.1 mm Thickness 1 mm – 1.1 mm
Field of view	9.2x7 mm
Acquisition time	Selectable form 1 to 4095 ms
Detector	½'' progressive scan CCD 1392x1040 pixels
Pixel resolution	6,67 μm
Illuminators	High power LEDs, 635 nm
Excitation filter	Center wavelength 628 nm, 40 nm wide band-pass filters
Excitation power	10±2 mW onto the detection area
Emission filter	Center wavelength 692 nm, 40 nm wide band-pass filters
Dynamic linear range	8-bit, (255:1) in single acquisition mode
Repeatability	Less than 3% of CV
Uniformity	Less than 8% of CV
Sensitivity	25 chromophores (Cy5)/μm2 (CPSM) at a signal-to-noise ratio of 2:1
Software	E@syCheck
Image format	16-bit Tiff or Bmp
Dimensions	18 L x 18 W x 31 H (cm)
Weight	3.6 Kg
Power	Voltage: 12 Vdc, 18 W

TOM Technical Specifications		
Monitor Size	10.4"	
Resolution	800x600	
Brightness	230 (cd/m2)	
Touch screen Type	5-wire Resistive Touch screen	
Touch screen Durability	36 million touches	
Dimensions	31 x 28 x 30 (cm)	
Weight	5.55 kg	
Environment	Operating Temperature	0ºC - 45ºC
	Storage Temperature	-20ºC - 60ºC
	Humidity	5 - 95% @40ºC, non-condensing
System	I/O	VGA, USB
	Power	36W power adapter, with AC 100~240 V input and DC +12V @ 3A output

Chapter 9

9 Glossary

IFU = Instructions for Use
API = Application program interface
Chip = VereChip™
HYB = Hybridization
LCD = Liquid Crystal Display
PCR = Polymerase Chain Reaction
TCM = Temperature Control Module
TCS = Temperature Control System
OR = Optical Reader
TOM = Touch Monitor
FIRM = Firmware
EB = Electronic Board
ECH = E@syCheck software
ECO = E@syControl software
H-EA = Express Acquisition software
H-MAT = Microarray Analysis software
TPE = Temperature Protocol Entities
CLT = Calibration Data
GUI = Graphical User Interface
CF = Compact Flash
SW = Software

10 Appendix A – List of requirements for VerePLEX™ Platform installation

Hardware requirements for TCS-03 and OR-02 PC-Connection

➢ **Desktop/Laptop:** IEEE 802.3 Ethernet board for each PC where the OR and TCS has to be connected.

Cable requirements for connecting the TCS, OR and TOM to the Power Network

➢ Power cords, minimum length 1.5 meters, are included in the shipment package

TCS, OR and TOM power cords end with a SCHUKO/IEC 16A plug**.** You can make it suitable to the Power Network by using an adaptor or changing the power cord.

TCS Power supply

Input Voltage: 100 - 240 Vac (extended range 90 ¸ 264 Vac)
Input Frequency: 50 - 60 HZ (47 - 63Hz)
Input power: 260W maximum
Automatic switching

READER AC/DC Converter

Switching AC Adapter input features:
100-240 Volt AC
0.4 Ampere
50-60 Hz

Switching AC Adapter output features:
12 Volt DC
2 Ampere
Center Positive

TOM Power supply

Switching AC Adapter input features:

100-240 Volt AC
1.5 Ampere

50-60 Hz

Switching AC Adapter output features:

12 Volt DC
3 Ampere
Centre Hole Positive
Outer metal sleeve connected to Negative

Other devices

➢ 2D Barcode Reader compatible with Data Matrix.

Please verify that the Barcode Reader connector is compatible with the laptop available ports.

11 Appendix B – Standard user, power user and admin

The VerePLEX™ Biosystem software has different user access levels that can login the application according to different type of users:

- Standard User. In this case the user can perform only the following operations:
    - o send protocol to TCMs
    - o start and stop a single PCR/HYB process
    - o capture Microarray image

- Power User. In this case the user can perform the standard user operation and the additional one
    - o access to BioApplication Mode (view, change)
    - o reset single TCM
    - o access to protocol management

- Admin User. In this case the user can perform the power user operation and the additional one:
    - o configure TCS
    - o set BioApplication for other users
    - o Create/modify groups and users
    - o view/save log file

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