



# ROBOBACT

Module for the growth and isolation of bacteria and yeasts from biological samples

(CE Diagnostic Device - IVDD 98/79)

## OPERATING MANUAL GUIDE TO THE SYSTEM

**This manual applies to the following models of the ROBOBACT instrument:**

<b>Code</b>	Description
<b>94200</b>	<b>ROBOBACT</b>
<b>94210</b>	<b>ROBOBACT <i>Special</i></b>

**LIST OF MANUAL REVISIONS**

<b>REV.</b>	<b>VERSION</b>	<b>DATE</b>	<b>APPR.</b>	<b>MODIFICATIONS</b>
0.00	1.02	04/2000		Initial revision
0.01	1.02.b	07/2000		Addition of description of the LED functions.
0.02	2.12	11/2002		Addition of description of atmosphere control of the Robobact Special
0.03	2.13	03/2003		Connection of settings windows
1.00	2.17	01/2004		IVDD/CE version
2.00	2.18	01/03/2006		Sanitising and "Special" emergency opening procedures inserted

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# Robobact

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## SYMBOLS

### Legend of symbols used in this document:



ATTENTION, potential hazard of personal injury, all the conditions indicated in the associated text must be read and understood before proceeding



WARNING, potential hazard of damage to the device all the conditions indicated in the associated text must be read and understood before proceeding.



N.B., Important information.



BIOHAZARD, danger of contamination with potentially infected substance.

### Legend of Electrical and Safety Symbols used on the instrument:



Warning, danger of electrical shocks



Read the manual, observe the symbols relating to safety

### Preliminary notes:



Before installation and use of the instrument, for a **correct and safe use**, it is recommended to **carefully read** the warnings and instructions contained in this instruction manual.

It is important for this instruction manual to be kept together with the instrument for future consultation.

In the event of selling or transferring the instrument, make sure that this booklet always accompanies the instrument for allowing the new owners to be informed about the operation and relative warnings.  
The use of this instrument is only recommended for **authorised and competent personnel**.

## INTRODUCTION

### *The Robobact system in microbiology*

The **Robobact System** is a modern, fully automatic process that allows for sowing and developing bacteria in order to obtain results that are comparable with the traditional slide method, with the added advantage of avoiding having to open the sample containers, thereby guaranteeing *maximum safety* for the operator and complete *standardisation* of the cultures. The *simplicity* of its use and the *timesavings*, coupled with a vast *range* of mediums available, make this a **unique** method of its kind.

Following is a rapid description of the main system components:



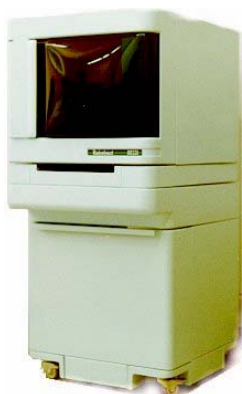
Stool



Urine

- **Containers** for the collection and transportation of the samples, differentiated by type: stools, urine and swabs.
- **Device** containing: A) one *SLIDE* with a double culture medium and calibrated loops for the sowing and isolation of the colonies. B) stand for inserting the sample container

- **Automatic instrument** with thermostat, with 35 random access positions, that carries out the following for each sample:
  - Identification of the sample from the barcode label
  - Identification of the Type of Device
  - Enriching of the sample under shaking
  - Breaking of the sample container
  - Simultaneous sowing of the two cultures of the device
  - Monitoring of the temperature set for the incubation.
  - Possibility of sending notification of negative samples to the Host-Computer (after command from the operator).



Steel trays are also available with the instruments (**Robobact Tray** Code 94005), each with 18 positions for facilitating the preparation and transporting of the devices.

The instrument is a modular system that can be equipped with the following components in accordance with the laboratory requirements:



- **ROBOBACT Module** (Code 94200) – This is the basic instrument that must be connected to a computer.
- **ROBOBACT SPECIAL Module** (Code 94210) - This module allows for management and control of the quantity of **Oxygen** present inside instrument. It requires a nitrogen and CO<sub>2</sub> distribution system (fixed or in bottles) and it must be connected to a computer.
- **PROCESSING UNIT Section** (Code 94224) with LCD VIDEO on a pullout panel and pointer support of the “Touch Screen” type. This is the computer for managing the ROBOBACT and ROBOBACT SPECIAL modules (as many as six). Built for being the natural base of one or two overlapping modules.
- **TROLLEY** (Code 94220) - The trolley for holding the PROCESSING UNIT and as many as two ROBOBACT modules. Fitted with four wheels and a spacious internal compartment, it frees this instrument all all restrictions and solves the problem of space on the laboratory tops.
- **Generator TROLLEY** (Code 94222) - The trolley that contains the NITROGEN generator inside, while externally it can be equipped with CO<sub>2</sub> bottle support (CO<sub>2</sub> Bottle Support - Code 94200), for the ROBOBACT SPECIAL Module. This makes the instrument completely autonomous even in laboratories where this system is not present.

## The Manufacturer's liability

DIESSE DIAGNOSTICA SENESE S.p.A. declines all liability deriving from incorrect use of the instrument, or in any case not compliant with the provisions specifically laid down in this manual. The liability is however limited exclusively to the malfunctioning of the instrument, only during **the use foreseen** for the same (Directive 1999/34/CE which modifies the European Directive 85/374/EE acknowledged in Italy with Presidential Decree no. 224 dated 24 May 1988 [Legislative Decree. nr. 25 dated 02/02/2001]) and only if the power cables supplied with the instrument are used.



**Before use, read this manual carefully.**

It is recommended that **only qualified and competent personnel** be permitted to use this instrument.



See **ENCLOSURE A** - Declaration of CE compliance

## Reference norms

DIESSE DIAGNOSTICA SENESE S.p.A., a company with **ISO 13485 and ISO 9001** certification, declares that it has observed the Directives concerning safety described in Enclosure A of this manual for the design and construction of the ROBOBACT instrument.

DIESSE DIAGNOSTICA SENESE S.p.A. subjects all its products to strict testing, however, should this instrument present malfunctioning, you are invited to contact the Authorised Technical Assistance Centre indicated at the time of taking delivery of the instrument.

## Warranty

DIESSE DIAGNOSTICA SENESE S.p.A. guarantees the ROBOBACT instrument against material and manufacturing defects for a period of 12 months from the delivery date. If defects are detected in the instrument during this warranty period, the Authorised Assistance Centres will repair these and only charge you for the transport expenses.

## Warranty conditions

1. The materials and manufacturing of this product shall not be considered as defective if the machine has been adapted, changed or adjusted in order to make it comply with national or local norms that differ from those for which the product has originally been designed and constructed.
2. This warranty does not cover periodic controls - maintenance and repairs of parts deriving from normal wear and tear – transport costs and risks directly or indirectly connected to the warranty of this product, including the transferral from the Technical Assistance Centre to the Customer's domicile, – damage due to negligence or incorrect use of the instrument – malfunctioning of the instrument due to modifications or repairs carried out on the same by unauthorised third parties - damage caused by the installation of parts or pieces not approved by the manufacturer.

*For greater detail please refer to the sales contract stipulated with the distributor*

## Material required for use of the instrument

In order to use the instrument, **only** materials belonging to the Robobact line produced by DIESSE DIAGNOSTICA SENESE S.p.A. must ever be used. Before use, always read the instructions for use accompanying each product; any other type of component or accessory used on the machine could cause damage or give incorrect results. For this reason all liability is declined for damage deriving from this cause.

### Special precautions



It is pointed out that despite the fact that the Robobact System guarantees good safety in managing the samples (stools, urine or swabs), there is still the presence of ***potentially infected material***. All precautions envisaged by law must therefore be observed. The reject material at the end of the cycle must also be treated in the same manner as all other materials similar to hospital waste.

## SANITISING PROCEDURE

The scope of this protocol is to provide the technical laboratory operator with a cleaning and decontamination procedure for inside the ROBOBACT instrument in order to ensure perfect hygiene and reduce the risks for the operator him/herself. Irrespective of the type of disinfectant or biocide used, the dosing of the product must be compliant and applied for the minimum recommended contact time.

For this purpose the instruments and equipment must be cleaned before the disinfection operation in order to eliminate the biofilm thus exposing the microorganisms to the disinfecting action. It is therefore a good idea to always keep the instruments and equipment clean.

### MATERIALS

The product indicated in this protocol is UMONIUM 38, which, besides having a disinfectant activity, is also a detergent. Included among the recommended applications there is also cold disinfection of the heat-sensitive instruments and medical devices.

Features:

UMONIUM38 SPRAY: ready-to-use solution in a spray form which is active against a wide variety of bacteria, moulds and viruses.

UMONIUM38: a solution to be diluted with water.

Produced by Huckert's International; Chaussée de Namur, 60; B-1400 Nivelles; Belgium; [www.huckerts.net](http://www.huckerts.net).

PROCEDURE: THE FOLLOWING OPERATIONS MUST ALL BE CARRIED OUT WHILE WEARING APPROPRIATE PERSONAL PROTECTION DEVICES (gloves, mask, protective glasses).



Ordinary cleaning (daily):

Turn off the Robobact instrument. Spray Umonium38 on the first section of the sample tray and rub with a paper towel as far as the 3<sup>rd</sup> – 4<sup>th</sup> section. Repeat the spraying operation on the next section and rub with a paper towel over the remaining sections. Let dry.

Special cleaning

In the case of contamination, consistent dirt, or accidents (e.g. spilt biological sample) spray each section of the tray and leave to dry. If necessary, remove any dirt or debris from inside each individual well on the tray, unscrew the sections one by one and immerse in an aqueous solution with 0.5% Umonium38\*. Let the sections soak for 10 minutes, rinse with distilled water and leave to dry or dry with paper towels.

\*N.B.: The aqueous solution may be stored and used again within a maximum of 20 days, however a fresh solution must be used if any turbidity or residues are observed.

Umonium38 is also used for cleaning and decontamination of the external parts of the Robobact instrument including the LDC monitor (**turned off**).

## TECHNICAL DATA

### *Composition of the Instrument. Technical features External connections and measuring units.*

This section of the manual provides illustrations and descriptions of the most important units making up the Robobact instrument.

### Technical description of the Robobact module

The ROBOBACT module consists of a single body containing all the operating parts necessary for the bacteriological isolation. The door on the front panel allows for inserting the samples. The power supply unit and the optical fibre inputs for serial connection to the PROCESSING UNIT are installed at the rear of the instrument. Following is a description of the functional units of the module.

#### Sample-holder tray

The sample-holder tray consists of a revolving circular crown divided into seven sections, each of which contains the wells for holding five samples, for a total of 35 positions.

#### Thermostat unit

The working temperature is set for each method. During operation the temperature is measured and compared with the set temperature, and in the event of any variations ( $\pm 0.5^{\circ}\text{C}$ ) the heating will be turned on/stopped. A resistor with fan is installed in the centre of the instrument for this purpose. Whenever the instrument is not operating, a standby temperature of  $18^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{C}$ ) is maintained.

#### Identification of the type of analysis and its status

This is carried out by a barcode reader which, after reading the barcode attached to the external surface of the device, identifies the type of sample being examined, in this way associating the same with the times and methods of enrichment, breakage, sowing and incubation that have been set for that specific type of analysis. Moreover, an optical sensor installed at the height of the spherical extremity of the sowing fork determines the status, identifying all samples that have already been sown.

#### Shaker unit

This consists of four stations, each containing a horseshoe-shaped magnet. The magnets are made to revolve by means of a belt driven by a motor at 450 rpm. The

rotation of the magnets makes the shaker devices move that are installed inside the sample containers, thus favouring the enrichment process.

Unit for breaking the bottom of the sample container

This consists of a metal block equipped with an up-down movement transmitted by worm screws from a step-step motor. When the block descends it pushes the sample container downward, thus breaking the bottom and letting the liquid inside flow into the culture-containing sector of the Device.

Culture unit

This consists of an arm with a pair of tweezers at the end that carries out a jaw opening and closing movement. The arm carries out two movements, up and down and forwards and backwards. With the downward movement the tweezers move as far as the spherical extremity of the culture fork of the device, after which the tweezers-closing movement is activated in order to grasp the spherical extremity. A sensor located inside the jaws of the tweezers checks the presence of the extremity. After this, two movements are activated simultaneously, up and down and backwards and forwards, in order to carry out the sowing of the agarised cultures from the calibrated loops mounted at the end of the fork. Once the sowing has been carried out the loops are locked in a stable manner to prevent them from dropping downwards. Following this, the jaws of the tweezers open and return to the resting position.

## Description of the PROCESSING UNIT section

This section is integrated with the others but still remains separate from the same. It may be replaced by a normal personal computer. It is set up to act as a base for one or two overlapping ROBOBACT modules and the assembly may be positioned on the specific wheeled trolley. The power supply unit and the serial outputs for the optical fibres (4 default outputs, although as many as six can be installed on request). The video is mounted in a pull-out drawer at the front of the instrument. On the left-hand side of the drawer there is a specific compartment containing the barcode reader for the samples.

Description del computer

The motherboard is the industrial type. It houses a 486 processor with a cooling fan, 4MB of RAM memory, and also has a free PC slot. Apart from the optical fibre outputs for connecting the ROBOBACT modules, the following are also installed on the rear panel: a **Parallel** port set up for connection to a printer, a **Serial** port for connecting up to a host computer if necessary, and the outputs for external keyboard and monitor. There is also a section housing the power supply unit that can be connected to an external floppy disk reader (necessary for any backing up of the software).

Description del video

The video is a 9.6-inch colour LCD (Liquid crystal) monitor of the TFT type with high resolution. It comes with a "Touch Screen" type pointer backup that allows for software management by pressing of a finger directly onto the screen.

Description of the sample barcode reader

The barcode reader, which is positioned to the left of the video drawer, can be raised up for reading the barcodes identifying the patients when present on the sample containers. It is programmed by default to recognise the EAN type codes, however during the installation phase (or afterwards), it can be programmed from the software to recognise the specific type of barcode used in the laboratory.

## General illustration of the instrument and external connections

The connections for hooking up to the mains power supply (110/220 V) and the optical fibres which are connected to the PROCESSING UNIT by means of a specific cable (A) are installed in the rear section of the Robobact module).

Four ROBOBACT modules can be connected to the PROCESSING UNIT section (and as many as six can be installed on request).



A) Optical fibre cable

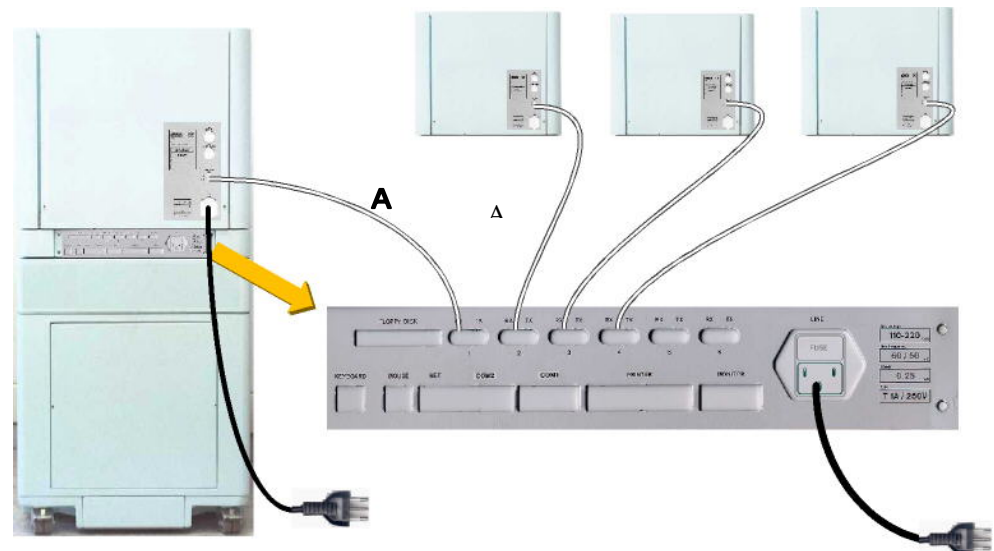
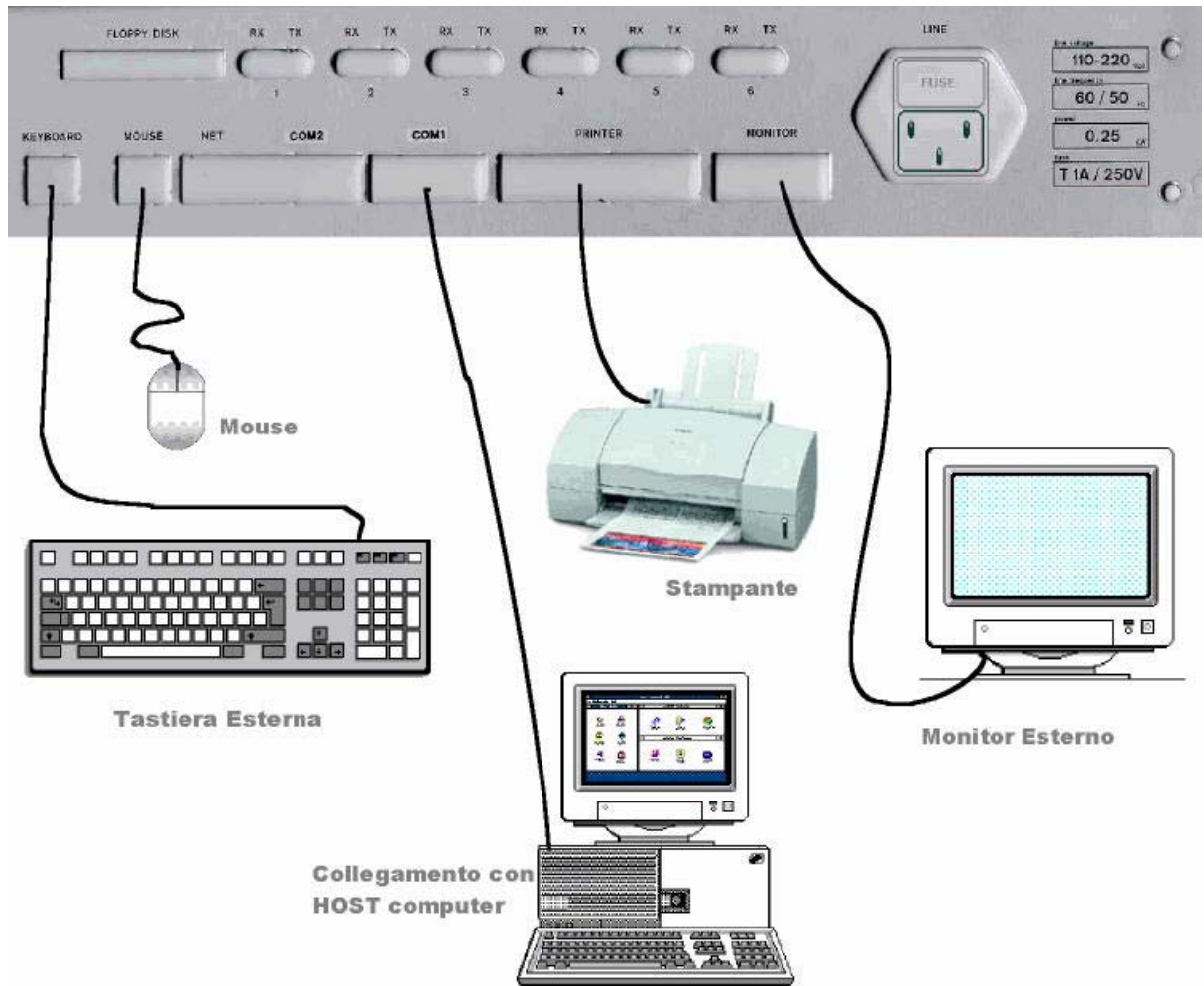


Figure 2.1

The power supply cable for the module and the processing unit must be of the following types: IEC International Standard [Female Plug IEC 320 C-13; Male Plug Schuko EEC 7-VII; Rating: 10A/250Vac], less than 3 metres long.

Various peripheral units can also be connected up to the PROCESSING UNIT section such as the mouse, external keyboard, external monitor, printer, etc.

Figure 2.2 - Peripheral units that can be connected to the PROCESSING UNIT (*Mouse - printer - external keyboard - external*



*monitor - connection with HOST computer)*

If the PROCESSING UNIT section (Code 94224) is NOT present but an EXTERNAL PERSONAL COMPUTER is available, it will be necessary to use the specific SERIAL ADAPTOR (Code 94230) to connect the modules (in this case only as many as 4) to the serial port of the Computer. The following are included in Code 94230: the external power supply unit for the adaptor and the serial cable for connecting to the computer.



Figure 2.3 - Serial adaptor

## Technical features

Robobact module and ROBOBACT Special

POWER SUPPLY 110/220/240 V – 50/60 Hz

FUSES 2x T 5A Delayed

INPUT (Max.) 1000 W

DIMENSIONS	65 x 55 x 50 (cm)
------------	-------------------

WEIGHT	45 kg
--------	-------

WORKING TEMPERATURE between +15°C and +45°C

RELATIVE HUMIDITY 20% - 80% without condensation

NOISE FACTOR lower than 80 decibels

PROCESSING UNIT

POWER SUPPLY 110/220/240 V –50/60 Hz

INPUT (Max.) 1000 W

DIMENSIONS	65 x 55 x 8 (cm)
------------	------------------

WEIGHT	8 kg
--------	------

Trolley

DIMENSIONS	65 x 55 x 70 (cm)
------------	-------------------

WEIGHT	30 kg
--------	-------

Trolley generator

POWER SUPPLY 110/220/240 V –50/60 Hz

INPUT (Max.) 1000 W

DIMENSIONS	65 x 55 x 70 (cm)
------------	-------------------

WEIGHT	90 Kg
--------	-------

## Measuring units

The measuring units are expressed according to the INTERNATIONAL MEASURING SYSTEM as indicated by the Technical Standard CNR-UNI-10-003.



## INSTALLATION

*Packaging. Handling and positioning. Accessories. Setting up operations carried out by the Customer. Disposal.*

The installation must be carried out by expert personnel, trained and authorised by the distributor company. The ROBOBACT is a precision instrument and must be treated as such. Improper actions could damage the internal parts. Follow the instructions contained in this chapter, in order to guarantee the safety of the instrument and the operator.

### Transportation and handling



The instrument must only ever be transported and handled with its original packaging which guarantees resistance against loading operations on trucks, aeroplanes, ships, etc. It is important to observe the TOP/BOTTOM indications and avoid excessive tipping over that could damage the instrument. In view of its large overall dimensions and weight, it is recommended to use a forklift to transport the instrument.



Never leave the instrument out in the rain or in a humid environment even if in its packaging. In the event of remaining for more than 24 hours in temperatures below 10°C, the installation can only be carried out after leaving the instrument at room temperature for an hour.

### Packaging characteristics

The packaging of the instrument consists of two flexible wooden crates (birch plywood 6 mm thick) of the same size. The interior is lined with polystyrene foam. The contents of the crates are divided up as follows:

Conserve the original packaging complete with the internal padding interne.

- **Crate A** -- ROBOBACT Module (Code 94200)  
+ (if included) PROCESSING UNIT (Code 94224)
- **Crate B** -- Trolley (code 94220)

		<b>A</b>	<b>B</b>	
Width	cm	78	78	The two crates have the following characteristics:
Depth	cm	65	65	
Height	cm	84	91	The total weight of the two crates complete with the instruments, trolley and accessories is approximately <b>150 kg</b>
Weight of empty body	kg	25	25	
Weight of full body	kg	90	60	

## Standard material

The ROBOBACT instrument is supplied with the following standard material:

- INSTRUCTION MANUAL
- A power supply cable- IEC International Standard [Female Plug IEC 320 C-13; Male Plug Schuko EEC 7-VII; Rating: 10A/250Vac] for the module
- A power supply cable - IEC International Standard [Female Plug IEC 320 C-13; Male Plug Schuko EEC 7-VII; Rating: 10A/250Vac] for the PROCESSING UNIT (optional)
- A pair of optical fibres cables for connections between the module and the CPU.
- Handles for manual lifting of the Robobact module
- Two spare delayed T 5A (250V) fuses
- **Robobact Tray** (2 stainless steel trays for transporting the devices) (Code 94005) (optional)
- Floppy disk for installing the software (MAIN SETUP DISK)
- Document dealing with the “**HARDWARE PARAMETERS**” of the module.
- Licence of the DOS<sup>®</sup> operating system (if present in the C.P.U. section (Code 94224))
- Packing-list

## Positioning



The analysis laboratory represents the work environment foreseen for this instrument. For normal safety needs, and depending on the type of examination to be carried out, the instrument must not be positioned near heat sources, in areas where liquids can come in contact with it, or in dusty environments. In the event of not using the specific supporting trolley, place the instrument on a solid, perfectly flat bench that is not subject to vibrations. In order to allow timely intervention on the switch and the power supply cable in the case of hazards, allow sufficient space between the walls of the laboratory or other instruments and the ROBOBACT. Never place anything on top of the instrument.

Moreover, it is recommended to position the instrument as far away as possible from generators of Electro Magnetic Waves (e.g. laboratory

refrigerators, centrifuges) or any instrumentation lacking the CE mark, as they could influence its correct operation.

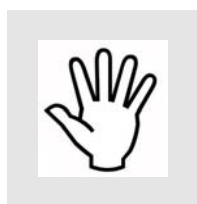
## Setting-up operations to be carried out by the customer

The safety the instrument and the operator will not be guaranteed if non-compliant with any of the following conditions.

- The power supply mains must be compatible with the voltage and current specifications indicated on the metal nameplate affixed to the rear panel of the instrument.
- The mains must be equipped with the earthing connection according to the regulations in force.
- The instrument is fitted with an internal stabilising that withstands voltage fluctuations of 10%. If there is pronounced interference on the electricity line, use a stabiliser on an external network.
- Before making the connections with external instruments (printer, monitor, keyboard etc.), it is necessary to check their compatibility.
- Before turning the instrument on, it is recommended to first check that the sample-holder tray is free of any extraneous items that could compromise its rotation.

It is prohibited:

- To remove or modify the safety guards and protection devices.
- To remove or introduce the devices while the sample-holder tray is in movement.
- Introduce foreign bodies inside the instrument
- Access prohibited internal areas.



## Installation procedure

1 – Unpack the instrument contained in CRATE A):

- Use a screwdriver to unscrew the 4 anchoring screws on the lid of the wooden crate (one on each side) and the other 4 screws on the base of the crate.
- Lift off the lid, check the material inside (**check the packing-list**), remove the PROCESSING UNIT section (if present) then slide the side panel upwards out of the crate.



2 – Unpack the trolley from CRATE B) (as per point 1 ).

---

## Installing the instrument:

- First position the trolley and lock the wheels with the relative brakes, or clear a space on the bench chosen for housing the instrument.
- Carefully lift the PROCESSING UNIT section and place it on top of the trolley. Screw the 4 bases for the feet of the module onto the brackets of the trolley.
- Screw the handles onto the lid of the Robobact module.
- Once the PROCESSING UNIT has been fitted onto the trolley, carefully position the Robobact module on top.
- Remove the handles and put inside the trolley (accessible from the rear). Attach the 4 bolts for anchoring the lid. Release the wheels of the trolley and move into position. Lock the wheels again.
- Tie the polystyrene foam sticks together into a bundle. Fold the central parts of the wooden crate and squash flat. Store together with the lid, the base and the handles in the event of having to move the instrument again in the future.



Only use the power supply cables supplied with the instrument

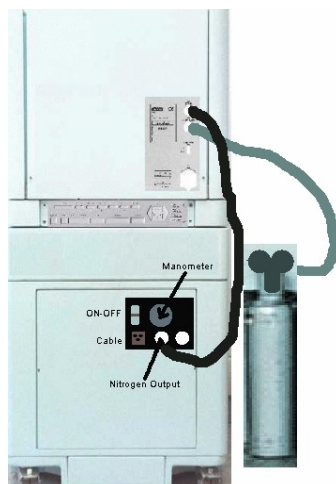
5 – Connect the PROCESSING UNIT and the Robobact module to the power supply mains (two separate power supply unit). (See Fig. 2.1 Chapter 2)

6 – Make the optical fibre connection between the Robobact module and CPU section. (See Fig. 2.1 Chapter 2)

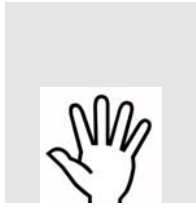
7 – Turn on the instrument (See Chapter 4).

8 - For the **Robobact Special** (94210) it is also necessary to make the connection with the external CO<sub>2</sub> and N<sub>2</sub> bottles with the tubes supplied. The bottles must be fitted with pressure reducers and pressure gauges. The output pressure must be between 3 and 6 Bar. The output tube diameter from the pressure gauge must be male and 3/8 inch.

The TROLLEY GENERATOR (code 94222) with the “Nitrogen generator” incorporated may be used to replace the N<sub>2</sub> bottle. In this case the tube will be connected directly to the output of the nitrogen generator. After being turned on, the nitrogen generator will begin to recharge, (1 Bar/hour), until reaching 6/7 Bar. It is recommended to turn it on at least four hours before starting the cycle that requires a modified atmosphere (Campilobact).



## Restrictions and warnings



DISCONNECT from the power supply mains before any technical intervention or in the case of malfunctioning of the instrument.

**IN CASE OF FIRE OR GENERAL HAZARDS, TURN THE INSTRUMENT OFF AND DISCONNECT THE POWER SUPPLY CABLE.**

It is only permitted to use fingers on the TOUCH for giving commands.

It is prohibited to OPERATE the machine while there are parts in movement (it is only permitted to enter commands from the keyboard).

**It is prohibited to INTRODUCE** fingers or objects between the tray and the safety guard of the instrument.

**It is strictly forbidden to MOVE** the tray manually while the instrument is running.

## Operations for disinstallation and reinstallation in the same room or in another site

It is advisable to differentiate between two cases:

A – disinstallation and reinstallation in the same room or in a site that can be reached using trolleys and lifts (the presence of authorised personnel is necessary for this procedure).

1 – Turn off and disconnect the two power supplies. Release the trolley wheels and carefully move to the new work place.

In the absence of the trolley, insert the handles into the Robobact module, lift it up and free the PROCESSING UNIT section (that acts as its base). Arrange the latter in the new position selected and fit the module on top again. Then remove the handles and reconnect the two power supplies.

B – disinstallation and reinstallation in different premises or in a site that is NOT accessible using trolleys and lifts. The presence of authorised personnel is necessary for this procedure.

## Composition of the machine – Dismantling

The instrument consists of the following materials in the percentages specified:

<i>Material in %</i>	ROBOBACT	PROCESSING UNIT	Trolley
IRON	78	70	95
COPPER	3	4	/
ALUMINIUM	7	5	/
PLASTIC materials (PVC, ABS...)	7	11	4
SILICA and GERMANIUM	0.5	1	/
Others	4.5	9	1

For the DISMANTLING of the instrument at the end of its life cycle refer to the local regulations in force for the disposal of waste materials.

## USE

### *Instructions for the operator. Programming the machine. Loading the samples*

Before consulting this section of the Manual it is important to read the preceding chapters in order to prevent any problems for the instrument or the operator.

### Turning on the instrument

Make sure that the power supply sources of the instrument have been connected to the mains and that the optical fibre connections have been made between the module and the CPU.



Turn on the Robobact module and CPU/Video in sequence, by pressing the two start buttons located on the left hand side, the LEDs of which will turn green.

If an external Computer is used, first turn on the instrument and then the computer



Slide the drawer out horizontally that contains the DISPLAY.

**ATTENTION:**  
If the drawer is closed after about a minute the display will automatically turn off. It turns on as soon as the drawer is opened again.



Follow the instructions of the software on the Video and observe the green LED inside the ROBOBACT door.

After being turned on, the computer carries out the initial booting operations and then automatically starts the instrument management software. After a few seconds the following window will appear on the screen:



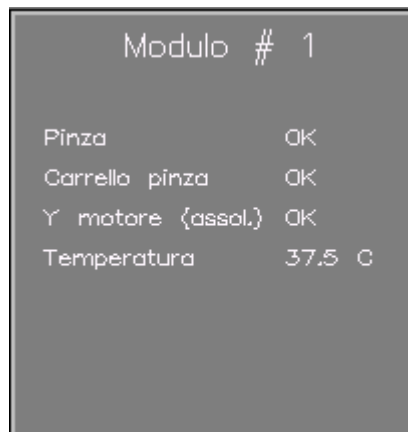
*(Check connections – module #1 connected – Firmware version)*

If the Robobact module has not been turned on or the optical fibre connections have not been carried out, the following message will appear:

**“ Not connected “**

In this case, turn off the machine by pressing the two start buttons again. Check the power supply and the connection and then repeat the starting operations again. If the machine fails to connect contact the technical assistance service.

If the connection is correct, the instrument will begin the HARDWARE and SOFTWARE Reset functions, initialising a test programme for checking the efficiency of the motors and all the machine functions.



*(Module # 1 – tweezers – Tweezers-holder Y motor (absol.) - Temperature )*

If all the controls are O.K. the main page of the programme will be displayed.

If any of the controls are NOT OK, contact the TECHNICAL assistance service.

## Description of the indications of the LEDs

A series of GREEN LEDs is installed inside the door in the lower section of the instrument, as indicated in the figure below.



When these LEDs are turned on they are clearly visible from the outside through the holes in the door.

The functions they refer to are as follows:

The first small LED (1)(on the left) indicates that the module is TURNED ON.

ACCESS



If only one module is present these 2 LEDs are always turned on

MODULE  
DISPLAYED ON THE  
SCREEN

The two longer LEDs (2 and 3), turn on simultaneously to form a single luminous bar, indicating that the information of the software on the display relates to that module. (Useful information if using more than one Robobact module).



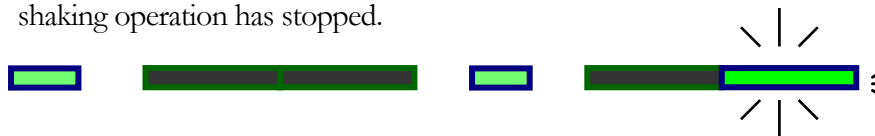
WORK CYCLE IN  
PROGRESS

When the central LED turns on (4) (smaller) this indicates that the module is functioning, in other words, that the instrument has started the work cycle.



THE ENRICHING  
PHASE IS  
ACTIVATED

The LED on the far right (6) displays the shaking operation of the machine, and it must BLINK during the enriching phase. It will remain fixed or turned off once the shaking operation has stopped.



SIGNALLING OF AN  
ERROR

Finally, the second to last LED on the right (5) will turn on to indicate the presence of an ERROR occurring during the machine operations.





## Description of the main menu

This is the main page of the programme.

If a TOUCH SCREEN system is used, when the centre of each page viewed is pressed, an online manual will always be available describing the functions of the keys

Sample table

If an external keyboard is used, the function keys indicated in the top left hand corner must be pressed for enabling the corresponding function.

Dialogue window

N. Test	Stato	TRes	N. Test	Stato	TRes
1			19		
2			20		
3			21		
4			22		
5			23		
6			24		
7			25		
8			26		
9			27		
10			28		
11			29		
12			30		
13			31		
14			32		
15			33		
16			34		
17			35		

### Online help

Online help is available for each page displayed that describes the main functions of the keys present. To access these just press the centre of the page with your finger.

Aiuto

Sono disponibili 2 versioni del Robobact:

- Robobact Standard
- Robobact Special, concepito in particolare per crescita di batteri in atmosfera modificata.

In seguito il Robobact Special sarà chiamato RoboS.

**Finestra di Stato**

Nella parte bassa dello schermo la finestra di stato mostra lo stato di ogni modulo, insieme ai parametri di processo; la temperatura e la concentrazione di ossigeno e lo stato dei due gas N2 e CO2 per il RoboS. In quest'ultimo, qualora uno dei due gas di riempimento sia esaurito, viene generato

PgUp   PgDn   Chiudi

In the case of using a Computer with a Monitor that is not Touch Screen, press the “H” key on the external keyboard.

*It is recommended to use the Online Help pages as they contain targeted, summarised information that is updated with the version of the software installed on the instrument.*

### Software date and version

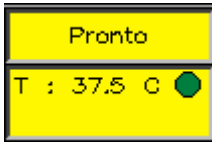
A white window in the top right hand corner indicates the date and time. The version of the software used by the instrument will be displayed in the top centre after the word Robobact.

### Module visualised on the display




If more than one module is connected to the Processing Unit, a number will appear in the top left hand corner indicating which module is being visualised on the screen at that moment. In order to view the situation of another module, press the corresponding dialogue window on the screen.



Dialogue window



A box is present in the bottom left hand corner with a yellow background divided into two sections. The lower section indicates the temperature measured in real time inside the module, and alongside, a symbol that has the following meanings:

-  = Internal temperature **higher** than the set temp.
-  = Internal temperature **lower** than the set temp.
-  = Internal temperature equal to the set one (+/- 0.5 °C)

N.B. *Normally the temperature set for the analysis is reached within 10 minutes after starting the cycle.*

On top of the temperature there are messages relating to the functioning of the machine during the various operations. This is a real dialogue window, always updated with regard to the activities of the module during its use.

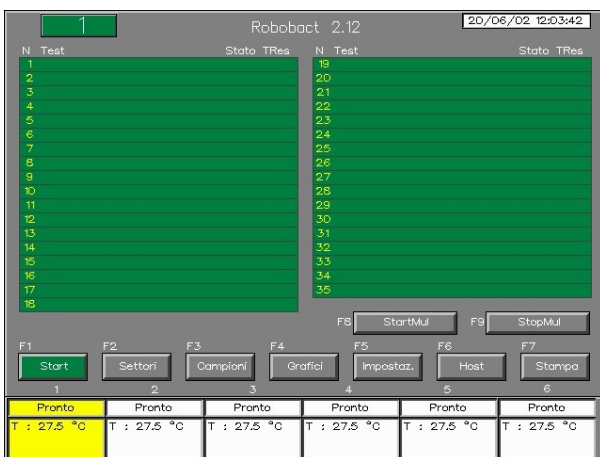


The status messages that may be displayed in the dialogue window are the following :

<b>READY</b>	= The instrument is ready for the cycle to start.
<b>STANDBY</b>	= A cycle has started, the motor resetting phase is in progress
<b>IDENTIFICAT.</b>	= A cycle has started, the sample recognition phase is in progress
<b>BREAKING</b>	= The instrument is in the breaking phase of the sample that occupies the position indicated by the arrow.
<b>SOWING</b>	= The instrument is in the sowing phase of the sample that occupies the position indicated by the arrow.
<b>IN CYCLE</b>	= General running conditions.
<b>STANDBY</b>	= If we stop a cycle we have to wait for the operation in progress to be concluded.
<b>NOT CONNECTED</b>	= Connection problems between the module and the PC.



Some messages, such as BREAKING of the sample container and SOW, indicate operations that the machine is carrying out on a specific sample which is indicated in the main menu with an arrow next to the number of the position it occupies.



If there are 2 or more modules connected to the **Processing Unit**, the same number of dialogue windows will be displayed as the modules connected.

Each module will be numbered (from 1 to 6)

To display the situation relating to a specific module on the screen, press the corresponding dialogue window.

Otherwise press the number corresponding to the module you want to select on the keyboard.

Table of the samples

The central section of the page contains 35 rows divided into two columns. The following is indicated in order in each row:

N	Test	Stat.	TRes
---	------	-------	------

- N** = the number of the position of the sample-holder tray
- Test** = the type of test being performed
- Stat.** = the current status of the test or error status (See table below)
- Tres** = the time (HOURS: MINUTES) remaining until the end of the current status

The " **Stat.** " column in the sample table may take on the following values:



- **WAIT** : standby phase for the urine test before the sowing
- **WRK** : breaking or sowing phase
- **ENR** : enriching phase
- **INC** : incubation phase
- **END** :end of sample analysis
- **ERR1** : incongruence with the sample status
- **ERR2** : barcode-reading error during the identification
- **ERR3** : sowing error
- **ERR4** : test not found in the test configuration table.

Robobact SPECIAL

Once the cycle has started, the dialogue window of the Robobact **Special** module will also show the indication of the percentage of oxygen (Ox:) measured inside the machine.

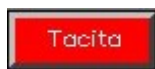
The correct functioning of the solenoid valves that allow access of the **NITROGEN** and **CO<sub>2</sub>** into the instrument is also displayed by means of the following indications:



-  The gas is introduced correctly.
-  The gas indicated is not available. (e.g. bottle empty).



In this case an **acoustic alarm will** be activated a red key will appears with the word **"Silent"**. The cycle will not be stopped. If there is a new bottle on hand it is possible to replace it during this phase without interrupting the cycle. After connecting the new bottle the alarm will stop and the **"Silent"** key will disappear. The acoustic alarm will stop and the functioning indications for the two GASES will turn green again.



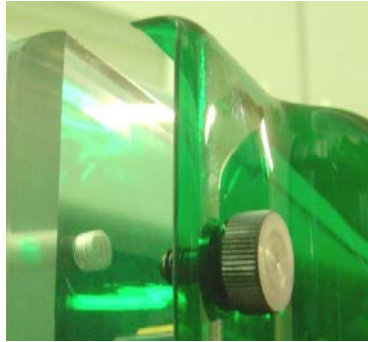
If there is no reserve bottle on hand it is still possible to turn of the acoustic alarm by pressing the **"Silent"** key, and continue the test cycle while still showing the indication of the oxygen percentage that has been reached.

The bottle can also be replaced at any time later on without stopping the cycle.

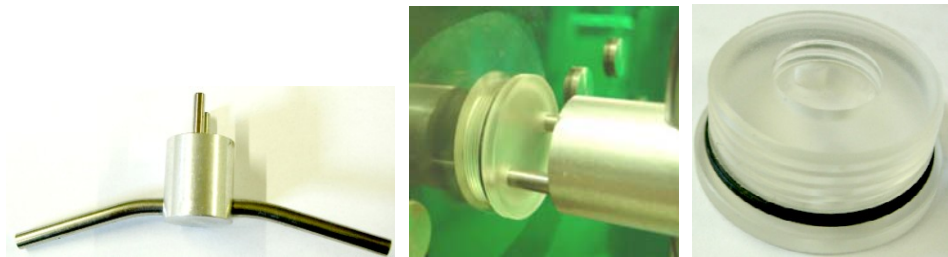


**WARNING:** in case of the electrical current being cut off or whenever the door of the ROBOBACT SPECIAL remains locked, in order to OPEN the door and retrieve the samples it is possible to use the emergency key, by following the procedure below:

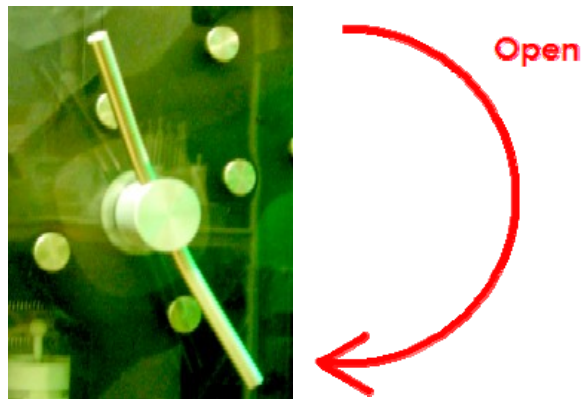
Loosen the two black bushings anchoring the green plastic cover of the lid, and then open the green cover.



Insert the key into the centre of the door and remove by turning the plastic cap in an anticlockwise direction.



Then insert the key into the centre once again and force it in a CLOCKWISE direction to open the door.



Once the door is open, replace the central cap turning it in a clockwise direction by hand, then attach the green plastic cover again and tighten the two black bushings.

Description of the controls:



This starts up the cycle. The word "**Start**" becomes "**Stop**" and the key turns red. The door, which must be closed, is locked.

---



This stops the cycle. The "**Stop**" key turns orange until the instrument is ready to stop. The sample being processed will however be terminated.



- An acoustic signal warns that the door is unlocked and can now be opened.
- The cycle is over, and the word "**Stop**" on the key becomes "**Start**".



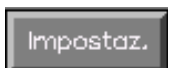
This command allows the user to enter AUTOMATIC sample insertion mode. (See INTRODUCTION OF SAMPLES – Insertion with automatic mode).



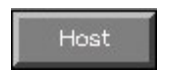
This opens a new window (**Process Table**) where it is possible to view all the information regarding the samples, sector by sector.



This opens the window containing the graph of the temperatures recorded over the last 50 hours. In the Robobact Special the oxygen concentration is also displayed.



This control allows the user to enter the machine programming pages and start up the Service sub-programme.



This key can be used for displaying the status of the samples to be sent to the HOST COMPUTER. It only works if the connection with the HOST has been configured.



If a printer is connected to the Processing Unit it will be possible to print the work plans in progress.

If two or more modules are connected up to the same *Processing Unit*, two additional control keys will also be displayed.



With the **MULTIPLE START** it is possible to start up the cycle on all the connected modules, obviously the start up will take place gradually, one module at a time, starting from module 1. Once module 1 has finished the recognition phase, the cycle starting phase will pass on to module 2, and so on until the automatic starting of the last module connected.



In the same way it is possible to stop all the modules involved in the cycle by pressing the one single **MULTIPLE STOP** key.

## Description of the "Process Table" window



This window, selected by pressing the **Campioni** key on the main menu, displays all the information regarding the samples present.

The table shows the 5 positions all at once, and for each sample it indicates the following:

Tabella di processo 05/06/00 12:45:51 **DIESE**

Posizione	1	2	3	4	5
Desc. Test	Urine culture	Urine culture	Urine culture	Salmonella Shigella	Rectal Swab #2
Cod. campione	0123456	3MDD1234	00112233	00112234	00112235
Data/Ora inizio	05/06 12:37	05/06 12:44	05/06 12:43	05/06 12:43	05/06 12:43
Arricchimento				□□□□□	□□□□□
Semina	05/06 12:38	05/06 12:46	01/01 00:00	05/06 18:45	05/06 18:45
Incubazione	□□□□□□□□□□	□□□□□□□□□□	□□□□□□□□□□	□□□□□□□□□□	□□□□□□□□□□
Data/Ora fine	06/06 02:38	06/06 02:46	01/01 09:02	06/06 12:45	06/06 12:45

F1 Modulo    F2 SettPrec.    F3 SettSucc.    F4 Esci

- The position of the sample
- The description del test
- The sample barcode (if present)
- Date and time of beginning the process
- Total enriching time (set) and time spent in graphic form
- Date and time of sowing. If grey, this indicates the estimated time. If green, the sowing has already been carried out
- Total incubation time (set) and spent in graphic form.
- Date and time estimated until the end of the process (if grey). If green, the sample has already finished the cycle.

Each square in the graphic form represents 1 hour set for that specific phase and it changes colour with each hour that passes.

In the example on the left there are 12 squares, four of which are coloured, meaning that 12 hours have been set for the incubation and that the sample has already carried out four of these.



This control allows the user with a multi-module structure to pass from module to the next.



This shows the five samples of the previous section on the tray.



This shows the five samples of the next section on the tray.

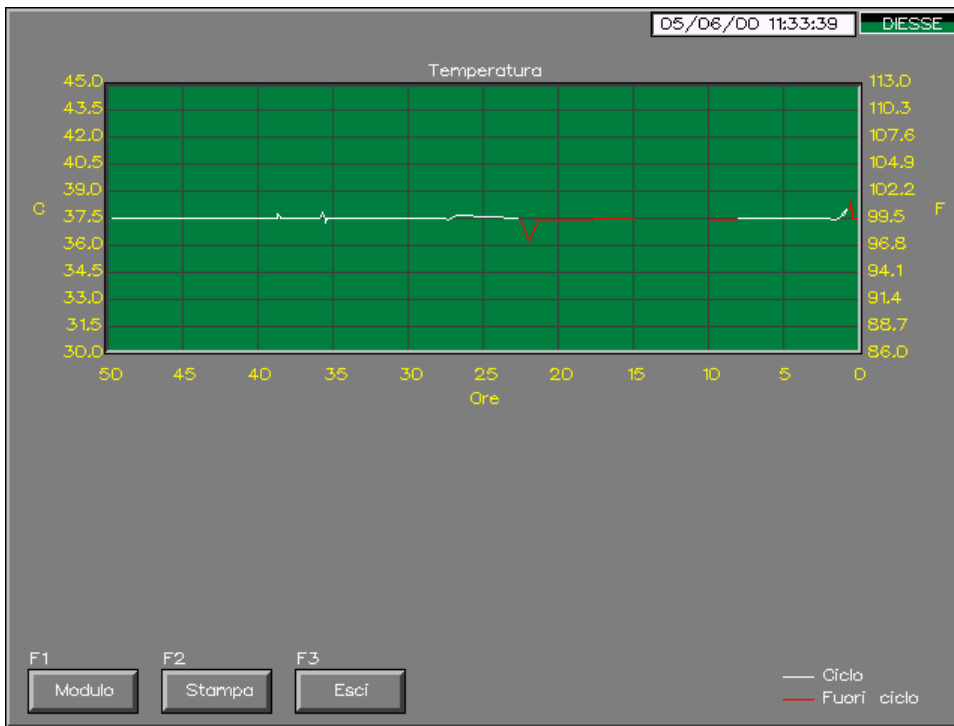


This closes the window and returns to the main menu.

## Description of the graphs

Grafici

By pressing the **Grafici** key on the main menu it is possible to view the recordings of the temperature data in °F and °C over the last 50 hours.



As the hours pass the temperature curve takes on the shape of a line with the following characteristics:

- **white** dots: the module is active and undergoing the cycle.
- **red** dots: the module is active but outside the cycle.
- **no** dots: the module is turned off.

In case of power supply cutouts it is possible to estimate how many hours the instrument remains turned off by the length of the missing section on the line of dots.

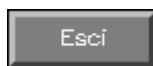
The temperature range displayed is between **30 °C** and **45 °C**. No dots will be indicated outside this range.



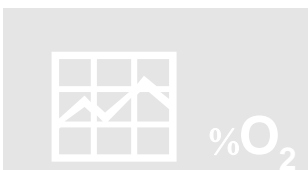
This control allows the user of a multi-module structure to scroll from one module to another.



This creates a black and white printed copy from a standard parallel printer.




This closes the window of the graphs and returns to the main menu.



In the Robobact **SPECIAL** module the graph of the **oxygen** % recorded in the machine over the last 50 hours will also be displayed.



## Programming the machine. Description of the "SETTINGS" menu

By pressing the  key on the main menu when the machine is NOT operating in the Cycle, the following menu will be displayed:



- By pressing the **MODULE ACTIVE** key the user can modify the current module in the multi-module operation.


- By pressing the **GENERAL SETTINGS** key the user can set the Date and Time.

- By pressing the **SET METHODS** key the user can change the enrichment and incubation times in the methods, as well as the temperature and enabling of the breaking of the Par-Test.

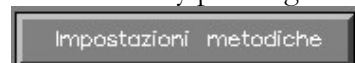
- By pressing the **SERIAL NUMBER** key the serial number of the module will be displayed.

- By pressing the **SERVICE** access is gained (by means of the password) to the Service sub-programme that allows the user to change the machine parameters.

- By pressing the **EXIT** key the user returns to the main window.

If the machine is operating in the Cycle by pressing the  key from the main menu the following **reduced** window will be displayed:

In this case by pressing the key:



it will ***only be possible to view*** the enrichment and incubation times that have been set. During the cycle these parameters cannot be modified.





## Description of the " General Settings" menu

By pressing the  key on the SETTINGS menu, the following page will open:



This page allows the user to set the following parameters:

- System date
- System time

**N.B.:** The parameters described can only be modified when no work cycles have been activated in the instrument.


In order to modify a value, just select the value with your finger. It will turn green and at this stage press the



key and a virtual keyboard



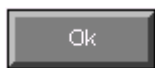
Will appear on the screen. The item you have selected will be displayed at the top as well as the field to be modified.

To cancel the current value press the .key.

Then enter the new value using the numeric keys.

To transfer the modification confirm by pressing the .key.

The keyboard will disappear and the new value will be displayed.



This closes the window and saves all the modifications.

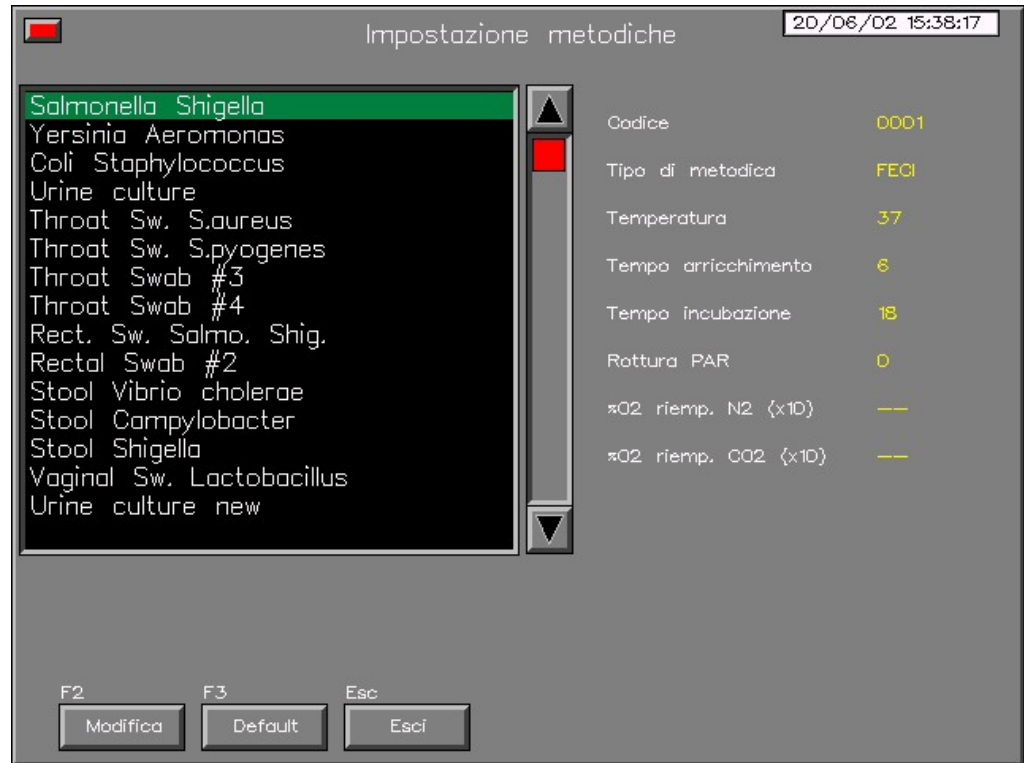


This closes the window WITHOUT SAVING any of the modifications.

## Description of the " Set methods" menu

Impostazioni metodiche

By pressing the **Impostazioni metodiche** key on the SETTINGS menu the following window will open:



This menu allows the user to view the characteristics of the enrichment and incubation methods as well as the temperatures and times.

To change a method, just select the one you want with your finger (or use the arrow keys) and press the **Modifica** key to make the **change method** window

Default


Attention: by pressing this key all the method characteristics will be taken back to the Default values set on the machine (those recommended by DIESSE Diagnostica Senese S.p.A.). All the changes made to the methods, enrichment and incubation times etc., will be lost.

Esci

This closes the window.

**N.B.:** The parameters described can only be changed if the system is not operating in the work cycle.

Changing the parameters of a method

By pressing the  key the following window will be opened:



The parameters that can be changed are:

**Temperature**, settable between 30° and 45°C.


**Enrichment time**, corresponding to the *hours* of mixing the sample before sowing.

**Incubation time**, the hours of incubation after the sowing, at the end of which the instrument will indicate END.


**Breaking PAR-test**, if using the par-test set this value to **1**.

It is also possible to change several parameters concerning the type of atmosphere that has to be generated inside the machine for that specific method.



By pressing the  key the user can select a type of pre-defined atmosphere for the method:

**Normal, Campylobacter, Anaerobic, and with 10% of CO<sub>2</sub>.**

By pressing the  key instead, it is possible to create a special atmosphere, and set the values of the % of O<sub>2</sub> to be reached, using **Nitrogen** or the **CO<sub>2</sub>** (the values are multiplied by 10).



The value of 240 (equal to 24%) means that you do not want to use that gas for lowering the % of O<sub>2</sub>.

**It is recommended to use these parameters only after consulting the technical personnel of DIESSE Diagnostica Senese S.p.A..**

Obviously the methods that envisage special incubation atmospheres (e.g.. *Stool Campylobact*), must only be used in the **ROBOBACT SPECIAL** systems.

## Introducing the samples

To prepare the samples read the **technical instructions** enclosed in the package.




ATTENTION: the samples contain potentially infected material

Two different methods can be selected for introducing the samples.

- **A) “MANUAL METHOD”** – this foresees the disabling of the revolving motor of the sample-holder tray and therefore, the manual handling of the same for introducing the samples.
- **B) “AUTOMATIC METHOD”**, this allows the introduction of samples with the barcode via the automatic movement of the tray, moving forwards with groups of five positions at a time.

Pronto

In order to introduce the samples move onto the main menu, the instrument must be in the READY condition (displayed in the dialogue window). If the instrument is in the cycle, it must first be stopped by pressing the  key

The cycle can be stopped at all times. Any samples already present inside will be stored in the memory and consequently recognised on starting up a new cycle, with their processing starting up from where it left off.



In the case of samples using a modified atmosphere (*Robobact Special*) it is recommended to limit the insertion/withdrawal actions of the samples to two/three times a day only. This will prevent the loss of the correct concentration of air every time the door is opened and the consequent restoring of the same due to the high consumption of the gases.

🔒 Whenever the instrument is operating in the work cycle, the door will be locked.

🔓 To open the door it is necessary to stop the cycle.

After having pressed the STOP key, a request for confirmation will be displayed:



Press the  key, and the sign  will appear.

Wait a few seconds until the ready  sign appears.

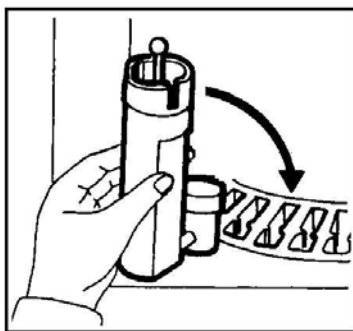
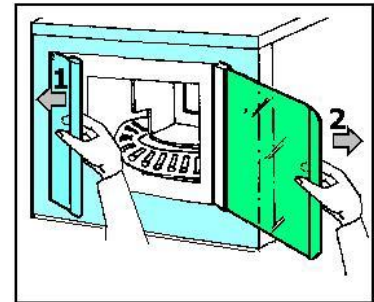


An acoustic signal will advise that the door has been unlocked.

At this stage it is possible to start introducing the samples.

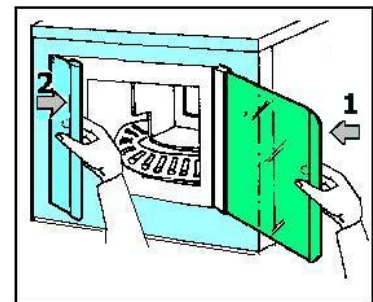
### Introducing samples with the "MANUAL METHOD "

Open the door and follow the sequence shown in the figures.

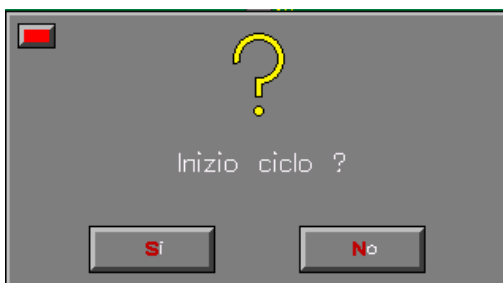



Insert the devices into the accessible housings and start moving the tray forwards manually, until all the samples to be tested have been inserted or the maximum capacity of the instrument has been reached (35 samples).

Then close the door again following the sequence in reverse.



Press the  key on the main menu.



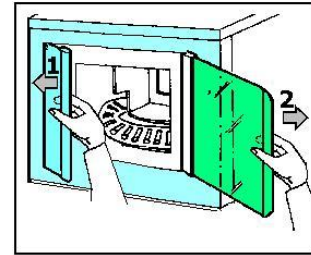
Give consent to start the cycle on the confirmation menu by pressing the  key.

 At this stage the door will be locked and the cycle will start up.

Introducing samples with the " AUTOMATIC METHOD "

This method is used whenever the BARCODE of the sample has to be inserted

Open the door following the sequence in the figure.



Press the key present on the main menu. A new menu will appear similar to the previous one called " **Introduction of samples** "



**ATTENTION: THE SAMPLE-HOLDER TRAY WILL START MOVING. IT IS PROHIBITED TO REMOVE OR INTRODUCE THE DEVICES WHILE THE TRAY IS IN MOVEMENT.**

Introduzione Campione 05/06/00 12:20:11 **DIESE**

N	Codice	Test	Stat.	N	Codice	Test	Stat.
1		Urine culture	INC	19		Urine culture	WAIT
2		Urine culture	INC	20		Rectal Sw Salmon.Shig	ENR
3		Urine culture	INC	21		Urine culture	WAIT
4		Rectal Sw Salmon.Shig	ENR	22		Salmonella Shigella	ENR
5		Rectal Swab #2	ENR	23		Urine culture	WAIT
6		Urine culture	INC	24		Rectal Swab #2	ENR
7		Rectal Swab #2	ENR	25		Urine culture	WAIT
8		Urine culture	INC	26		Urine culture	WAIT
9		Throat Sw S.aureus	ENR	27		Throat Swab #3	ENR
10		Rectal Swab #2	ENR	28		Urine culture	WAIT
11		Urine culture	INC	29		Rectal Swab #2	ENR
12		Throat Swab #3	ENR	30		Rectal Swab #2	ENR
13		Urine culture	WAIT	31		Throat Swab #3	ENR
14		Rectal Swab #2	ENR	32		Rectal Swab #2	ENR
15		Rectal Swab #2	ENR	33		Throat Swab #3	ENR
16		Throat Swab #3	ENR	34		Rectal Swab #2	ENR
17		Urine culture	WAIT	35		Rectal Swab #2	ENR
18		Throat Swab #3	ENR				

F1 SettPrec F2 SettSucc Esc Esci

**ATTENZIONE! MOV. VASSOIO**

Quando si è pronti, chiudere la porta per iniziare il ciclo

Attesa  
T : 37.5 C

The instrument positions itself with the first 5 positions in front of the door.

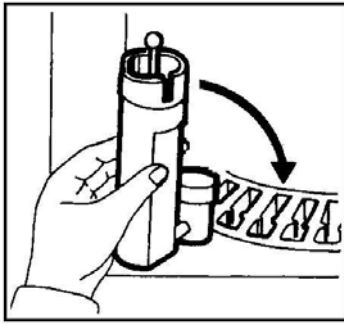
The 5 positions will be highlighted with a white background on the display.



**ATTENZIONE! MOV. VASSOIO**

**ATTENTION:** Every time a sector is moved, the tray will be in movement. Wait for this message to disappear before inserting the samples.

If the instrument is connected to the HOST computer and the barcode is present on the samples, it will be possible to match the position occupied by the device with the barcode of the sample.





Before introducing the sample container into the device make a reading of the barcode (by means of the reader located to the left of the video, or by using an external barcode reader). Then introduce the sample container into the device and insert this into the free positions in the sample-holder tray located in front of the door. The sample barcode will immediately be displayed on the screen in the position on the tray in which the device has been inserted.

**ATTENTION: DO NOT REMOVE OR MOVE THE DEVICE ONCE IT HAS BEEN MATCHED WITH A POSITION.**

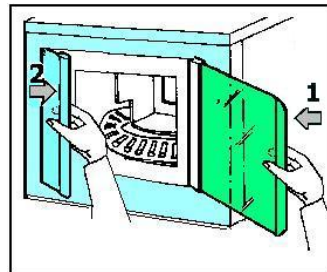
Continue as indicated above with the introduction of all the devices into the accessible positions.

**DO NOT MOVE THE TRAY BY HAND!**

Move onto the 5 following positions, press the  key and continue until there are no more free positions left.

To return to the previous sector press the  key and continue introducing the samples until there are none left to be tested or until the maximum capacity of the instrument has been reached (35 samples).

Then close the door again.



ATTENTION:

**After the door has been closed the cycle will start up automatically**

The video will display the main menu again and the work cycle will start up **AUTOMATICALLY**.

Identification and processing of the samples

Once the cycle has started up, the instrument begins the sample identification phase.



The position that is being analysed at the moment will be highlighted with a white background on the main menu and if a device is present the following information will be displayed:

- description
- status (if Enrichment ENR or Incubation INC)
- the time remaining until the end of that status.


At the end of the identification phase the processing of the samples present will begin, always by observing the following priorities during the operations:

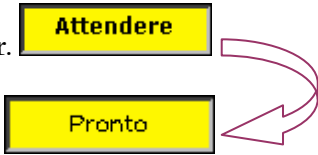
- the urine samples have precedence over the others and will immediately be moved on to the sowing phase.
    - After this, the instrument carries out the sowing of the samples that have already terminated, or do not call for enrichment.
- Finally, it waits until the termination of the enrichment of the remaining samples and then starts to process these.

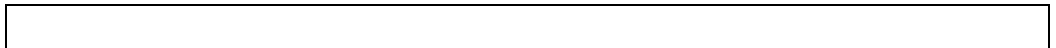
During the cycle the instrument displays the type of operation in progress in the dialogue window (e.g. sowing, breaking of sample, etc.), and at the same time indicates



the specific sample in question with an arrow alongside the number illustrating the position.

The cycle can be stopped at any time by pressing the  key.

Wait for the “READY” sign to appear before opening the door. 



**DECLARATION OF CE COMPLIANCE****In accordance with the EC 98/79/EC directive on in vitro diagnostic medical devices*****Diesse Diagnostica Senese S.p.A.***

The company DIESSE DIAGNOSTICA SENESE S.p.A. with office in Milan, Via San Vittore 96/1

**Declares**

that, on the basis of its design and type of constructions, as well as the version already marketed, the in vitro diagnostic medical device defined hereunder,

**is compliant**with the **“98/79/EC DIRECTIVE ON IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVD)”**

via the fulfilment as per Enclosure III (except for section 6) and as per the fundamental prerequisites in Enclosure I.

This declaration shall be devoid of validity in the case of:

- any modifications made to the machine in question without our authorisation
- an incorrect use of the instrument
- any technical intervention carried out by unauthorised personnel
- the installation of non-original spare-parts.

Product: **Automatic bacterial sowing and incubation unit**Type: **ROBOBACT / ROBOBACT Special**Technical data: **110-220 Vac (50-60 Hz)**Product: **Control and processing unit**Type: **PROCESSING UNIT**Technical data: **110/220 Vac (50-60 Hz)****is compliant**

as an assembled unit and in all its individual parts, with the following regulations and amendments :

**EN 61010-1 “ Safety requirements for electrical equipment for measurement, control and use in laboratories – Part 1: General requirements ”.****EN 61326-1 “Equipment for Measurement Control and Laboratory Use – Requirements for electromagnetic compatibility – Part 1: General requirements”.**

and therefore satisfies the minimum requirements of the following community directives and their amendments:

**EC Directive on low tension (73/23/EEC)****EC Directive on electromagnetic compatibility (89/336/EEC) and (93/68/EEC)**

Milan,

2004

Signature: General Manager

A handwritten signature in blue ink, appearing to read "F. W. ...", written over a horizontal line.