



SPITALUL ORĂȘENESC BUHUȘI

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Revizia
Exemplarul.....

Protocol Incubator Digital pentru teste biologice Dupa Manual de utilizare tradus din Limba engleza

Model: DI SCBI

Continut:

1. Instalare
2. Utilizarea incubatorului
3. Garantie
4. Calibrare incubator
5. Certificat de conformitate

Figura 1/ pag. 1

1. INSTALARE

Pentru asigurarea unei utilizari optime a Incubatorului digital SCBI, va rugam sa urmati instructiunile date in acest capitol pentru instalarea sa

1.1 Locatie

Incubatorul trebuie sa fie situat intr-un mediu necoroziv si in acelasi timp sa nu fie in apropierea surselor cu radiatii electro-magnetice (cum ar fi motoare, centrifuge, etc.), a unor surse de caldura sau plasat direct la soare.

El trebuie sa fie asezat pe o suprafata spatiosa si plata. Pastrati-l la distanta de cel puțin 15 cm de cel mai apropiat perete.

Figura 2/ pag. 2

Placuta cu numarul serial al aparatului Conectare cu cablu Buton de Pornit/ Oprit

1.2 Alimentarea

Inainte de conectarea Incubatorului la sursa de current trebuie observate cateva aspect ale sursei de current, trebuie facute cateva simple verificari.

1.2.1 Calitatea alimentării

Este foarte important să conectăm Incubatorul la un sistem electric de calitate. Este foarte important ca prize de alimentare să aibă împământarea făcută.

Orice problemă de funcționare a Incubatorului trebuie anunțată, dar mai întâi opriți aparatul și verificați dacă acesta nu este plasat în apropierea unei centrifuge sau alt echipament care conține un motor cu acțiune electro-magnetică, ce poate genera zgomot puternic. În acest caz, plasați Incubatorul departe de orice asemenea echipament.

1.2.2 Verificarea tensiunii și frecvenței alimentării

Incubatorul este proiectat să lucreze la următoarele tensiuni:

220 V AC 50 Hz, monofazic, cu împământare (Gama 90-270 CAC/ 50-60 Hz)

Atenție: Utilizarea sub gama menționată mai sus poate cauza defectiuni iar Incubatorul nu poate funcționa corect și se poate strica.

1.2.3 Alimentarea

Dacă tensiunea este cea recomandată pentru Incubator, continuați astfel:

- Verificați ca butonul este în poziția Oprit
- Conectați cablul, mai întâi la aparat și apoi la rețeaua electrică
- Acționați Butonul în poziția Pornit.

2. Utilizarea Incubatorului

2.1. Comenzi

În Figura 3, de mai jos, puteți observa panoul frontal de comandă. Va rugăm citiți și verificați comenzile.

Afisari:

- a) Display – arată meniul și parametrii de proces
- b) Putere – Se aprinde de fiecare dată când aparatul este conectat
- c) PWM – Se aprinde constant și intermitent când menține temperatura

Figura 3/ pag. 4

Comenzi:

- 1) Buton Start/ Stop – Porneste sau opreste incubarea
- 2) T1: Incubare pentru sterilizarea la abur – Selectează parametrii pentru incubarea pentru abur
- 3) T2: Incubare pentru sterilizarea cu ETO - Selectează parametrii pentru incubarea pentru eto
- 4) T3: Incubare pentru sterilizarea cu plasma - Selectează parametrii pentru incubarea pentru plasma
- 5) SET- Nu se utilizează .

2.2 Operarea cu Incubatorul

Pornind Incubatorul sunt prezentate urmatoarele afisaje:

Afisaje de pornire

Acestea sunt aratate de fiecare data cand micro-procesorul porneste si senzorii sunt verificati

Figura 4/ pag. 5.

SP Medikal - Buton pornit

Cuva uscata a incubatorului - Pornit

Verificarea senzorului - Pornit/ PWM

Dupa fereastra initiala, in figura 5, mai jos este prezentata urmatoarea fereastra. Aceasta va invita sa selectati T1, T2 sau T3. Selectati una din cele 3 cicluri de incubare apasand unul din butoanele.

Fig. 5 / pag. 6

Dup ace ati selectat T1, fereastra va va arata ciclul selectat de incubare si incepe sa incalzeasca sau sa scada temperature la valoarea necesara. Incalzirea va dura numai 5 minute cand temperature mediului inconjurator este in jurul valorii de 20 grade Celsius. In timpul incalzirii ledul PWM va fi aprins continuu.

Racirea intregului dispozitiv , de la 58 la 37 grade Celsius, dureaza aproximativ 30 minute . Tineti capacul deschis pentru a permite partii din aluminiu negru sa se raceasca mult mai rapid.

Fig. 6/ pag. 6

Abur	58°C	Putere	PWM
Incalzire	21°C		

Odata ce temperatura a ajuns la valoarea necesara, display-ul va arata doua mesaje intermitente de ex.:

“Temperatura atinsa” si “Apasati tasta START”. De indata ce ati pus in incubator fiolele si ati inchis capacul, puteti apasa butonul START si poate incepe procedura de incubare.

Fig. 7/ pag. 6

Abur	58°C	Abur	58°C
Temperatura atinsa		Apasati tasta START	

Dupa ce procesul de incubare a inceput, urmatoarea fereastra va ramane active pana la sfarsitul perioadei de incubare. Pentru abur 24 ore

Fig. 8/ pag. 7

Abur	58°C	Timp	23:59:59
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Dupa perioada de incubare, cand expira timpul si este 00.00.00 un semnal de alarma este auzit pana cand este apasat butonul Start/ Stop.

Fig. 9/ pag. 7

Abur 58°C

Timp 00:00:00

Fereastra este in zona de selectie din nou.

3. Garantie

Producatorul a acordat foarte multa atentie producerii Incubatorului. Acesta a fost supus unui program de testare de 24 ore inainte de a fi impachetat. Impachetarea este astfel realizata incat sa garanteze livrarea pana la clientul final.

Va rugam sa verificati integritatea cutiei la receptive. Daca este vizibila o deteriorare a ambalajului va rugam sa anuntati printr-o nota transportatorul. Eventualele plangeri referitoare la ambalaj trebuie facute transportatorului iar cele referitoare la continut in maximum 24 ore de la receptive.

Incubatorul are garantie 1 an. Va rugam pastrati ambalajul sau original in eventualitatea ca el va trebui schimbat.

ELABORAT : AS. PR. MED
MAREȘ MARIANA

DATA: 24.03.2015

VERIFICAT : DIRECTOR MEDICAL.

VERIFICAT : BIROU CALITATE



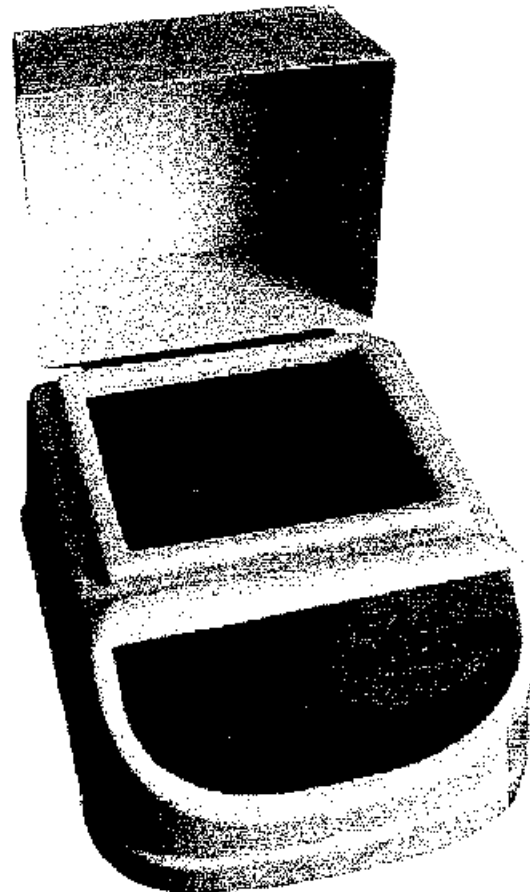
APROBAT : MANAGER



User Manual

Digital Incubator for Self-Contained Biological Indicator

Ref.: 120.001.0001
Model: DI SCBI



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- 2 Operation of the incubator
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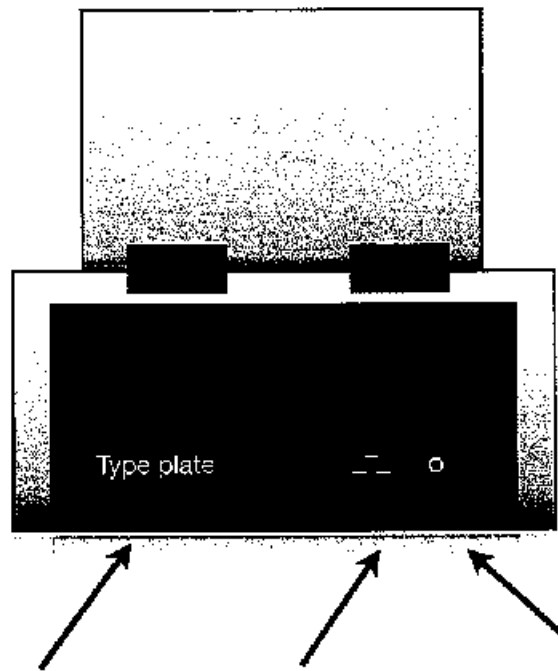
1 Installation

In order to ensure an optimal operation of the Digital SCBI incubator, follow the instructions given in this chapter to install it.

1.1 Location

The Incubator must be situated in a dry and non-corrosive environment. In addition, it must not be near a source of electro-magnetic radiation (such as motors, centrifuges, etc.) or a source of heat, nor directly placed in sunlight.

It must be located on a flat and spacious surface. Keep a distance/gap of at least 15 cm to the nearest wall at all sides.



Type plate with serial number

Power cable connection

Power Supply Switch

1.2 Power supply

Before connecting the Incubator to the power supply, some aspects of the electrical supply to which it is to be connected should be observed, as well as carrying out some simple checks.

1.2.1 Quality of power supply

It is very important to connect the Incubator to a good electrical system. It should be as exclusive as possible, and it is absolutely imperative for it to have an earth connection for a correct working.

If a malfunctioning of the Incubator is noticed, switch-off the unit and check that it is not near centrifuges or machines containing motors or electro-magnets, which can generate strong electrical noise. In such a case, place the Incubator far from such equipment.

1.2.2 Checking the supply voltage and frequency

This Incubator is designed to work at the following voltages:

220 V AC 50 Hz single phase incl. earth connection (Range 90- 270 VAC / 50 – 60 Hz)

ATTENTION: Working beyond the range limits will cause the Incubator to function incorrectly and the Incubator may be damaged.

1.2.3 Connection to power supply

Once the voltage of the power supply is checked to be corresponding to that of the Incubator, proceed as follows:

Check that the switch is in the OFF position.
Connect the power cable, first to the apparatus, then to the electrical power supply.
Put the power supply switch in the ON position.

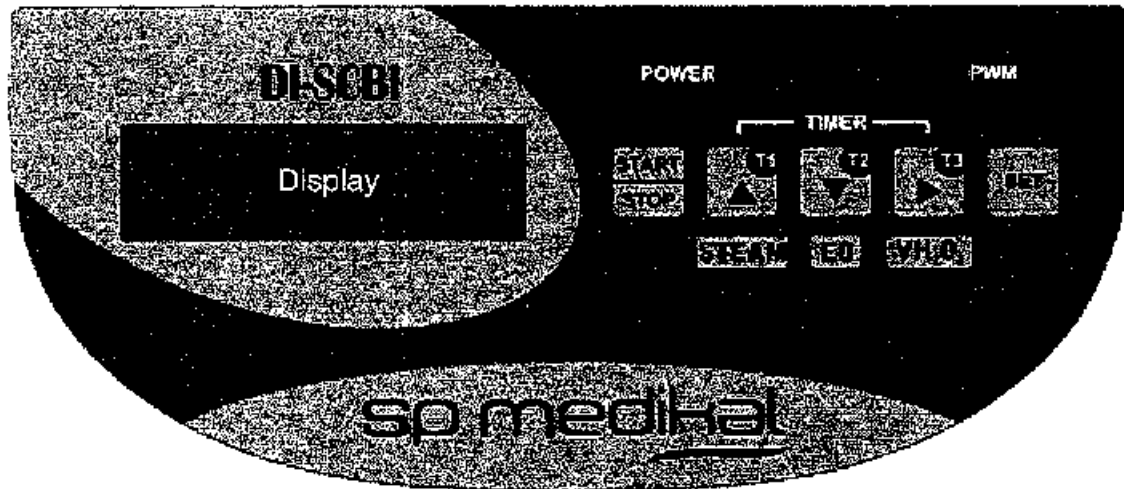
2 Operation of the incubator

2.1 The controls

Below you see the front control panel of the Incubator. Please read and check the controls.

Displays:

- | | |
|------------|--|
| a) Display | Display the menu and process parameters |
| b) Power | Is light up at all times when the main switch is switched on |
| c) PWM | Will constantly light while heating up, blinking at maintaining temp |



Controls:

- | | |
|------------------------|---|
| 1) Start / Stop button | To start or stop the incubation count-down |
| 2) T1: STEAM SCBI | To select the STEAM SCBI process parameters |
| 3) T2: EO SCBI | To select the EO SCBI process parameters |
| 4) T3: Plasma SCBI | To select the Plasma process parameters |
| 5) Set | Not used by users. |

2.2 Operation of the Incubator

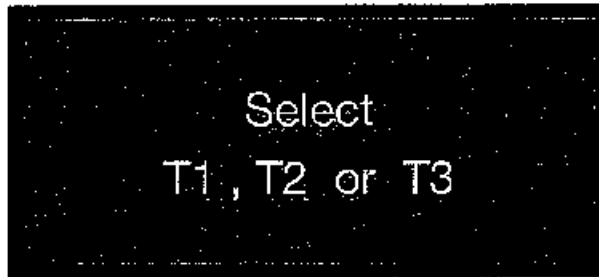
At switch on the Incubator the following screens will be presented:

Welcoming screens.

These are shown after each other while the micro-processor is starting and sensors are checked.



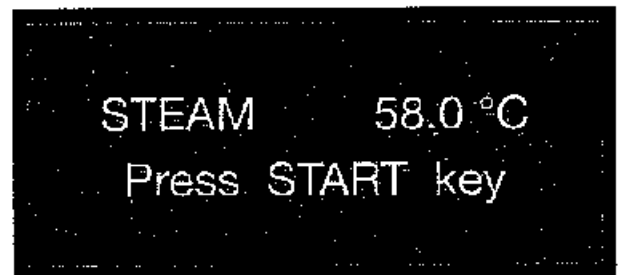
After the opening screens have passed the following screen is presented. It invites you to make a selection from T1, T2 or T3. Just press one of the three required Incubation cycle by the respective push buttons.



After you selected T1 the screen will show you the selected Incubation cycle and starts heating up or cooling down to the required temperature. Heating up will take only 5 minutes when the surrounding temperature is around 20 degrees Celsius. During heat up the PWM Led will continuous light. Cooling down is costing about 30 minutes from 58 to 37 degrees Celsius as the complete block need to cool down. Please keep the cover open to let the aluminum block cool off more rapidly.



Once the temperature has been reached the display will show you two intermitting messages i.e. 'Temp. reached' and 'Press START key'. Once you placed all SCBI and closed the cap you may press the START key to start the incubation timer.



After the incubation process started the following screen is displayed until the end of the incubation time has reached. The Time is counting back.



After the Incubation time has been reached, timer is 00.00.00 an audible alarm starts beeping until the Start/Stop button has been pressed.



The display is returning to the selection screen again.

3 Warranty

We have paid much attention to the Incubator while producing them. They have undergone 24 hours of testing before packing them. The packaging has been specially developed in order to guarantee a delivery to our customers.

Please check the carton upon receipt. When any damage is visible report this on the delivery note of the forwarder upon receipt. Later claims of broken or damaged packaging cannot be claimed afterwards with most of the forwarders.

Upon receipt please check the content carefully. Only complaints reaching us within 24 hours after receipt will be taken into account.

The Incubator has a 1 year warranty on defective parts by exchange. Please keep the original packing for future use.

Certificate of Conformity

This Digital Incubator DI- SCBI has been designed and tested in accordance with the current European directives applicable for these kind of laboratory equipment.

To whom it may concern

In accordance with European directives 2006/95/EC (Low voltage directive) and 2006/42/EC (EMC directive) we hereby declare that the listed products conform to the published specification and complies with the requirements of the following European Standards and to their current amendments.

- ★ BS EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
- ★ BS EN 61326-3-1:2008 Electrical equipment for measurement, control and laboratory use. EMC requirements. Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety). General industrial applications

Further to these type tests each individual unit has been undergoing 24 hours of works test and finally a works calibration to meet the 1,0 degrees Celsius accuracy.

Based upon the above mentioned tests and their results the Digital Incubator is carrying a CE-mark at the back the unit.

16th June 2012


Seda Kücüylmaz
Quality Department


Peter M. den Uil (B. Sc.)
Managing Partner