

3 SPECIFICATIONS OF THE INCUBATOR

3.1 Technical specifications

MODEL	DG THERM	
LOAD CAPACITY	<ul style="list-style-type: none"> • 24 DG Gel cards • 24 sample tubes 	
INCUBATION BATCHES	2 batches with independent timer	
INCUBATION TEMPERATURE	37 °C ± 1°C	
TEMPERATURE UNITS	Programmable, °C or °F	
INCUBATION TIME	15 minutes, modifiable	
PREHEATING TIME	Approximately 6 minutes	
ALARM SYSTEMS	Yes, two independent sensors to measure and control temperature	
ACOUSTIC ALARM	Yes, to indicate end of incubation and error situations	
VOLUME OF ACOUSTIC ALARM	Programmable, 3 levels	
INTERFACE	LCD screen and Buttons	
SUPPLY	Voltage:	100–240 V ~
	Frequency:	50-60 Hz
	Input power:	270 W
PROTECTION AGAINST ELECTRIC SHOCK	Class:	I
INSTALLATION CATEGORY	Overvoltage category II (local level, appliances, portal equipment, etc.)	
DIMENSIONS (mm)	325 (depth) x 295 (width) x 95 (height)	
WEIGHT (Kg)	Approximately 4 kg.	

1 INTRODUCTION

**THIS EQUIPMENT IS AN *IN VITRO* DIAGNOSTIC MEDICAL DEVICE
(IVD).**

These Instructions for Use, which are intended for the OPERATORS of the *DG Therm* incubator, contain all the information that is necessary for safely and adequately working with the instrument.

Please carefully read all this information before attempting to work with the equipment, especially on the maintenance section, the suggestions for correct use and the information about contaminating liquids.

If you have any doubt please contact the manufacturer or corresponding distributor before starting any operation.

These Instructions for Use should be accessible to all the personnel who work with the instrument.

1.1 Intended use

The *DG Therm* incubator enables carrying out thermostatisation at 37°C of *DG Gel* cards for a pre-established incubation time.

1.2 Purpose, limitations and operator training

1.2.1 Purpose

The *DG Therm* incubator has been especially designed to carry out thermostatisation of 24 *DG Gel* cards and/or corresponding sample tubes of those techniques that require incubation at 37°C. For more information, consult the Instructions for Use of the *DG Gel* cards for the different techniques.

Incubation will take place by means of a dry heating bath at 37°C for a pre-established time of 15 minutes. The *DG Therm* incubator has two independent timers that will enable carrying out two independent incubation batches.

1.2.2 Limitations

The *DG Therm* incubator is only prepared to carry out incubation of *DG Gel* cards as described in section 1.1 "Intended Use" and should not be used for any other type of test different to those for which it was designed.

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of *DG Gel* cards into the Block as the opening is connected to a card elevation system located in each Incubation area.

4.1.3 Start/stop timer buttons

The *DG Therm* incubator has two Start/stop buttons (Ref. (3), Figure 1), **P1** (Ref (1), Figure 4) and **P2** (Ref. (2), Figure 4), that allow to start/stop both incubator timers independently.



Figure 4: **P1** and **P2** buttons.

- (1) **P1**: Start/stop timer button 1
- (2) **P2**: Start/stop timer button 2

4.1.4 Display

The Display (Ref (4), Figure 1) informs the OPERATOR of the remaining time to the end of incubations (controlled by Timer 1 and 2) and the temperature of the Thermostated block. It also informs of possible error situations.

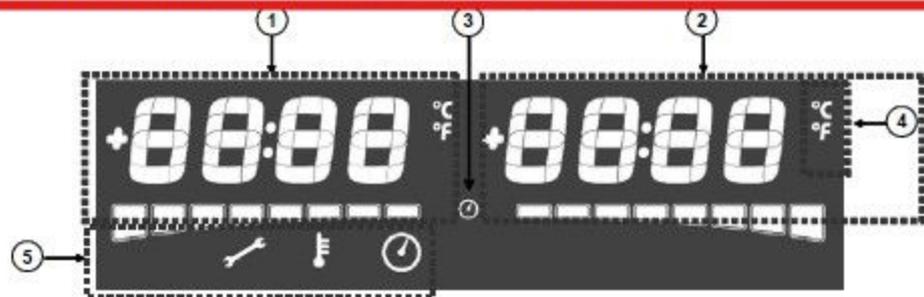


Figure 5 : Display

- (1) Timer 1 information
- (2) Timer 2 information
- (3) Timer measurement indicator
- (4) Temperature units
- (5) Warnings area

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DGtherm



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Declaración CE de Conformidad

EC Declaration of Conformity

Fabricante:
Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvià, 24
08150 - Paret del Vallès
Barcelona. ESPAÑA

Producto y referencia:
Product and reference:

DG Therm 213734

Clasificación de acuerdo con la Directiva 98/79/CE:
Classification according to Directive 98/79/EC:

No listado en Anexo II de la Directiva 98/79/CE /
Non-listed in Annex II of Directive 98/79/EC

DIAGNOSTIC GRIFOLS, S.A. declara bajo su propia responsabilidad que el producto indicado anteriormente cumple los requisitos esenciales del Anexo I de la Directiva sobre Productos Sanitarios para Diagnóstico In Vitro 98/79/CE, habiéndose seguido el procedimiento de evaluación de conformidad del Anexo III.

DIAGNOSTIC GRIFOLS, S.A. declares under sole responsibility that the product specified above complies with the essential requirements given in Annex I of the Directive on In Vitro Diagnostic Medical Devices 98/79/EC and Annex III is used as the conformity assessment procedure.



Paret del Vallès, 6 de Julio de 2015
Paret del Vallès, 6th of July of 2015

Albert Hernández Botey
Director Técnico
Technical Director