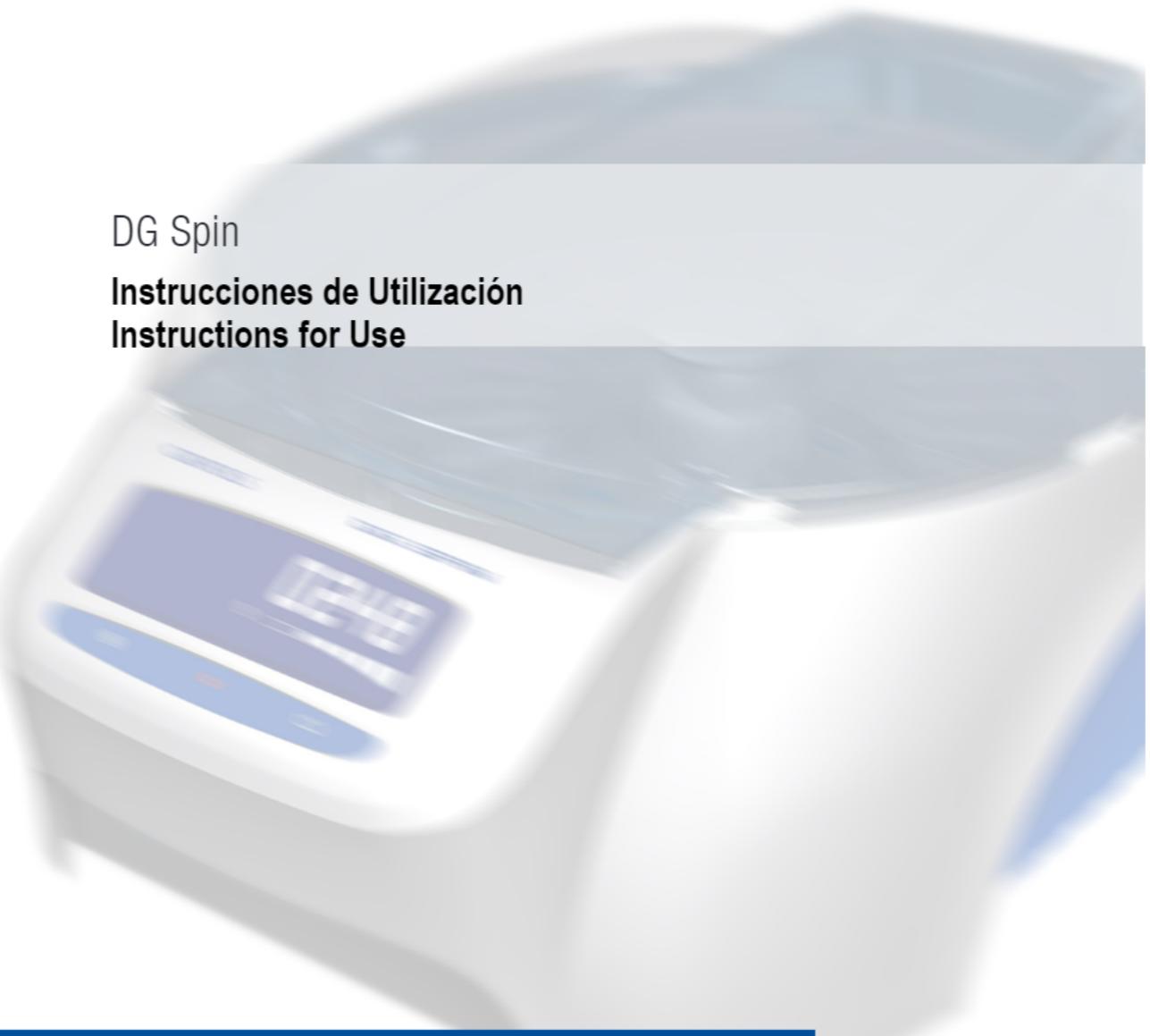




DG Spin Instrucciones de Utilización Instructions for Use



DG Spin
Instrucciones de Utilización
Instructions for Use

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DG SPIN

Instructions for Use

PLEASE READ THESE INSTRUCTIONS FOR USE CAREFULLY BEFORE
STARTING TO WORK WITH THE **DG SPIN** CENTRIFUGE

Information about matter relating to the equipment safety can be found in the chapter 2 “Safety information”.

The symbols used in these Instructions for Use are as follows:

DANGER!

Any kind of injure – critical or not- for people (including patients), that only can be diminished following the instructions shown.



WARNING!

Any kind of injure for people (including patients) for which other protection systems are provided, but it is convenient the RESPONSIBLE



Definitions:

RESPONSIBLE AUTHORITY: Individual or group responsible for the use and maintenance of the equipment and for ensuring that operators are adequately trained.

OPERATOR: Person operating equipment for its intended purpose. The OPERATOR should have received appropriate training for this purpose.

QUALIFIED TECHNICIAN: Person responsible for the installation, reparation and special maintenance of the equipment who has received specific training for this purpose.

All restrictions referred to RESPONSIBLE AUTHORITY are valid for the OPERATOR.

Equipment design and specifications are subjected to change without previous notification.

This document is available in various languages. Translations have been carried out from the master document in English. In case of doubt or discrepancies, what is expressed in the master document in English will be given priority.

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1 INTRODUCTION

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

These Instructions for Use, which are intended for the OPERATORS of the *DG Spin* 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

2 SAFETY INFORMATION

2.1 Important safety instructions

The following indications are directly related to the safety of the equipment:

DANGER!

Misuse of the equipment can impair the protection provided by itself.

**DANGER!**

To avoid risk of electric shock, this equipment should only be connected to a supply main with protective earth.

**DANGER!**

—

WARNING!



This equipment only must be used by the
**RESPONSIBLE AUTHORITY, OPERATORS and
QUALIFIED TECHNICIANS.**

WARNING!

Electromagnetic compatibility and electrical safety tests have been performed using the cord supplied by the manufacturer. However, if it is necessary to use another cord, be sure that the new cord meets the following specifications:

Cable type: Flexible cable with insulation and PVC cover with 3 conductors (neutral, live and earth).

Cord length: 2 m.



WARNING!

Basic safety precautions should always be taken including those indicated in section 2.3 "Read before use". Furthermore, before installing the equipment, the rules of 5.2 "Installation requirements" section must be read.



2.2 Equipment labelling

The *DG Spin* centrifuge is labelled with the following labels:

- (4) Packaging label
- (5) Identification and Basic Technical Characteristics of the equipment label
- (6) Biological risk of the Centrifugation chamber.

- (1) Packaging label



Temperature range permitted during storage and transport



Relative humidity range permitted during storage and transport



European conformity

(2) Identification and Basic Technical Characteristics label

Label located on the rear part of the equipment containing technical information (mains tension, frequency and power) as well as the model, serial number, manufacturing date, name and address of the manufacturer and regulatory information.

100 - 240 V~	50 W
50 - 60 Hz	— 2 x T 2A L, 5x20 mm
SN 320-XXX-XXXX	CE

(3) Biological risk level

Located on the lateral part of the Centrifugation chamber, it indicates and warns of the biohazard caused by possible remaining substances deposited on the surface.



2.3 Read before use

- Use the equipment only for the purposes described in the Instructions for Use.
- Unless specifically instructed to do so by the Instructions for Use, do not drop or put anything into any opening in the equipment.
- Do not use the equipment if it is not working properly, or if it has suffered any damage. Examples of defects typically include:
 - Visible damage caused by dropping the equipment.
 - Visible damage caused by liquid spillage.
 - Visible damage caused by subjection to prolonged storage and

3 SPECIFICATIONS OF THE CENTRIFUGE

3.1 Technical specifications

MODEL	DG SPIN
LOAD CAPACITY	24 <i>DG Gel cards</i>
DG SPINHEAD	Removable and interchangeable
CENTRIFUGATION CONDITIONS	Pre-programmed. Those required for <i>DG Gel cards</i>
CENTRIFUGATION SPEED	990 rpm \pm 10 rpm (128.1 g \pm 1.0 %)
CENTRIFUGATION UNITS	Programmable, rpm or g
CENTRIFUGATION TIME	9 minutes
ACOUSTIC ALARM	Yes, to indicate end of centrifugation and error situations
VOLUME OF ACOUSTIC	-

WEIGHT (KG)	Approximately 15 kg	
WORK CONDITIONS	Indoor use	
	Temperature:	15°C to 40°C
	Maximum relative humidity non condensing:	80 %
	Maximum altitude:	3000 m
	Mains supply maximum voltage fluctuations:	±10 % of nominal voltage
TRANSPORT AND STORAGE CONDITIONS	Temperature:	-10 °C to 60 °C
	Maximum relative humidity non condensing:	85 %
USEFUL LIFE	5 years considering a normal function of 8 hours/day and 200 days/year.	

3.3 Regulatory

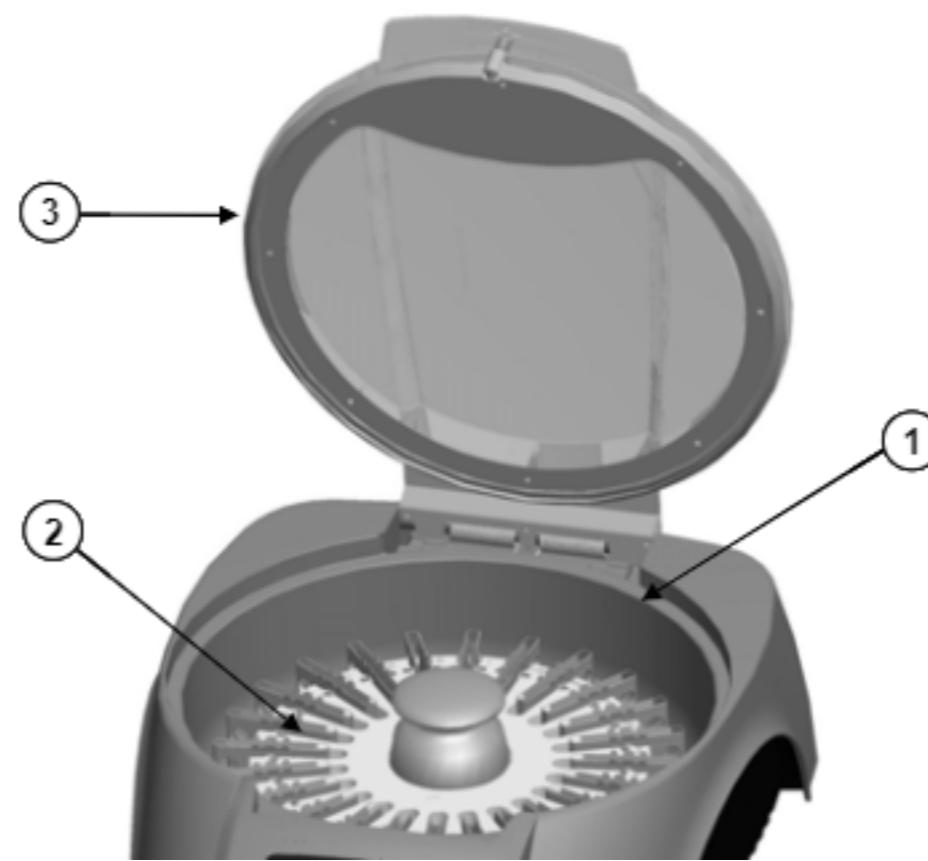
The *DG Spin* centrifuge conforms to the requirements of:

- EU Directive 98/79/EC on “*In Vitro* Diagnostic Medical Devices”.
- EU Directive 2002/96/EC on “Waste electrical and electronic equipment”.

4 DESCRIPTION OF THE CENTRIFUGE

4.1 General description of the centrifuge

Figure 1 and Figure 2 show, respectively a front and rear image of the *DG Spin* centrifuge.



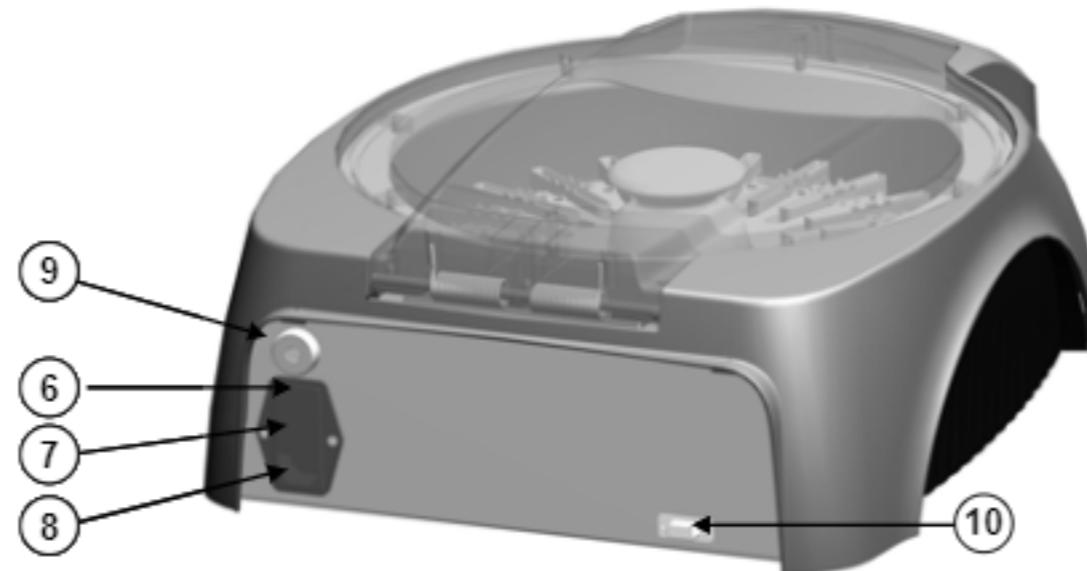


Figure 2 : Rear view of the *DG Spin* centrifuge

- (6) Main switch
- (7) Fuses housing
- (8) Mains cord connection
- (9) Security ring housing
- (10) Connection to a computer (for exclusive use of the authorised Technical Service)

4.1.1 Centrifugation chamber

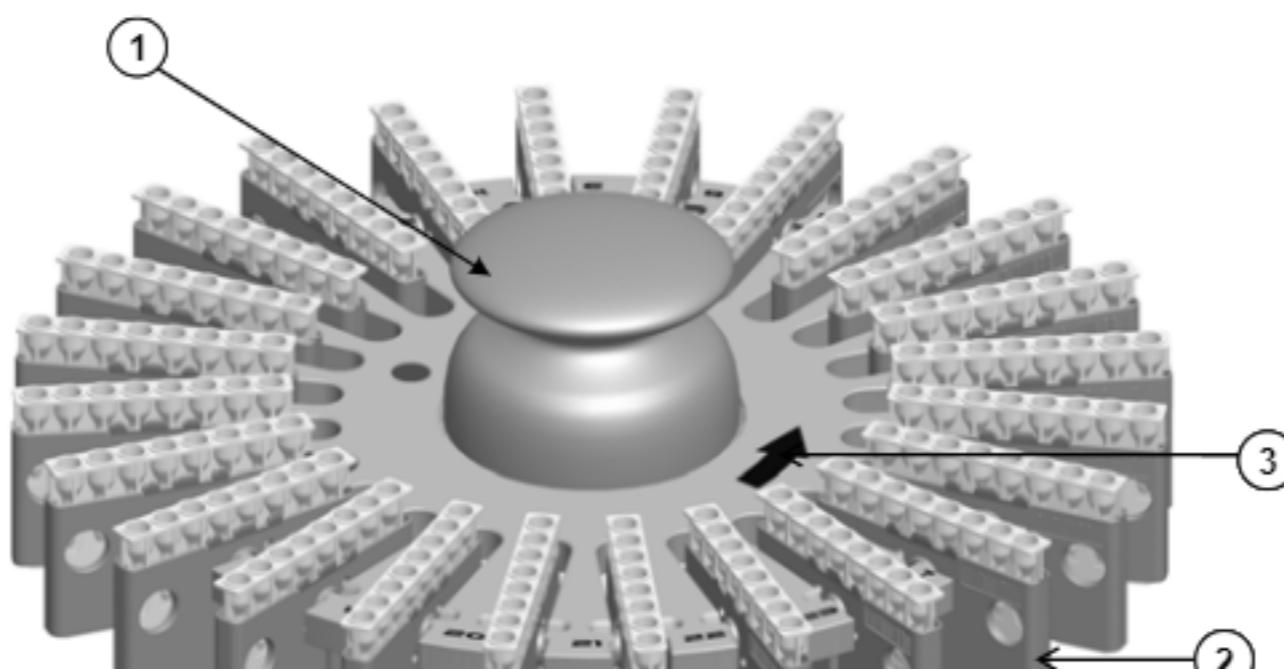
The Centrifugation chamber (Ref. (1), Figure 2) is the centrifuge's main working area.

- (1) Centrifugation chamber
- (2) Lean axle and Crosshead of *DG Spin* Head
- (3) Motor protective cover

The Centrifugation chamber also has a protective cover (Ref. (3), Figure 3) that protects the motor.

4.1.2 *DG Spin* head

The *DG Spin* head is a circular support with 24 positions numbered with Card holders (Ref. (2), Figure 4) to place the *DG Gel* cards for their centrifugation.



4.1.3 Centrifuge cover

The *DG Spin* centrifuge has a safety transparent cover (Ref. (3), Figure 1) with a hinge and an electromagnetic safety closure.

4.1.4 Control buttons

The *DG Spin* centrifuge has three buttons (Ref.(4), Figure 1) for control of centrifugation.

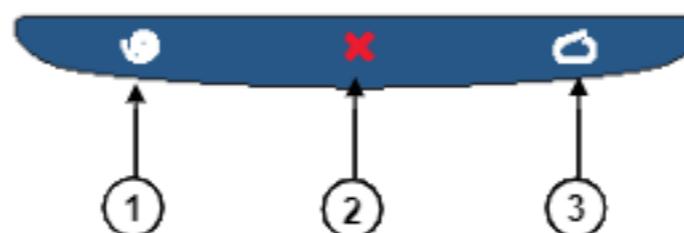


Figure 5 : Centrifugation Control buttons

- (1) Centrifugation starting button (螺旋)
- (2) Centrifugation stopping button (X)
- (3) Cover opening button (开门)

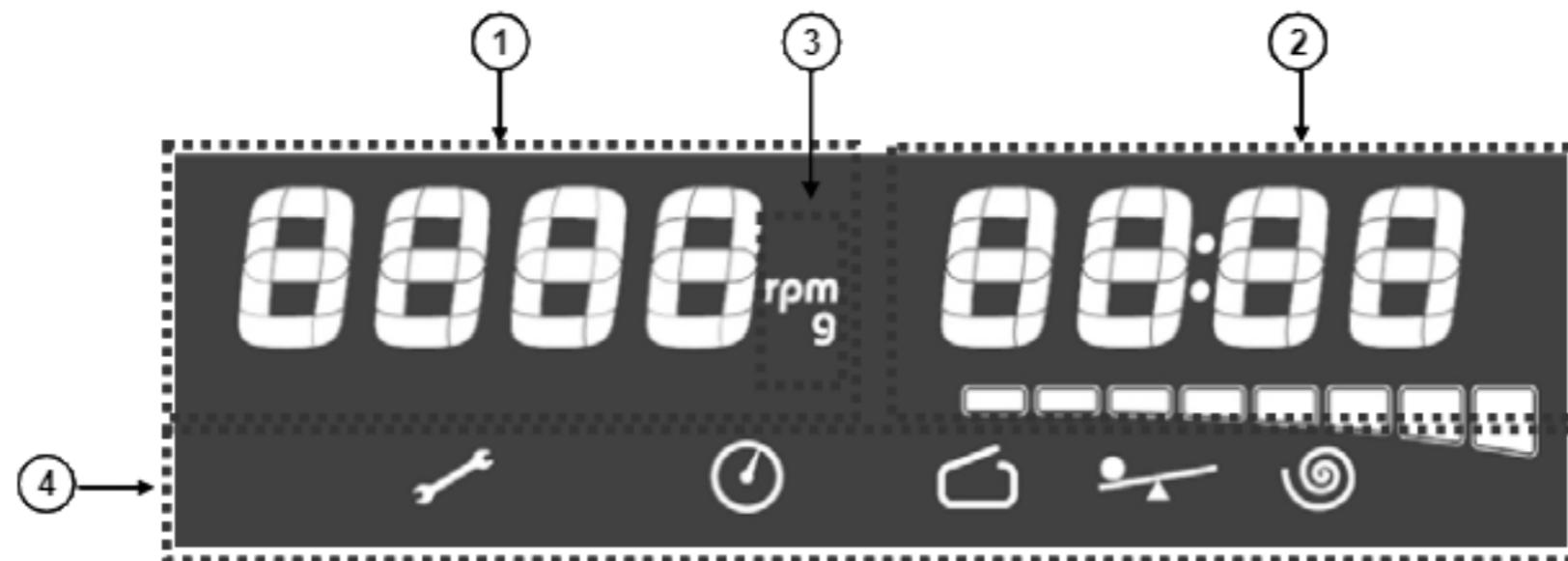


Figure 6 : Display

- (1) Centrifugation speed information
- (2) Timer information
- (3) Centrifugation speed units
- (4) Warnings area

4.1.5.1 Remaining centrifugation time information

In normal mode, the Display shows on the right, the time remaining up to end of centrifugation of the batch by means of a digital counter (Ref. (1), Figure 7) and a

4.1.5.2 Units

The *DG Spin* centrifuge informs the OPERATOR of the centrifugation speed in rpm or in g. To change the configuration that appears on the screen consult section 5.5 "Configuration of the equipment".

4.1.5.3 Warnings area

This is located on the left lower part of the Display (Ref. (4), Figure 6) and informs, by means of symbols, of alarm situations during initialisation or centrifugation batch. These symbols are described below.

For more information, consult section 12.1. "Warnings or Incidences".



Contact the Technical Service



Batch completed with Erroneous centrifugation time



The Cover centrifuge is opened

DG Spin

Description of the Centrifuge

During normal use of the *DG Spin* centrifuge, ensure that the ring is protected by the aforementioned lid.

WARNING!

Before use the Security ring, check that the centrifuge is unplugged and the *DG Spin* Head is not moving.



DANGER!

The use of the Security ring disconnects immediately the motor. However, take in mind that the *DG Spin* Head can still move.



5 INSTALLATION

5.1 Action upon delivery

This equipment may be installed directly by the OPERATOR or RESPONSIBLE AUTHORITY.

5.2 Installation requirements

The requirements for the place where the equipment is to be installed are as follows:

- If the equipment has been stored in environmental conditions different from work conditions, it should be kept for at least one hour under environmental work conditions before being plugged in.
- Environmental conditions: See section 3.1 “Technical specifications”.
- Space requirements: The equipment occupies a horizontal area of width 500 mm and 600 mm in depth (includes space for connection of the mains cord connection).
- Leave a safety space for additional installation of at least 300 mm around the centrifuge. No person or any dangerous material should be

5.3 Unpacking the equipment

Once the appropriate place is selected for installation, unpack the equipment according to the following instructions:

- Open the upper part of the box.
- Remove all protections and accessories.
- Remove the protection bag and place the equipment in the chosen position.
- Verify that all elements specified in the attached *Packing list* are included.
- Check that the equipment is not damaged due to the storage and transport.

5.4 Installation procedure

To install the *DG Spin* centrifuge, proceed as follows:

- Connects the mains cord (Ref. (3), Figure 2) to the centrifuge and the mains.
- Switch on the Main switch (Ref. (6), Figure 2).

- Wait for 30 seconds and verify that the *DG Spin* Head has stopped and the Display again shows the pre-established centrifugation time.

The *DG Spin* centrifuge is supplied with a conformity certificate stating that the centrifugation speed (990 rpm) has been verified using instruments calibrated by accredited entities. The *DG Spin* centrifuge does not need to be readjusted during its useful life if it is used under normal working conditions.

5.5 Configuration of the equipment

The *DG Spin* centrifuge has some predefined parameters that may be modified by the OPERATOR. Predefined values are the following:

- Acoustic signal volume: High
- Centrifugation speed units: rpm
- Date and time: GMT time zone.

NOTE:

The Date and Time parameters are used to maintain traceability in a "log file" with relevant information and possible incidences that have



- Press  to modify the value to the required level.
- Once the required level has been selected, press  to move onto the next parameter.
The Display will automatically show the following configuration menu: Selection of centrifugation speed units.
- To change the units, press  and select the required unit: rpm or g's.
 - SEL rpm: Centrifugation speed in revolutions per minute (rpm)
 - SEL g's: Relative centrifugation force (g)
- Once the required level has been selected, press  to move onto the next parameter. Automatically, the Display will show flickering digits corresponding to the Date (YYYY.MM.DD) and the Time (HH:MM). Press  to modify the value of each field and  to move onto the next field. The date and time of the centrifuge are pre-programmed with respect to the GMT system

NOTE:

To save the modification of any parameter (volume, units, date and time) it is necessary to keep  pressed down until the indicator emits the long and continuous acoustic signal. Otherwise, the OPERATOR will leave the Configuration mode without recording the changes made.



6 OPERATING PROCEDURE

CAUTION!

Do not use the *DG Spin* centrifuge if it does not work correctly or has been damaged.



6.1 Execution of a centrifugation batch

To correctly use the *DG Spin* centrifuge the following instructions should be followed:

- Activate the Main switch (Ref. (6), Figure 2) and verify that the Display (Ref. (5), Figure 1) is switched on and shows the predefined centrifugation time.
- Open the Cover by pressing and remove the *DG Spin* Head by pulling up vertically until it is released from the Lean axle.
- Place the *DG Spin* Head on a flat surface.

CAUTION!



The direction of centrifugation is important to standardise the work and make centrifugation conditions of the cards uniform.

Consequently, place the *DG Gel* cards in such a way that the bar code coincides with the barcode symbolised in the Card holder as shown by Figure 8.



WARNING!

Centrifugation heads different to those specified should not be used as they may cause deterioration and malfunction of the instrument.



- Once the cards have been distributed in the *DG Spin* Head, place it inside the centrifuge.
- Close the Cover by pressing the central front part thereby ensuring correct closure.
- Press  to start the centrifugation batch and activate the timer.
Once the centrifugation has finished, the *DG Spin* Head stops automatically and the *DG Spin* centrifuge shows the timer flashing and Acoustic alarm activated.
- Press  to open the Cover.
- Immediately remove the *DG Spin* Head from the inside of the centrifuge.

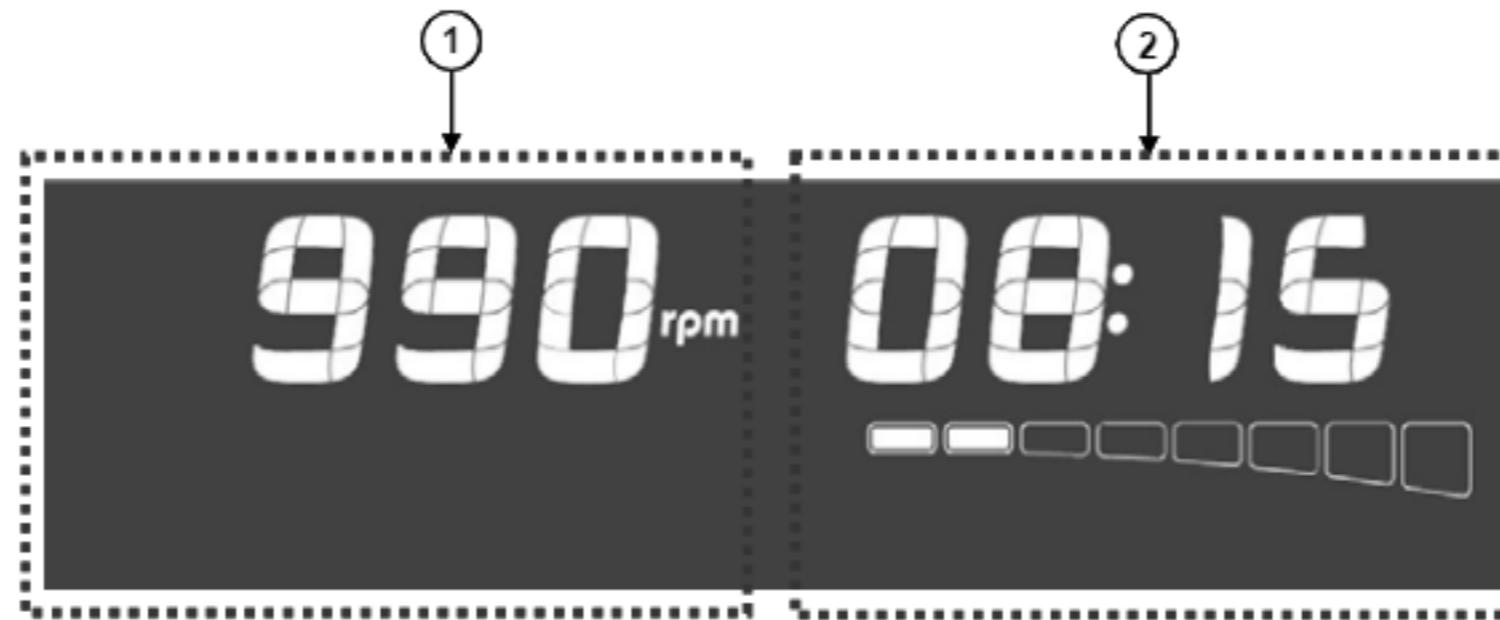


Figure 9: Centrifugation speed information on the Display

- (1) Centrifugation speed or force
- (2) Timer information

6.3 Centrifugation stop

If, for some reason it is necessary to stop the centrifugation before the established

WARNING!

If centrifugation is stopped, the cards should be invalidated.

Reliable results can only be obtained if the cards are subject to a complete and continuous centrifugation, only once.



7 MAINTENANCE

Maintenance of the *DG Spin* centrifuge only includes cleaning and decontamination.

7.1 Maintenance plan

Maintenance is a set of operations carried out at regular intervals to preserve function of the *DG Spin* centrifuge.

As a general rule and as long as there is no irregularity in the operation of the equipment, the maintenance plan that should be followed is the following:

PERIOD	ACTIVITY	CARRIED OUT BY
Whenever drops of samples or other substances split on the Centrifugation chamber or on the <i>DG Spin</i> Head	Cleaning of the Chamber and the <i>DG Spin</i> Head as indicated in section 7.1.1 “Cleaning procedures”.	RESPONSIBLE AUTHORITY / OPERATOR
Each month	Decontamination of the	

WARNING!

Before the cleaning and decontamination procedures, all samples and cards should be removed from inside the equipment.

WARNING!

The cleaning processes of the equipment surfaces should be carried out with the equipment unplugged from mains.

7.1.1 Cleaning procedures

The *DG Spin* centrifuge has been manufactured with top-quality materials. However, biological samples, saline solutions, acid or alkaline solvents should be eliminated from the exterior surface before these can cause deterioration.

Cleaning of the external surfaces should be carried out periodically with a damp cloth with a soft detergent.

7.1.2 Decontamination of the equipment

DANGER!

Any part of the equipment that could come into contact with blood, serum samples or any other biological liquid should be treated as potentially contaminant.



In order to prevent any risk of infection, it is important to carry out decontamination of the instrument before performing certain operations.

Decontamination of the equipment should be carried out monthly or in the following cases:

- After spillages, leaks, etc. of potentially contaminant liquids.
- Preparation of the equipment for its transport or storage.
- Before the intervention of the Technical Service.
- Equipment disposal.

To decontaminate the equipment, proceed as indicated below:

WARNING!

Before using any cleaning or decontamination product different to those recommended by the manufacturer, the RESPONSIBLE AUTHORITY should verify with the manufacturer that the methods proposed will not damage the equipment.

NOTE:

The procedures described above do not guarantee that the equipment is totally decontaminated, but it reduces the risk of contamination to a minimum.

7.1.2.1 Decontaminant liquids

During handling of these liquids, the following recommendations should be

8 OPERATION QUALIFICATION PROCEDURE (OQ)

The *DG Spin* centrifuge has two non-adjustable independent time basis controlled by the centrifuges program itself. Given that the speed has been calibrated by the manufacturer, if no function alarm is activated (see sections 12.1 and 12.2), it is warranted that *DG Spin* centrifuge will correctly work for all its useful life, without any additional calibration.

However, the procedure described below aims to provide a method for those laboratories which, under a quality management system, should periodically verify that the *DG Spin* centrifuge works under specifications.

The Operation Qualification Procedure (OQ) of the *DG Spin* centrifuge consists of verifying the correct function of the following parameters:

- Centrifugation speed
- Balance control system

8.1 Required materials

To qualify operation of the *DG Spin* centrifuge the following materials are required:

- Calibrated optical tachometer

NOTE:

It is advisable regular calibration of 1 year or that recommended by the manufacturer of the tachometer if its calibration validity period is lower than 1 year.

8.2 Procedure for qualification of centrifugation speed

To verify that the *DG Spin* centrifuge complies with the speed specifications described in section 3.1 "Technical specifications" proceed as described below:

- Switch on the *DG Spin* centrifuge to the mains and activate the Main switch (Ref. (6), Figure 2).
- Verify that the Display (Ref. (5), Figure 1) is switched on and the timer indicates the predefined centrifugation time.
- Open the Cover of the *DG Spin* centrifuge and remove the *DG Spin* Head.
- Place 24 *DG Gel* cards in the corresponding Card holders.

- Verify that the tachometer speed marked is within the speed range defined in 3.1 “Technical specifications”.
- Furthermore, verify that the speed shown by the Display when  is pressed, although is not exactly the same than the tachometer speed, is also within the speed range defined in 3.1 “Technical specifications”.
- Stop centrifugation by keeping  pressed down for a few seconds until earring a continuous acoustic signal.
- Open the Cover of the centrifuge; remove the *DG Spin* Head and the cards.
- Place the empty *DG Spin* Head in the centrifuge and close the Cover.

The verification of centrifuge speed implies verification of the equipment time basis and therefore, independent verification of the timer is not necessary.

NOTE:

Acceptance of the results enables ensuring correct function of the *DG Spin* centrifuge with respect to control of speed and time



- Verify that centrifugation is stopped and that the out-of-balance indicator () is activated in the Warning area of the Display during centrifugation

NOTE:



The centrifugation stop enables ensuring correct function of the *DG Spin* centrifuge with respect to out-of-balance control system. Otherwise, contact your authorised Technical Service.

9 TRANSPORT AND STORAGE

WARNING!

The equipment must be decontaminated before being transported and/or stored.



If the *DG Spin* centrifuge has to be stored for a long period of time, it is recommendable to pack it as for transportation.

The required environmental storage conditions are those indicated in section 3.1 "Technical specifications".

The space requirements for storing the equipment are as follows:

- Size: 320 mm height x 635 m depth x 530 mm width (with packaging).
- Approximate weight: 18 Kg

WARNING!



10 DISPOSAL OF THE EQUIPMENT

To dispose of the *DG Spin* centrifuge it should be completely cleaned and decontaminated and all remains of samples and reagents eliminated. Once this is done, it should be sent to an authorised centre for the processing of electronic waste.

DANGER!

This instrument should only be disassembled by authorised specialists.

**CAUTION!**

When the instrument is at the end of its useful life, local legislation procedures in force should be followed to dispose of it.



11 WARRANTY

The warranty conditions are established in separate documents. For more information, contact your distributor.

The warranty does not cover:

- Damages caused by its initiation and functioning in environments that contravene the Instructions for Use.
- Damages caused by accident, negligence or breach of the Instructions for Use.
- Damages caused for reasons of force majeure (atmospheric, geological phenomena, etc.).
- Damages caused by incorrect handling including that carried out by technical personnel not authorised by Diagnostic Grifols, S.A.
- Parts of plastic or rubber as well as enamel and paints that have deteriorated due to knocks or usage except in the case of a manufacture defect.
- The *DG Spin* Head, except in the case of a manufacture defect.
- Breakdowns or defects due to transport.

12 RESOLUTION OF INCIDENCES

During normal functioning of the *DG Spin* centrifuge certain warnings and incidences may appear that the OPERATOR can resolve without the assistance of the specialised Technical Service.

12.1 Warnings or incidences

MESSAGE	DESCRIPTION	VERIFICATIONS
	Out-of balance during centrifugation	<p>The equipment has detected an imbalance during centrifuge that has been stopped. Open the Cover and verify that:</p> <ul style="list-style-type: none">- The number of cards is an even number.- The cards are distributed symmetrically in the <i>DG Spin</i> Head.- The cards are properly placed in the Card holders.

		<p>timer shows by flashing, the value indicated at that moment.</p> <ul style="list-style-type: none">- A power cut has stopped the centrifugation batch. The time shows by flashing, the value indicated at that time and will emit some short sounds. <p>Press any button to stop the Acoustic alarm and leave the timer prepared for a new centrifugation batch.</p>
	 The Cover centrifuge is open	<p>For safety, the equipment is designed in such a way that centrifugation batch can not start with the Cover open.</p> <p>If the centrifuge is connected this indicator is shown as long as the Cover is open. The indicator disappears when the Cover is closed. Otherwise, ensure that the Cover is properly closed and if the situation is not corrected switch off the equipment and contact the Technical Service.</p>

	Contact the Technical Service	If the centrifuge detects any alteration in its function that cannot be resolved by the OPERATOR, the corresponding luminous indicator is activated. In this case, switch off the centrifuge and restart again. If the warning persists contact the Technical Service.
	Excessive consumption of the motor	The equipment has detected excessive consumption of the motor during execution of the centrifugation batch. The equipment stops centrifugation and activates the acoustic indicator. Press  or  to stop it. Open the Cover, remove the <i>DG Spin</i> Head and dispose of the cards. Switch off the centrifuge and restart again. If the error is detected again contact the Technical Service.

		as described in section 4.1.6 "Security ring". Restart again and if the error is detected again, contact the Technical Service.
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12.2 Error messages

Apart from the alerts and errors mentioned, the equipment may detect other error conditions. In these cases, the equipment will carry out the following actions:

- Stop the centrifugation in execution.
- Ignore Buttons ,  and .
- Activate the Acoustic alarm with short sounds.
- Activate the indicator .
- Show an  on the Display with the corresponding error code.

CAUTION!

If the *DG Spin* centrifuge shows an error

- If after a complete centrifugation batch the Cover has not been opened to remove the cards already centrifuged and the  button is pressed again to start a new centrifugation batch, the system emits some short sounds and the Open cover alarm flashes. To start a new centrifugation, it is necessary to open the Cover.
- If there is any error during centrifugation: Imbalances, centrifugation speed out of range, incorrect function of out-of-balance control systems, fault in the Cover opening system, excess current consumption of the motor, etc. the *DG Spin* centrifuge emits some short sounds and the corresponding indicator is displayed.

CAUTION!

To stop the Acoustic alarm, press  or , as appropriate. If the Acoustic alarm continues, contact your authorised Technical Service.



SERVICIOS DE MANTENIMIENTO REALIZADOS
MAINTENANCE SERVICES CARRIED OUT

Modelo:

Model:

Nº de Serie:

Serial Number:

Fecha de Instalación:

Installation date:

FECHA DATE	ACCIÓN REALIZADA WORK CARRIED OUT	TÉCNICO/OPERADOR TECHNICIAN/OPERATOR	TÉCNICO/AUTORIDAD RESPONSABLE TECHNICIAN/RESPONSIBLE AUTHORITY

DG Therm

Servicios de Mantenimiento Realizados / Maintenance Services Carried out

Modelo:
Model:

Nº de Serie:
Serial Number:

Fecha de Instalación:
Installation date:

FECHA DATE	ACCIÓN REALIZADA WORK CARRIED OUT	TÉCNICO/OPERADOR TECHNICIAN/OPERATOR	TÉCNICO/AUTORIDAD RESPONSABLE TECHNICIAN/RESPONSIBLE AUTHORITY