3 SPECIFICATIONS OF THE CENTRIFUGE

3.1   Technical specifications

MODEL	*DG SPIN*	
LOAD CAPACITY	24 *DG Gel cards*	
DG SPIN HEAD	Removable and interchangeable	
CENTRIFUGATION CONDITIONS	Pre-programmed. Those required for *DG Gel cards*	
CENTRIFUGATION SPEED	990 rpm ± 10 rpm (128.1 g ± 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 ALARM	Programmable, 3 levels.	
SAFETY SYSTEMS	• Out-of-balance control • Detection of door opening • Safety closure	
INTERFACE	LCD screen and Buttons	
SUPPLY	Voltage:	100–240 V ~
	Frequency:	50-60 Hz
	Input power:	50 W
	Fuses	2x T2AL 250 V, 5x20 mm
PROTECTION AGAINST ELECTRIC SHOCK	Class:	I
INSTALLATION CATEGORY	Overvoltage category II (local level, appliances, portal equipment, etc.)	
DIMENSIONS (mm)	525 (depth) x 410 (width) x 180 (height)	

GRIFOLS

3 SPECIFICATIONS OF THE INCUBATOR

3.1   Technical specifications

MODEL	*DG THERM*	
LOAD CAPACITY	• 24 *DG Gel cards* 5ρ • 24 sample tubes	
INCUBATION BATCHES	2 batches with independent timer	
INCUBATION TEMPERATURE	$37\ ^\circ C \pm 1^\circ C$	
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.	

GRIFOLS

1 Introduction

> THIS EQUIPMENT IS INTENDED FOR *IN VITRO* DIAGNOSTIC USE.

These Instructions for Use are intended for the users of the DG Reader Net and contain all the information necessary to safely and adequately work with the instrument.

Read all information contained herein carefully before starting to work with the equipment.

If you have any questions, contact your local Grifols service representative before starting any operation.

These Instructions for Use must be accessible at all times to all personnel who work with the instrument.

1.1 Intended Use

7A

The DG Reader Net is a device designed to read, interpret, and report the results of the processed Grifols gel cards. The instrument also identifies Grifols gel cards by reading their barcodes.

As a stand-alone or interfaced to the customer's Laboratory Information System (LIS), the instrument automates data management requirements using Grifols gel cards and digital image processing.

1.2 Principle of Operation

The DG Reader Net is a workstation especially designed to read the reactions and give the results according to the grading scales as defined in the Instructions for Use of the Grifols gel cards, allowing laboratories to:

- Increase process safety and traceability by reducing possible identification and eliminating transcription errors.
- Increase analytical reliability interpreting results with objective criteria.

The DG Reader Net reads and interprets the following gel immunohematology tests:

- ABO Red Cell and Serum Grouping.
- Rh(D) Typing.
- Antibody detection.
- Antibody identification.
- Extensive phenotypes.
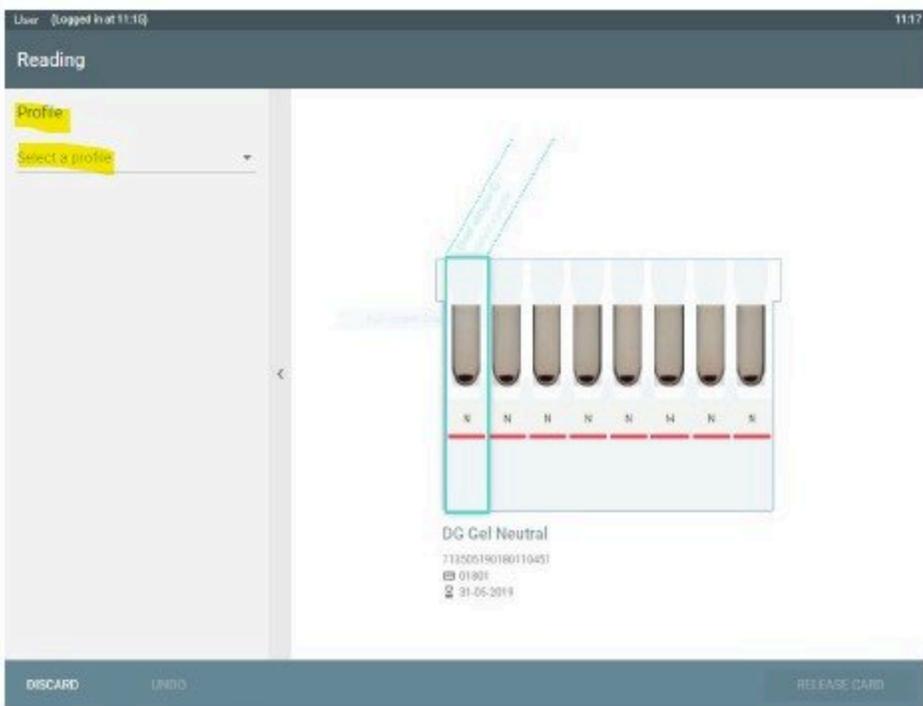- Direct Antiglobulin test.
- Compatibility Tests (Crossmatching).

Figure 14. Profile Assignment Screen

1. In the Sidebar, the list of available profiles for the read Grifols gel card is available (Figure 14).

2. By default, the profile assignment will start in the first free microtube (see in Figure 14). After selecting the profile, all microtubes contained in the profile will be assigned, consecutively.

8p.

> 📄 **NOTE:** In some Grifols gel cards, it is possible to modify the microtubes assigned by default. To do this, select the first well of the profile to assign.

3. The DG Reader Net software will display the following step, which is the sample ID identification (for further information see Section 8.2).

MODULE	SPECIFICATION
Remote connection	Yes. Under configuration, it is possible to authorized Operators by using the website DG Reader Net software application. It provides access to: • Pending Results. • Search Results. • User management. To Qualified Technician by using the Team Viewer for: • Support and maintenance purposes.
Sample barcode type	• Interleaved 2 of 5. • Code 3 of 9. • Codebar. • Codes 128 A, B & C (ISBT 128). • EAN8 / EAN13 / JAN8 / JAN13. • Others under configuration.

3.3 Program Specifications

The DG Reader Net presents an integrated computer with the software preinstalled. The main characteristics of the DG Reader Net software are:

• Reading of the Grifols gel cards.

• Digitalization and image processing to obtain the reaction grade of the reaction.

• Validation and report making, including the exporting of results to the LIS (Laboratory Information System).

9p.

• Database.

Other characteristics and services offered by the whole system:

• A color-coded user friendly interface which aids and improves the understanding of the information and its analysis.

• Validation by profiles of tests.

• Exporting of results to the Database and/or to the LIS.

• Availability of alarm algorithms that allow the detection of incidents when reading.

• User access control.

10 Searching Results in Database

The DG Reader Net software has a Database (independent from the Database in any connected LIS) where all results are stored, including the images. All of these results and images are accessible to the Operator at any time.

10.1 Searching and Viewing Results in the Database

To search and view results that have been stored in the Database:

1. Press the **Search Results** button (Figure 11, no. 3).

   The **Search Results** screen opens (Figure 25). It allows viewing results present in the Database.
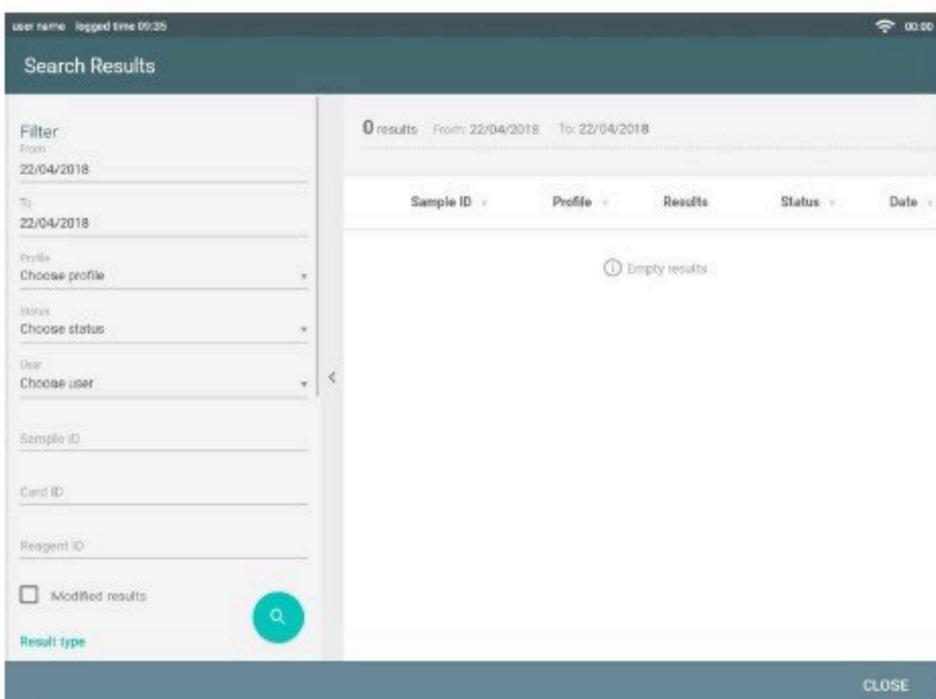

Figure 25. Search Results Screen

EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210700	DG Reader Net	The DG Reader Net is a device designed to read, interpret, and report the results of the processed Grifols gel cards. The instrument also identifies Grifols gel cards by reading their barcodes. As a stand-alone or interfaced to the customer's Laboratory Information System (LIS), the instrument automates data management requirements using Grifols gel cards and digital image processing.	843658373DGREADERNET77

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE IN CONFORMITY WITH THE REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS AVAILABLE UNDER THE PREMISES OF THE MANUFACTURER.

First emission date under IVDR: December 17th, 2021

Place, Date of Issue: Parets del Vallès, April 9th, 2024

Signature:

Marta Genís Lumbreras
Technical Director
Diagnostic Grifols, S.A.

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GRIFOLS

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EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210363	DG Spin	The DG Spin centrifuge is a device specifically designed to centrifuge Grifols gel cards.	843658373DGSPINPD

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE IN CONFORMITY WITH THE REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS AVAILABLE UNDER THE PREMISES OF THE MANUFACTURER.

First emission date under IVDR: May 21st, 2021

Place, Date of Issue: Parets del Vallès, January 10th, 2023

GRIFOLS
Diagnostic Grifols. S.A.

Signature:

Albert Hernández Botey
Technical Director
Diagnostic Grifols, S.A.

1 of 1

EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

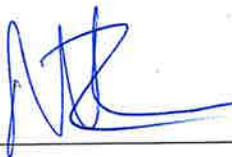| Catalogue Number	Name	Intended Purpose	Basic UDI-DI
213734	DG Therm	The DG Therm Incubator is a device specifically designed to incubate Grifols gel cards and/or sample tubes at 37 °C for immunohematology applications.	843658373DGTHERMXF

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE IN CONFORMITY WITH THE REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS AVAILABLE UNDER THE PREMISES OF THE MANUFACTURER.

First emission date under IVDR: April 22th, 2021

Place, Date of Issue: Parets del Vallès, January 10th, 2023

Signature:

Albert Hernández Botey
Technical Director
Diagnostic Grifols, S.A.

1 of 1

DGtherm

Digital Incubator

· 2 independent incubation zones

· Capacity for 12 DG Gel cards and 12 tubes each

· Digital on-screen display

· Fixed preset temperature of 37°C

· Adjustable, preset incubation time of 15 minutes

31 x 33 x 10 cm; 24 x 26 x 40 in
(W x D x H)
Approximately 4 kg; 9 lb

DGspin

Digital centrifuge

· Simultaneous centrifuge of up to 24 DG Gel cards

· Removable and exchangeable spinning head

· Pre-defined centrifuge parameters

· Digital on-screen display

· Automatic detection of incorrect placement of DG Gel cards
  on the spinning head

41 x 52.5 x 18 cm; 16 x 21 x 7 in
(W x D x H)
Approximately 9 kg; 20 lb

DGmanual station

Work station

· Aluminum support for DG Gel cards, sample tubes and
  reagents

· Capacity for 16 DG Gel cards, 2 bottles of DG Gel Sol
  diluent, 8 vials of reagents (5 and 10 mL) and 32 dilution
  tubes (13 mm) and 16 sample tubes (16 mm)

· Completely adaptable to suit both left-handed and
  right-handed operators

55.5 x 34 x 75 cm; 21.8 x 13.4 x 3 in
(W x D x H)
Approximately 0.75 kg; 1.65 lb