

96 Wells Microplate Reader for Measurement of ELISA Methods





Operation and Maintenance Manual





WARNING Please read carefully this manual before using the instrument and follow the given instructions.



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The application area – Purpose of use

see the table content

About this Manual

This manual contents:

- General Information
- Instrument Installation
- Instrument Operation
- Cleaning and Maintenance Procedures

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1 General Instructions and Safety

1.1 **About this Manual**

Manual for Operation and maintenance of the instrument is designed for users (e.g. laboratory technician) and contains information about the instrument DYNAREAD. The manual contains instruction for instrument installation, operation and maintenance.

Please read carefully whole manual before using the System. Keep manual next to the instrument, that operator will have access to the manual, whenever they use the instrument.

1.2 Symbols and Labelling

These symbols provide basic information and alert of potential hazards.

- Ι Switched on 0
 - Turned off



In vitro diagnostics devices



Warning: as hazards from biological agents

Warning: risk of damage of your health and yours immediate environment

Manufacturer



Date of manufacture

The separate collection of electrical and electronic devices

1.3 Area of Instrument Use

DYNAREAD is the instrument, which measure the optical absorbance in 96 well microplates.

Just trained operators can use the instrument.

The instrument can be used only in accordance with the specified application areas.

Warning: If the instrument is used in another way than mentioned in this manual, the protection provided by the instrument may fail.

Instrument version is in compliance with European directives and standards.

DYNEX

1.4 Labelling CE

On the basis of the following guidelines and information in the manual product carries the CE mark.

* For more information, see Declaration of Conformity.

1.4.1 Guideline 2014/30/EU: Electromagnetic compatibility (EMC)

The instrument was tested by an independent accredited test laboratory, which found that the instrument meets the requirements of technical standard ČSN EN 61326-1 electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

Measurement of radiated interference

Testing and validation was performed according to standard ČSN EN 55011 Class B industrial, scientific and medical equipment - Radio disturbance characteristics - Limits and methods of measurement.

Endurance

The instrument was tested by an independent accredited test laboratory, which found the instrument in accordance with the technical standard ČSN EN 61326-1 electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

Guideline 2006/95/EC Electrical safety (LVD)

The instrument was tested by an independent accredited testing laboratory, and is in conformity with the provisions of the NV no. 17/2003 Coll., Which is in accordance with Directive 2006/95/EC relating to electrical safety.

Testing and validation was performed according to the following technical standards:

ČSN EN 61010-1 ed.2: 2011 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

1.4.2 Guideline 2012/19/EU about waste electrical and electronic equipment

Liquidation Recommendation



When recycling / disposal, contact your supplier. Please note that in case of contaminated instrument is the user's responsibility to ensure that the product has been decontaminated before disposal, and the user is required to provide a certificate of decontamination for their suppliers, which will ensure the destruction of goods.

1.4.3 98/79/EC about diagnostic medical devices in vitro

Risk management analysis was conducted for this instrument. This analysis is part of the company's ISO documentation and CE documentation for the instrument.

1.4.4 ČSN EN 62304 Software of medical devices – Lifecycle of Software processes

The instrument software is in accordance with the requirements of standard ČSN EN 62304.



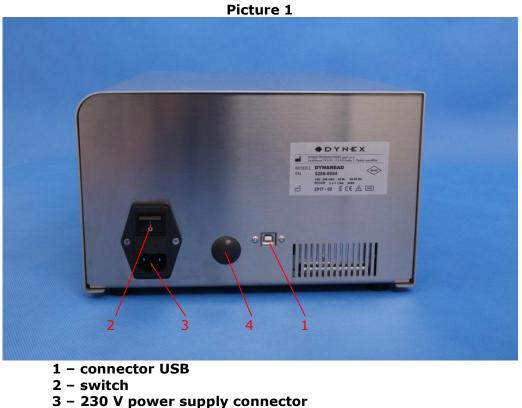
2 Technical Specification

Instrument Parameters:

- · · ·	
Range of wavelength	405 – 790 nm
Standard configuration	405, 450, 490, 630 nm
Measuring range	0,000 – 4,000 OD
Precision	0,000 - 2,000 OD ≤ 1.0% nebo 0,002 OD
	$2,000 - 4,000 \text{ OD} \le 1.5\%$
Accuracy	0,000 – 2,000 OD CV ≤ 1.0% nebo 0,002 OD
	$2,000 - 4,000 \text{ OD } \text{CV} \le 1.5\%$
Optics	12-channels with a reference channel
Light source	LED
Movement of the plate	Y axis
Plates	Standard 96 wells microplate
Control	External PC (not part of the package)
Communication interface	USB
Reading speed for 1 filter	10 s
Power supply	120-230V, 50-60 Hz
Input	30 W max
Fuse	200 mA/250V
Working conditions	Temperature 15 to 30 °C, RH max 80 %
Dimensions	426 x 280 x 174 (d x w x h) mm
Weight	7,2 kg

3 Instrument Description

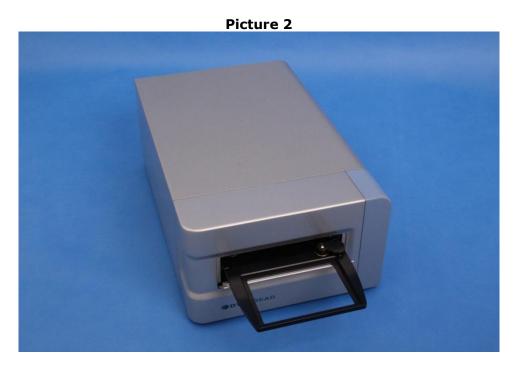
DYNAREAD is automatic 12 channel photometer, which can use standard 96 well microplates. Measurement is provided by control computer and operating software. The power supply connector is located on the back side of the instrument, power switch and USB power supply connector with computer see picture 1.



4 – rubber cap



Measured plate is added in the holder, which slides out from the front side of the instrument. Plate is added on the holder from the top with the position of well A1 in left upward see picture 2.



4 Transport, Installation and Instrument Assembly

4.1 Transport and instrument unpacking

The instrument and its components are transported in special transport packaging, which protects against damage.

Unpack the instrument and its components from transport packaging and check for completeness and condition of each item as listed below:

- 1. DYNAREAD
- 2. Power cable
- 3. Communication cable USB
- 4. Operation and Maintenance manual

In the case of incomplete or damaged some parts deliveries, contact DYNEX TECHNOLOGIES, spol. s r.o. or their representative.

4.2 Environmental requirements

The instrument is designed to be placed in an indoor environment. Place the instrument in a room so that it is protected from excessive dust, vibration, strong magnetic fields, direct sunlight, draught, high humidity or large temperature fluctuations.

Operating temperature:	+15°C - + 30°C IMPORTANT: If the instrument has been exposed to temperatures outside the range, must be equilibrate before use, in order to operate a given temperature range. Failure to do may result in damage to the instrument.
Storage temperature:	1°C – 50°C
Operating altitude:	to 2000 m a.s.l.
Maximum relative humidity:	80%, non condensing



4.3 Instrument assembly

Before the first start remove the rubber cap and unlatch the carousel with a screwdriver through the hole. Turn the locking screw by two turns counterclockwise, see picture 1. Put the rubber cap over the hole again.

Place the instrument on the working area in the way that there is enough space around instrument for installation and manipulation. Make sure the switch is in position 0, plug the power cord into the instrument and the wall outlet, connect the instrument to a computer using a USB cable see picture 2.

5 Description for control of instrument

5.1 Switch on instrument

Switch on the instrument using a switch in the back side. The green LED lights up – indicate switched on.

5.2 Measurement of optical densities

Measurement is controlled by the corresponding software. For installation and usage follow the corresponding instructions.

6 Maintenance

6.1 Instrument Cleaning

The instrument surface clean with moistened tissue. If it is necessary, use detergent. Do not use organic solvents for cleaning, alkalis or acid.

6.2 Long-term out of service

Remove the power cord and protect the instrument against dirt.