

Declaration of Conformity

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Product/Class: PKF08 Incubating Kinetic Tube Reader Class 1 IVD Medical Device
Directives: Low Voltage Directive 2014/35/EU
RoHS2 Hazardous Substance Directive 2011/65/EU
The Electromagnetic Compatibility Directive 2014/30/EU

Standards: EN 61326-1:2013 Electrical Equipment for Measurement, Control & Lab. Use
IEC 60601-1: Edition 3.1 (IEC 60601-1:2005+A1:2012);
EN 60601-1:2006+A1:2013; CAN/CSA-C22.2 No. 60601-1:14
BS EN IEC 63000:2018 - RoHS2

QMS: ISO 13485:2016 Quality Management System

Declaration: I certify that this equipment conforms to the requirements of the EMC and safety directives of the Europe Community Council Directive 93/68/EEC.

Preface: Thank you for purchasing and using this Incubating Kinetic Tube Reader. Lab Kinetics, L.L.C. is a specialist, and worldwide leader, in the manufacture of state-of-the-art high specification Kinetic Tube Readers. It is our privilege to have you as our customer. Please read this Manual carefully before operating this device. We reserve all rights to amend this manual without notice.

This product is designed for trained professionals in clinical laboratory or industrial environments.

Cautions: To protect you from injury and to ensure proper operation of the instrument, please ensure that the power cable and power outlet has a protective earth before connecting to the Kinetic Tube Reader and powering up. Ensure that the power outlet used is at the correct voltage (refer to the Technical Specification).

As thunderstorms can surge power and cause damage to this equipment, we recommend you disconnect the device from the power outlet before a thunderstorm. We recommend you do not plug or unplug devices during a thunderstorm. We also recommend using a surge protector between the outlet and power supply. Also insert the DC plug into the reader before applying outlet power.

Do not open the Kinetic Tube Reader enclosure. There are no user serviceable parts inside, and it will void any warranty. Service shall only be carried out by trained, authorized personnel.

In the event that there is a liquid spill or tube glass breakage inside the Kinetic Tube Reader, the instrument should be returned to the manufacturer for repair/cleaning accompanied with a signed and dated document stating that the reader is not contaminated with any hazardous materials.

ESD (electro-static-discharge) can build up on surfaces (esp. plastic) that are not grounded. Incidents are more prevalent when air humidity is low (often in winter). Static discharge through the instrument can cause the instrument to function incorrectly and so it is to be avoided. The tube reader design is such as to minimize the adverse effects of static discharge and has been shown to survive the EN60601 and EN61326 static discharge tests, however it is advisable to repeat any sample testing carried out when an electrostatic discharge has occurred.

Cleaning the Tube Reader should only be done with a damp, lint free cotton cloth.

Items Included: PKF08 reader, Dust Cover, Power Supply, Communication Cable, User Manual and Technical Documents.

Features: These instruments have individually controlled, optically independent tube wells meaning that, under software control (if featured), the size of batch is no longer dictated by the instrument; the user can stop, start or repeat a test in one or more wells without affecting the others.

The tube wells accept standard 11.6x65mm borosilicate glass tubes.

The operating wavelength is selectable - see Technical Specification.

Temperature release criteria: The heating block (measured at well#4) will maintain 36.5 to 37.0°C. (Typical deviation in temperature across the block is ~0.2degC)

Optical Precision release criteria: All empty wells should stay within +/-10mAb for 1 hour.

Calibration: Temperature and Optical Calibration should be checked on a regular basis. It is suggested that the period be 6 months.

Requirement: A computer with a USB port, running software for data logging/analysis/test.

Location: This instrument should be located in a suitable working area to achieve optimal results:-

Avoid positioning the instrument directly under air conditioning vents or in direct sunlight, or on an unstable work surface; the surface should be flat & horizontal with no vibration.

Avoid positioning directly adjacent to vortex mixers, particularly if these are likely to be in use during data collection.

As with all electrical equipment, position away from sources of water.

Use power outlet filtering if the power line is very noisy. It is recommended that filters be fitted to all power equipment on the same line - particularly motors, refrigerators and air conditioners.

Tube Reader Installation and Operation:

1. Connect the power supply to the power outlet and the 12Vdc output plug to the Tube Reader.
2. Connect the communications cable to the computer and Tube Reader.
3. Press the on/off power button on the Tube Reader, left side - there is a power-up/down sound.
3. Warming takes 5 to 10 minutes.
4. Allow to stand for a further 10 minutes or more, for best performance before use.
5. Run associated log/analysis software on the computer and follow the software instructions.
6. On inserting a tube into a well, an indicator turns from red to green. Push the tube fully in. Care should be taken not to break the tube in the well, they are fragile, and liquid and glass spillages will require careful cleaning with possible return to the manufacturer.

Temperature Calibration Check:

1. Insert a glass tube with 0.5" (13mm) water into well #4
2. Insert an accurate electronic thermometer with at least a 0.1°C resolution into the tube.
3. Wait until the temperature has stabilized.
4. If the temperature is within 36.5 to 37.0 °C then temperature calibration is not necessary.
5. This reader has automatic temperature calibration. If the temperature is not within 36.5 to 37.0°C then use the services of your supplier or technically trained personnel to perform the calibration.

Audible and Visual Indicators:

- Well LED indicators: Red - No tube inserted
- Well LED indicators: Green - Tube is present and normal testing is in progress
- Well LED indicators: Orange - The device is warming or running a temperature auto-calibration.
- Power switch: Push on-off. The LCD lights up green/yellow indicating the instrument is ON.
- Power-up: there is an audible set of two rising tones in quick succession.
- Power-down: there is an audible set of two falling tones in quick succession.
- If the block temperature rises to ~60°C a repeating "beep beep" will sound.
- If the block temperature rises to ~60°C the LCD will show "TEMPERATURE ERROR"
- The 2 line LCD (liquid crystal display) may show the following:
Line 1 can display the product serial number or any 16 character message directed by software.
Line 2 will display the wavelength '405nm', '495nm', '405nm.' and '405nm..' or an error message.

Recycling:

The Kinetics Tube Reader relies on the use of Borosilicate glass tubes. These tubes should be recycled in a responsible manner. Glass is an environmentally friendly product, it can in many cases be recycled simply by melting.

The Kinetic Tube Reader is RoHS 2 compliant (2011/65/EU)

Packaging: consists of paper based documents and carton with EVA foam lining to hold the product in place during transit and transparent polyethylene bags to keep dust away from the electronics.

Disclaimer:

The Incubating Kinetic Tube Reader, manufactured by Lab Kinetics, LLC excludes software or computer the software runs on. The Kinetic Tube Reader is offered as a complete system through our distribution channels and includes software for a particular market and should be seen as two separate products working together. Any failure of the software to perform (if due to errors in the software) cannot be seen as a fault in the design of the Incubating Kinetic Tube Reader and any failure of the Reader to perform (if due to errors in the Reader design) cannot be seen as a fault in the design of the software.

UDI (Unique Device Identification): This is an FDA established system to identify Medical devices. Here is the GS1-128 format we use. See the product label.

Technical Specification:
Wavelengths used: 405nm peak (± 5 nm), 495nm peak (-10 nm/ $+20$ nm)
Empty well Optical Precision: ± 10 mOD stability over a 60 mins period.
Incubation Temperature: 36.5 - 37.0 \square
Wells: 8 wells
Tube size: $\Phi 11.6$ mm $\times 65$ mm
Read Liquid Level: 350 μ l min.
Read interval: better than 5 seconds
Communication: HID USB-UART Bridge, Baud:500,000, D8PNS1

Operating Conditions:
Ambient Temperature Range: 10~30 \square
Relative humidity: $\leq 70\%$
Atmospheric Pressure: 86.0~106.0kPa
Safety Classification: Class 1 Type B
Mains Voltage: 100 to 240VAC (external medical power adapter)
Mains Frequency: 50Hz/60Hz
Power requirement: 10W typical
Dimension: 6.9" x 4.7" 1.4" (175x120x35mm)
Weight (excl. power adapter): ~15oz (425g)
Transportation and Storage Conditions:
Ambient Temperature: ~+55 \square
Relative humidity: $\leq 95\%$
Atmospheric Pressure: 55~106kPa

Firmware: firmware update capable

RoHS2 compliant product: 2011/65/ EU
EMC Standards conformity: Based on EN 61326-1: 2013
Conducted Emissions: EN 55011:2009 A1: 2010
Radiated Emissions: EN 55011:2009 A1: 2010
ESD: EN 61000-4-2:2009
Radiated RF Immunity 80MHz to 2.4GHz: EN 61000-4-3: 2006 + A2
Radiated RF Immunity 300MHz to 6GHz: EN 61000-4-3: 2006 + A2
Fast Transient Burst: EN 61000-4-4: 2004 A1
Surge Immunity: EN 61000-4-5: 2006
Conducted RF Immunity: EN 61000-4-6: 2009
Power Frequency Magnetic Field Immunity: EN 61000-4-8: 2010
Dips & Interruptions: EN 61000-4-11: 2004
Mains Harmonics: EN 61000-3-2: 2014
Flicker: EN 61000-3-3: 2013
Safety Standards conformity: IEC 60601-1: Edition 3.1
EN 60601-1:2006+A1:2013; CAN/CSA-C22.2 No. 60601-1:14

Symbols Used:
Power Adapter input is AC
Indicates compliance with the requirements of all the applicable EU directives
Warning - see accompanying documents
Indicates compliance with the EU WEEE directive 2012/19/EU
Type B - any applied parts are generally not conductive