Intellirod Spine Disposable System Reader Instructions for Use

Intended Use:

- The Intellirod Spine LoadPro system is intended to be used as an aid in the assessment of instrumented posterolateral or interbody thoracolumbar rod strains whenever the surgeon is concerned about the amount of strain imparted on the rod or the asymmetry of strain on bilateral rods. The Sensor is intended for application in the thoracolumbar spine from T1 to S1.
- The System is intended to be used by Surgeons, Nurses, Physicians Assistants, and Residents during the surgical procedure.
- The LoadPro Reader is intended to be use with the LoadPro Sensor (Model: 007-1001) only.

User Interface Description:

- Scan Button – Green button – initiates continuous reading
- Clear Button – Gray button (has dimple on top of button) – stops scanning
- Display – 2 line text display – displays strain values for all sensors within reading field. If more than 2 sensors detected, the display will scroll every second.
- On/Off switch – slide switch on end of handle
- Battery Door – on back side of handle – requires T8 Torx drive to open
- Battery – CR123 lithium battery – provides approximately 1 hour of continuous scanning.

Description of Operation

Once the Scan button is pressed, the Reader continuously scans and displays data from all sensors within the field with a maximum of 2 sensors. The Reader will beep for every valid Sensor data seen.

Pressing the Clear button at any time will clear the display and turn off the RFID Field. To begin scanning again, the Scan button will need to be pressed.

NOTE: if the display becomes dim or the Reader stops beeping (seeing sensor data) replace the battery (see Maintenance section for instructions on replacing the battery).

Max Load of the Sensor is +/- 3000 microstrain

Sensor data is displayed on the Reader as: 8-digit serial number +/-4-digit strain value.

Sensor data is displayed in whole numbers of microstrain.

Sensor data range is +/-2000 microstrain +/- 10%

Items required for Proper Use

- Sterile sheath large enough to hold the Reader
- Fresh/new CR123 battery

Operating Instructions:

1. Prior to use, inspect the Reader's plastic enclosure for damage and make sure the batter door is fully inserted and screwed down.
2. Always insert a new battery before each use (see Maintenance section for instructions on replacing the battery)
3. Pass the Reader into sterile field by placing the Reader into a sterile sheath and close the end of the sheath.
4. Keeping the Reader inside the sterile sheath, slide the power switch to ON.

5. When ready, press the Scan (Green) button. The RFID field will turn on and start scanning for Sensors.
6. Hold the Reader, in the sterile sheath, over the Sensor(s) within 3" of the top of the sensors. The Reader will beep for every Sensor read. The display will update with every reading. 1 Sensor per line.
7. If scanning needs to stop, press the Clear (Gray) button. The RFID field will be turned off and the display cleared.
8. To restart scanning, press the Scan (Green) button.
9. When finished, press the Clear (Gray) button, slide the power switch to the OFF position, and remove from the sterile sheath.
10. Dispose of the sterile sheath as appropriate for bio-hazardous waste.
11. If the Reader is not going to be used for more than 1 day, remove the battery. (DO NOT STORE THE READER WITH THE BATTERY INSTALLED)
12. Dispose of the used battery as appropriate for your location.

Maintenance:

If the Reader is damaged, please return to the manufacturer for repair or replacement.

No calibration is required for the Reader

The external surface of the Reader can be cleaned with a soapy water or isopropyl alcohol as needed. Do NOT bleach. Do NOT sterilize.

The only serviceable part of the Reader is the battery. It should be replaced before the start of every procedure.

Battery Info:

- **USE CR123 BATTERIES ONLY**. (**Lithium 3.0V 1500mAh (to 2.0V))**
- Battery holder is keys so it only inserts one way. Positive terminal towards on/off switch.
- Dispose of the battery properly for your location.
- T8 Torx driver required to access battery compartment.

Troubleshooting

No Data Provided/No Readings	Verify a fresh/new battery is installed Verify Power switch is in the ON location Verify the Reader is in Scan mode Verify the Reader is within 3" of the Sensors and parallel to the top of the Sensors Verify the insertion tools are removed from the Reader's RFID field i.e. not near the Sensor
Reader Display does not work properly Doesn't clear all lines at power up, only partial characters are displayed, Numbers and Letters do not display properly	Return Reader to Intellirod for repair or replacement

Reader remains in Scanning Mode	Verify the Reader is within 3” of the Sensors and parallel to the top of the Sensors Verify a fresh/new battery is installed Verify the insertion tools are removed from the Reader’s RFID field i.e. not near the Sensor

If after trying all the troubleshooting steps, please return the Reader to Intellirod Spine for repair or replacement.

Manufacturer

Intellirod Spine
554F White Pond Drive
Akron, OH 44320 USA

Model/Reference Numbers for the LoadPro System:

- Intellirod Spine LoadPro System: Model 007-1000
- Intellirod Spine LoadPro Sensor: Model 007-1001
- Intellirod Spine LoadPro Reader: Model 007-1002
- Intellirod Spine LoadPro Instrument set: Model 007-1004
- Intellirod Spine LoadPro Manuals: Model 007-1003

Symbols and Warnings

-  Read Instructions for Use before using
-  Reader battery ON
-  Reader battery OFF
-  Storage humidity must be kept between 10% and 100% non-condensing.
-  Storage temperature must be kept between -40˚C and 70˚C
-  Caution: Federal Law (USA) restricts the use of this device to sale by or on the order of a physician
- Due to the RFID output at 13.56MHz, use of the Reader within 12” of other equipment may cause the other equipment to have unintended operation. DO NOT PLACE THE READER NEAR

OTHER EQUIPMENT WITH THE RFID FIELD ENABLED. Always press the Clear (Gray) button or turn the power switch OFF before placing the Reader within 12” of other equipment.

-  The Reader should not be used if the integrity of the plastic housing has been compromised (cracked, broken, or missing battery door). If the Reader is damaged, please return to the manufacture for repair or replacement.
-  WARNING: No modification of this equipment is allowed.

MODEL: 007-1002
FCC ID: 2ADUW-007-1002 (RFID)
FCC ID: T9J-RN42 (Bluetooth)
This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.