

ISKD Monitor Manual

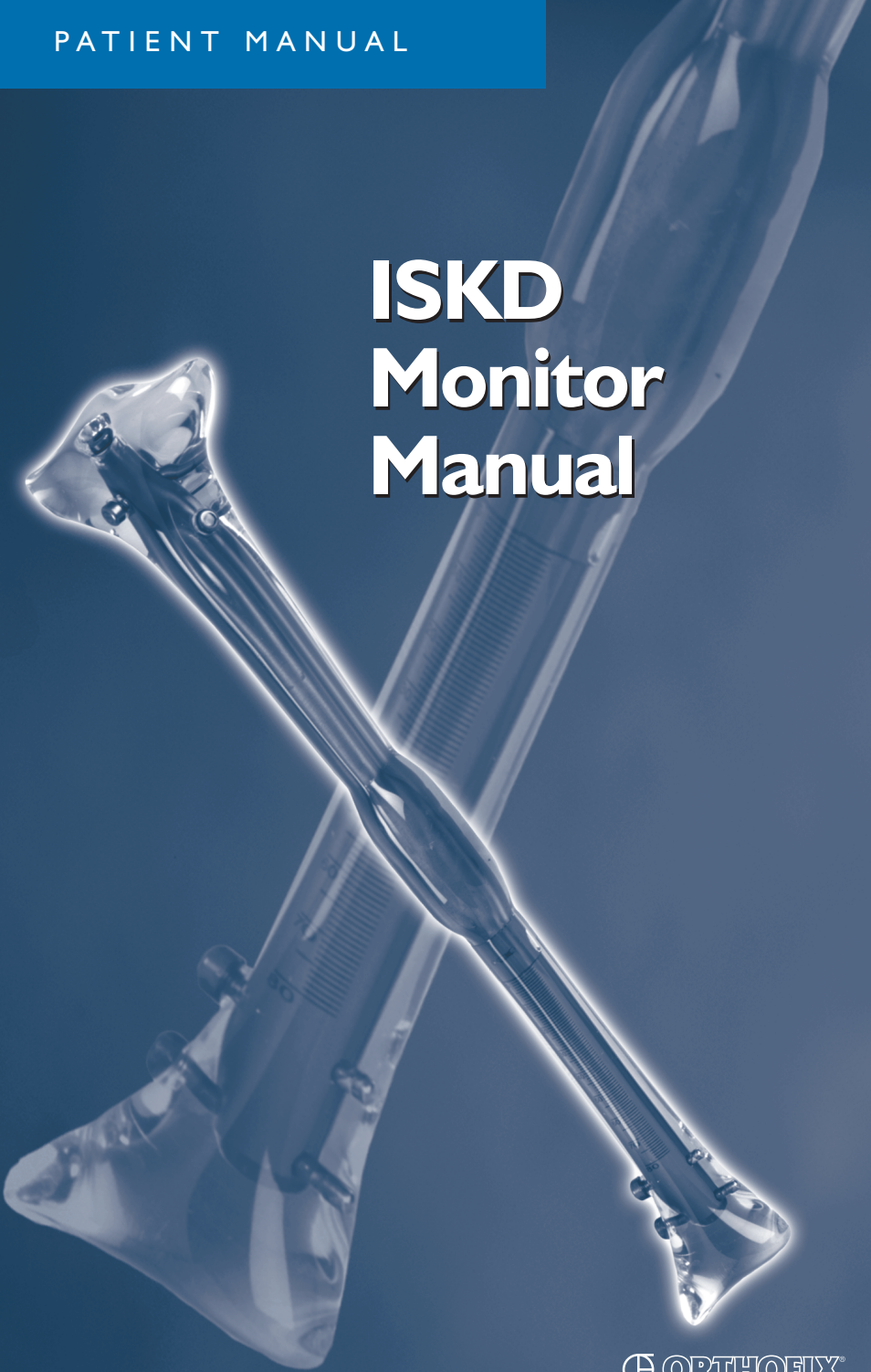


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PACKAGE CONTENTS:

1-ISKD MONITOR

2-ISKD 9-VOLT BATTERY

INTENDED USE, WARNINGS AND PRECAUTIONS

Intended Use:

The ISKD Monitor is intended to enhance the functionality of the ISKD Internal Limb Lengthener by enabling the patient and doctor to externally monitor the daily progress of the limb lengthening process.

Warnings:

1. When turning the Monitor ON, hold the Monitor at least three feet away (approximately one meter) from the limb implanted with the ISKD Internal Limb Lengthener and any other magnetic source. Failure to do so could affect the Monitor's ability to accurately detect and track the magnet inside the ISKD Internal Limb Lengthener.
2. Important: the Monitor cannot make accurate length calculations if measurements are not taken often enough. Measurements should be taken multiple times per day, as well as during and after increased patient activity.

Precautions:

1. The data provided by the ISKD Monitor is not intended to replace radiographic assessment. Treatment decisions should be based on standard methodology.
2. Examine the ISKD Monitor carefully prior to use to assure proper working condition. If you believe an ISKD Monitor to be faulty, damaged or suspect, contact Orthofix or your local representative.
3. Do not apply too much pressure when using the ISKD Monitor on the thigh. Apply only enough pressure to hold the unit in a steady position.
4. If the Monitor does not indicate any increase in length after one day and you have been active according to physician instructions or if the Monitor cannot detect a pole when taking a measurement, call your doctor. If it is suspected that the Monitor is not functioning properly, contact your doctor.
5. Periodically, the measurement mark on your limb should be refreshed with an indelible marker as it may fade due to perspiration, bathing, etc.
6. Under no circumstances should rechargeable batteries be used with the ISKD Monitor nor should any attempt be made to recharge the original battery provided.

Important:

Always bring your ISKD monitor with you to your doctor's appointments.

INTRODUCTION

Congratulations. You are in the process of lengthening your limb with the ISKD Internal Limb Lengthening System. The following information and instructions are intended to help you use the ISKD Monitor correctly. Consistent and accurate measurements during the lengthening process help ensure overall successful lengthening. Please read the following information carefully prior to use of the ISKD Monitor to ensure optimum results. If you do not understand these instructions, or if you have questions concerning the ISKD Internal Limb Lengthener that is implanted, please contact your doctor.

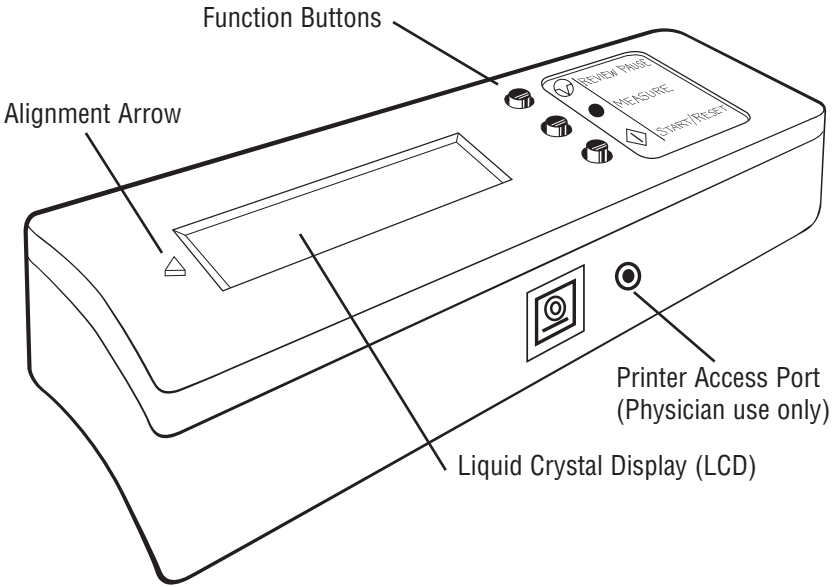
LIMB LENGTHENING WITH THE ISKD

The ISKD System is intended for limb lengthening of the tibia and femur. The ISKD Monitor is intended to enhance the functionality of the ISKD Internal Limb Lengthener by enabling you and your doctor to externally monitor the daily progress of your limb lengthening process.

It is important to understand that the ISKD Monitor DOES NOT control limb lengthening. Lengthening with the ISKD Internal Limb Lengthener occurs as a result of your own movement (e.g., small rotations of the leg, walking with crutches, etc.). It is your movement that causes the ISKD Lengthener implanted in your leg to distract and thus lengthen your leg. The rate of lengthening is determined by how much activity you perform. The Monitor is merely used to track and record the amount of lengthening that has been achieved and the rate at which that lengthening is occurring. The information provided by the Monitor is intended to assist you and your doctor in determining your daily goal for lengthening and the amount of activity you need to perform to reach that goal.

DESCRIPTION OF THE MONITOR

The ISKD Monitor is a hand held device provided with the ISKD Limb Lengthening System to enable you and your doctor to monitor the limb lengthening process on a daily basis. The monitor has three function buttons, a liquid crystal display (LCD), an alignment arrow to facilitate correct placement, and a printer access port for physician use only. When used correctly, the Monitor detects, tracks and records changes in the position of the north and south poles of the magnet that rotates inside the ISKD Internal Limb Lengthener that is implanted in your leg. A microcomputer within the ISKD Monitor converts these rotations into millimeters of distraction.



The distraction amounts are displayed on the Monitor's LCD. With the ISKD Monitor, you and your doctor can track the amount of lengthening achieved and the rate at which lengthening is occurring.

The information provided by the Monitor can also serve to inform you and your doctor if lengthening is occurring at a rate that is too fast or too slow. If your lengthening is occurring too slowly and you are not meeting the daily goal prescribed, call your doctor. You may simply walk, perform exercises, etc. according to your doctor's orders to increase the rate of your lengthening. If your lengthening is occurring too fast, and you are exceeding the daily goal prescribed, call your doctor. You may simply decrease your amount of activity according to your doctor's orders.

HOW THE MONITOR TRACKS LENGTHENING

The ISKD Monitor contains a “magnetic sensor” much like an electronic compass that detects the small magnet sealed inside the ISKD Internal Limb Lengthener implanted in your leg. As the implanted ISKD Internal Limb Lengthener distracts, (i.e., lengthens) the magnet inside rotates. The ISKD Monitor tracks and records the changes in the position of the poles of the magnet. When placed correctly over the implanted ISKD Internal Limb Lengthener, the Monitor detects which of the two poles of the magnet (north or south) is present at the measurement mark drawn on your leg by your doctor. The north pole is represented by an “N” and the south pole is represented by an “S” on the Monitor’s LCD.

Each time the Monitor detects a change in poles since the previous measurement (i.e., north to south or south to north) it determines that a 180° rotation of the magnet has occurred. Each 180° rotation of the magnet represents approximately 0.37mm of length that has been gained. It should be noted that the Monitor will only display a change in length if at least 0.37mm of lengthening has been gained. Thus, lengthening less than 0.37mm may have been gained, but is not indicated by the Monitor.

Each time a measurement is taken, the microcomputer inside the Monitor compares the magnetic pole (i.e., north or south) that is currently present at the measurement mark to the magnetic pole that was present at the measurement mark from the previous measurement. If a change in the poles has occurred, the Monitor adds 0.37mm (equal to 180° of rotation) to the total length gained for the day and also to the total length gained from the time the Monitor was activated. If the Monitor does not detect a change in the poles (i.e., no rotation detected), it records that a measurement was taken, but no length will be added to the totals.

The Monitor cannot make accurate length calculations if measurements are not taken often enough. For example, if the magnet rotates such that two pole changes occur between measurements, the Monitor will not detect a different pole at the measurement mark and will record that no lengthening has occurred. However, this is not likely to occur as the ISKD lengthening rate is very gradual. A minimum of five measurements spread throughout the day is recommended.

USING THE MONITOR

The ISKD Monitor is easy to use and will assist you and your doctor in monitoring the lengthening progress. There are three basic steps to begin using the ISKD Monitor.

1. To turn the Monitor ON, press and release the START/RESET button and wait for the display to read “Zero” and you hear a rapid beeping sound.
2. Position the Monitor on your leg at the measurement mark drawn by your doctor.
3. Press the MEASURE button.

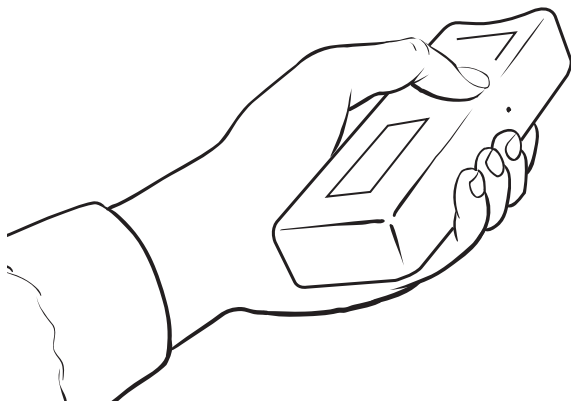
Repeat this process each time the alarm sounds and at any other time you choose to take a measurement.

TAKING A MEASUREMENT

Measurements can be taken at any time you or your doctor feels it is appropriate. It is not necessary to wait for an alarm to sound before taking a measurement. In fact, it is particularly important to take measurements during and after periods of increased physical activity as it is likely to cause more lengthening of the ISKD Internal Limb Lengthener.

Turning the Monitor ON

Hold the Monitor approximately three feet (about one meter) away from the limb and any other magnetic source. Turn the Monitor ON by pressing and releasing the START/RESET button. Continue to hold the Monitor away from the limb and allow the Monitor to go through the start-up routine until the display reads “Zero” and you hear a rapid beeping sound. You must wait for the Monitor to reset and display “Zero” indicating that the reset process is complete or the Monitor will not take a measurement.



TAKING A MEASUREMENT (CONTINUED)

Monitor Start-Up

Watch the Monitor's LCD readout. During the start-up routine, the Monitor will display the following information: Limb Identification, the Date (expressed as month/day/year), the current time, North or South (representing North pole or South pole respectively) as detected by the Monitor the last time a measurement was taken.

Positioning the Monitor on the Limb

The curved end of the Monitor goes against the bone being lengthened. Place the alignment arrow (↑) on the curved end of the Monitor against the measurement mark that has been drawn on your limb by your doctor. The Monitor should be perpendicular to the surface of the skin with as much of the curved end of the Monitor in contact with the skin as possible. (Only enough pressure should be applied to hold the Monitor in place. You should not see the soft tissue compressing significantly under the pressure.) See Figure below.

NOTE:

In some cases, there will already be a small amount of length showing on the Monitor display when you take your first measurement. This is referred to as "offset". This initial starting length has been set by your doctor and represents the small distance that usually exists between the two bone segments following surgery.



Using the Measure Function

As you hold the Monitor at the measurement mark, the Monitor begins to sense the presence of the magnet within the ISKD Internal Limb Lengthener, and the audible alerts will change in tone and frequency. Once an “N” or “S” is displayed, press the MEASURE button. The Monitor will calculate and record the measurement.

If the Monitor displays “Zero” when placed on the measurement mark, it may mean that the magnet pole is located slightly to the left or right of the measurement mark. If this occurs, slowly move the Monitor clockwise on the limb until the Monitor detects a pole. Once an “N” or “S” is displayed, press the MEASURE button and the Monitor will record a measurement.

Note: It is important to search for the magnet in the same direction each time (i.e., clockwise). Otherwise, the Monitor may detect false pole changes and add more length than has actually been gained.

Important: If you experience difficulty in taking a measurement or obtaining a reading, review these instructions again. If you continue to experience difficulty, contact your doctor.

The Monitor display will show the amount of lengthening for the day (midnight to midnight) as well as the total length achieved to date. There is no need to write down these measurements as the Monitor stores them for you.

Important: The Monitor cannot make accurate length calculations if measurements are not taken often enough. If the magnet rotates such that two pole changes occur between measurements, the Monitor will not detect a different pole at the measurement mark and will record that no lengthening has occurred. Measurements should be taken at the scheduled alarm times, as well as during and after increased activity.

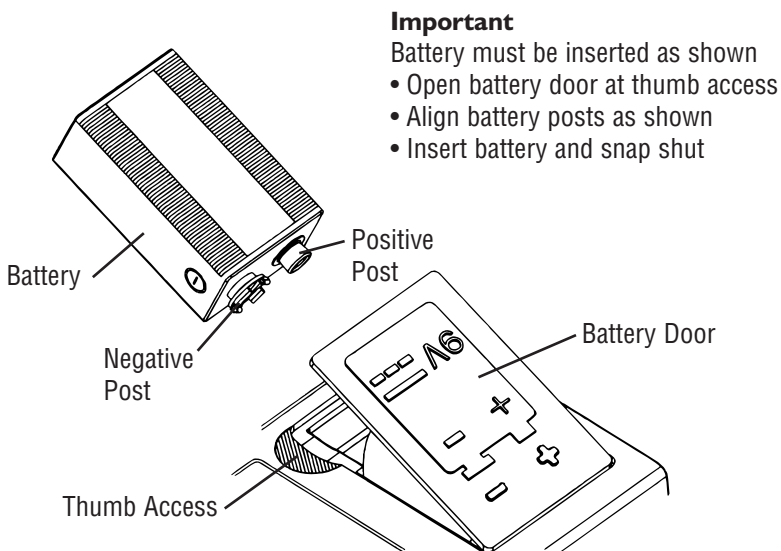
Please note that the ISKD Monitor has a finite capacity for recording measurements. Taking an excessive number of daily measurements may eventually result in a memory “FULL” indicator message. Depending on the duration of the lengthening process, daily measurements in excess of 10 per day are not recommended.

CARE FOR YOUR MONITOR

Initial and Replacement Battery Installation

The ISKD Monitor is powered by a single 9-volt disposable battery supplied with the device. If battery replacement is required, the ISKD Monitor will display “Replace Battery”.

Note: The measurement alarm will not sound until the battery has been replaced.



To install or replace the battery, open the battery door on the back of the unit. Remove the old battery and replace it with a new 9-volt disposable battery supplied with the device. After installing or replacing the battery, the Monitor will turn on. You must take a measurement at this time or the Monitor will continue the rapid beeping. Continue normal operation of the ISKD Monitor. Dispose of battery according to manufacturer's instructions.

Care and Cleaning

The ISKD Monitor has been designed to withstand daily use. However, it is a precision electronic device and should be handled with appropriate care. Dropping or other mishandling of the Monitor may cause damage.

Storage Conditions

Storage Temperature Range: -10°C to +50°C

Operating Temperature Range: +5°C to +40°C

Relative Humidity: 5% to +95%, non-condensing

- Do not expose the Monitor to direct sunlight for long periods of time.
- Do not expose the Monitor to excessive heat. (In warm climates, the temperature in an enclosed automobile or trunk can exceed 71°C.)
- Do not dispose of Monitor battery in an incinerator.
- Under no circumstances should the Monitor be immersed in water.
- The Monitor may be cleaned by wiping with a clean damp cloth.









ISKD MONITOR REFERENCE GUIDE

ISKD Monitor LCD Indicators		
LCD Display	Meaning	Action
REPLACE BATTERY	9-volt battery has fully discharged	Replace battery immediately
FULL	Memory Full	Monitor operational, but will not store data. Call for Service
NO DISPLAY	Battery discharged or defective	Replace battery; Call for Service
NO DISPLAY	No power or mechanical failure	Check battery installation and press and release Start/Reset button. If the Monitor still does not turn on, call for service.

Quick Reference And Troubleshooting Guide

Function	System Reaction
START/RESET (press & release)	Turns on Monitor
MEASURE	Takes measurement and records pole, length gained date and time of measurement
ALERT	Scheduled measurement time

Equipment Classification and Symbol Descriptions

Symbol	Description
	Attention, Consult Accompanying Documents
	Type BF Applied Part
	CE Mark
	Printer Access Port
	Review Pause
	Start/Reset
	Measure
	Storage Temperature Range

SERVICE

Contact (800) 266-3349 or your local representative.

For Assistance, call (800) 266-3349 or your local representative.



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