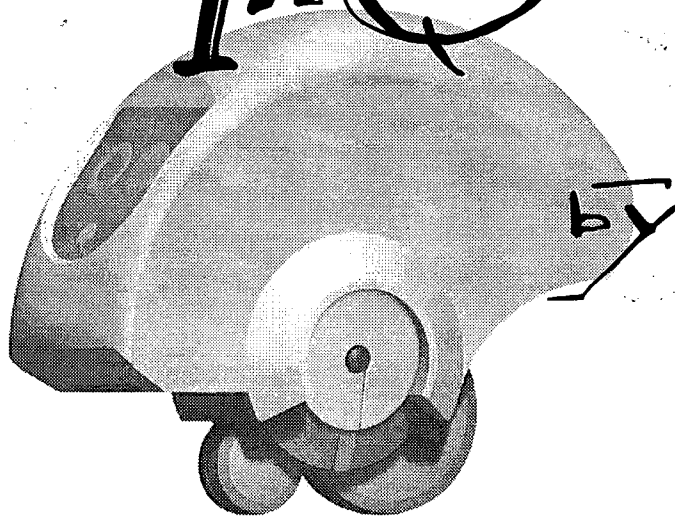


M a n u a l

Version 2.3

Spinal mouse®



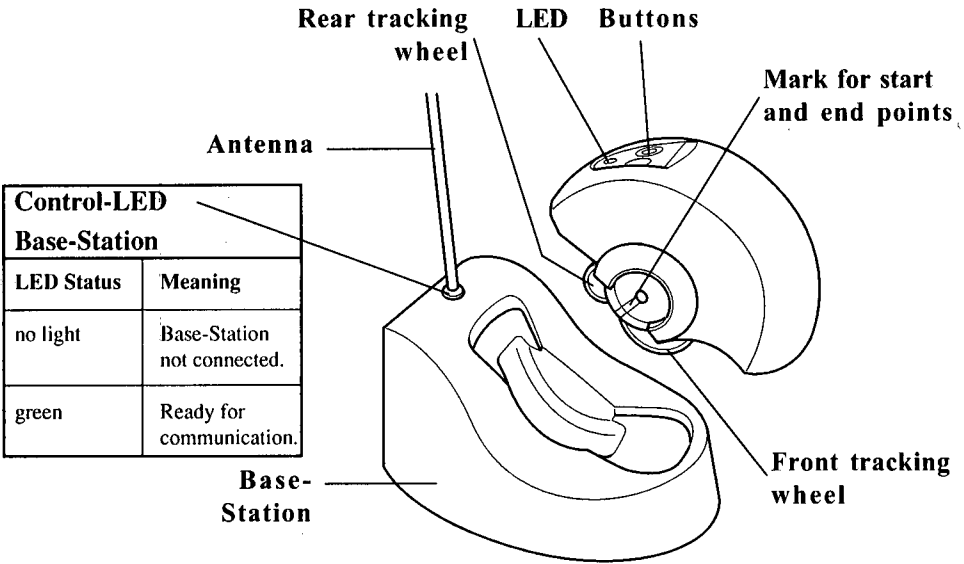
swiss made



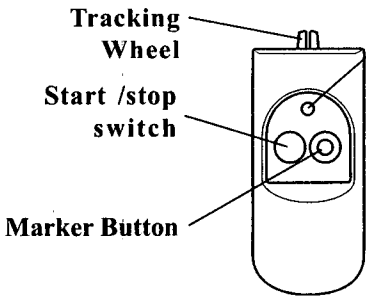
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PARTS

The SpinalMouse and Base-Station



Control-LED Base-Station	
LED Status	Meaning
no light	Base-Station not connected.
green	Ready for communication.



LED Indicator lights (amber/green)	
LED Status	Meaning
No lights	SpinalMouse is in power save mode.
green permanent	SpinalMouse activated
green flashing	Measuring in progress
green flashing fast	Repeating data transmission
amber flashing	Replace batteries

Please read the „User manual“ and the guarantee agreement before you use the SpinalMouse®. If you have any questions about the SpinalMouse® and/or its accessories do not hesitate to contact us at the address below. To ensure the fastest possible service please have your serial number ready when you call.

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GLOSSARY OF SYMBOLS

Symbols and words used in this manual



DANGER: immediate and imminent DANGER for life and limb. Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



WARNING: signals potential harm to equipment, operator or patient if instructions are not followed.



CAUTION: signals potential harm to equipment if instructions are not followed.



Note Information and tips which are important for optimal use of the functions of the SpinalMouse®

Symbols used on the SpinalMouse® and Base-Station



Class II Equipment



Attention, consult accompanying documents.



Protection against electric shock



Type BF Equipment



Alternating Current



Direct Current



Battery



Data Communication

WARNING STATEMENTS



DANGER

- Equipment not suitable for use in the presence of a flammable (e.g. anaesthetic) mixture with air or with oxygen or nitrous oxide.
- Possibility of an electric shock. The handling including mounting, installation and operating has to be carried out by instructed and well trained personnel.



WARNING

- SpinalMouse® is not able to provide any kind of diagnosis but only indications. SpinalMouse® provides geometric data of the spine and hip tilt.
- SpinalMouse® does not take over any responsibility for any kind of diagnosis made on the basis of SpinalMouse® measurements. Responsible for diagnosis is uniquely the medical expert.
- Do not define medical or therapeutic treatments simply based on SpinalMouse® measurements.
- SpinalMouse® results show geometric data of spine and hip tilt. This has the characteristics of indications and not of diagnosis.
- The medical expert is fully responsible for any kind of medical or therapeutic treatments following a measurement. Therefore SpinalMouse® disclaims any kind of responsibility for medical or therapeutic treatments.
- Do not use the SpinalMouse® over injuries or irritated skin.
- Retain this manual for your reference.
- The manual must be available for the SpinalMouse® user at anytime.
- Review this manual periodically and prior of using the SpinalMouse.

INTRODUCTION

The SpinalMouse® is a sophisticated electronic measuring-device designed to measure sagittal back shape and mobility. The SpinalMouse® is unique - compared to standard procedures it offers significant improvements in the areas of precision, objectivity and data-presentation. The main single advantage however, is that it is non-invasive and radiation-free which is a major benefit to the patient and user and improves significantly the cost-benefit ratio associated with objective back measurement.

The SpinalMouse® is run along the spinal column of the patient with the measuring wheels tracking the contour of the back. A scientifically-proven algorithm reliably converts the raw data into the following clinically relevant parameters.

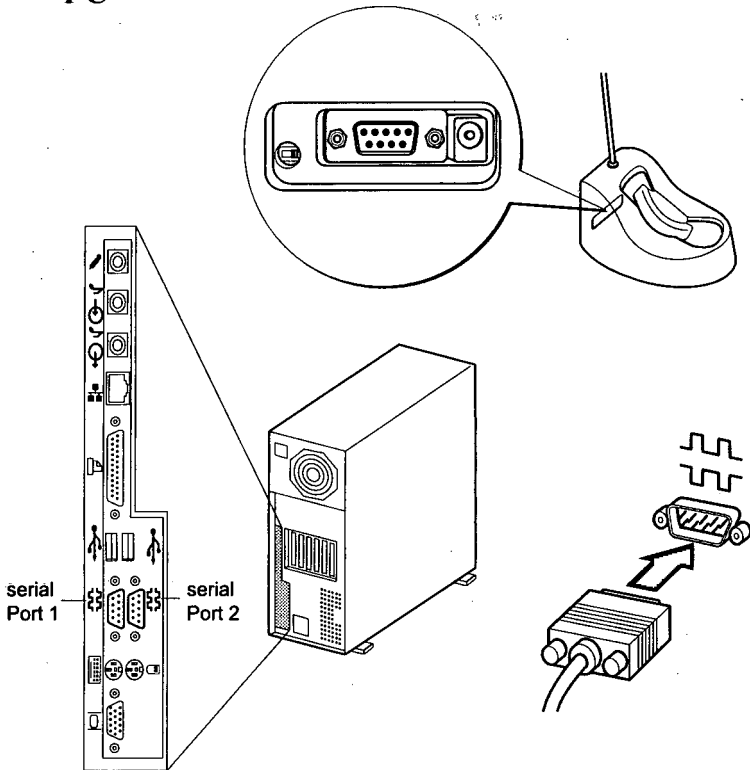
- Inclination relative to the vertical
- Kyphosis and Lordosis of individual spinal sections
- Segmental angles
- Sacral angle resp. pelvic tilt
- Back-length

SpinalMouse® measurements exhibit high validity and reliability. A wide variety of applications exist in clinical and general practice for assessment and treatment of postural or flexion problems - for example, objective follow up of the progress of back therapy for quality control or course reports.

It is also an excellent scientific research tool. With it, mass screening is now a realistic proposition allowing physiological and illness-specific norms to be defined.

The key to reliable data is a good run along the patient's back. The ergonomics and user-interface were developed to make it as easy as possible to obtain reliable results. Data is transmitted by a radio-link to the host computer and analyzed by the software supplied. The user-friendly program interface presents the data graphically for easy assessment and makes provision for further data-processing.

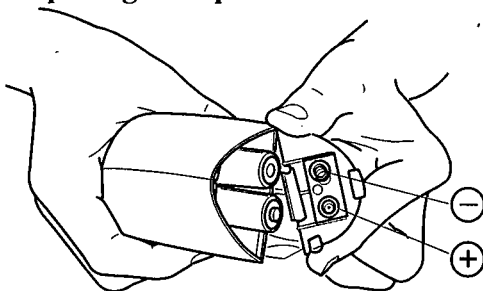
Connection of the Base-station to the PC



- The Base station should be placed in an easily accessible location which is not more than 3 meters (10 ft) away from where the patient will be measured. Over greater distances, the quality of the radio-link diminishes.
- Connect the base-station to your PC's serial port using the serial cable supplied.
- Extend the base station antenna fully - this improves the range of the radio-link.
- Connect the power cable to a grounded socket.

INSTALLATION

Preparing the SpinalMouse



Battery Installation

The following situations require a battery installation on the SpinalMouse®:

- before first use.
- when the battery power is insufficient to run the SpinalMouse®, the LEDs will flash Amber-Green.



- Open the cover of the battery compartment and pop in the batteries. Watch for correct polarity.
 - The SpinalMouse® and/or the batteries may be damaged if the polarity of the inserted batteries is wrong.
 - Remove batteries if SpinalMouse® is not likely to be used for some days or weeks.
 - The batteries contain corrosive liquid. If a battery leaks: Do not let the liquid come into contact with skin, eyes or mouth. If it does, flush the affected area of your body with water for at least 15 minutes. Consult a doctor. Do not inhale vapor. Immediately clean the leakage from the unit with a soft towel and dispose of the towel. Idiag accepts no responsibility for injury to patients, or damage to the device caused by leaking or defective batteries.
 - Do not charge non-rechargeable batteries.
 - Take care of our environment; properly dispose of used batteries!
-
- The life of the batteries is about 3 months, depending how much you use the device.
 - Only use high quality 1.5 V batteries. See „Technical Data“

Installing the software the SpinalMouse® program 2.30

Place the CD into your CD-Rom drive. The installation program will start automatically within 20 seconds.

If your PC is not prepared for autoinstallation install the program as following:

1. Press Start > Run >
2. Press Browse > Look in: >My Computer double-click on the SpinalMouse® symbol.
3. Choose the "start.exe"-file and press the Open button
4. Click on Okay in the Run-dialog box
5. The installation process starts. Select the language you want to use.
6. Follow the instructions on the screen.
We recommend that you accept the original settings, just press Continue to complete the installation.
7. Finish the installation process when asked to do so and reboot your system.
8. The SpinalMouse® icon will now appear on the screen or press Start > Program > SpinalMouse®

We hope you will enjoy working with SpinalMouse®.

Uninstalling the software

To remove (delete) the SpinalMouse® software from your computer, proceed as you would to remove any normal program installed under Windows. i.e. select:

Windows-Start-Menu-Settings, System Control, Software

Select the SpinalMouse® Software from the program list and then click «add/remove». The SpinalMouse® software will be deleted.



Note

- The Base-station must be plugged into the Serial Port (COM1 or COM2) before you start the computer. If you plug it in when the computer is already running, it will not be recognized and it may cause the computer to work improperly.
- Proximity to certain equipment which may be present can impair the functioning of the radio link, e.g. cordless-phones, field-generating medical equipment, computers etc. Should you experience problems in data-transmission, try to locate the base-station as far away from potential interference sources as possible.

Measurement process

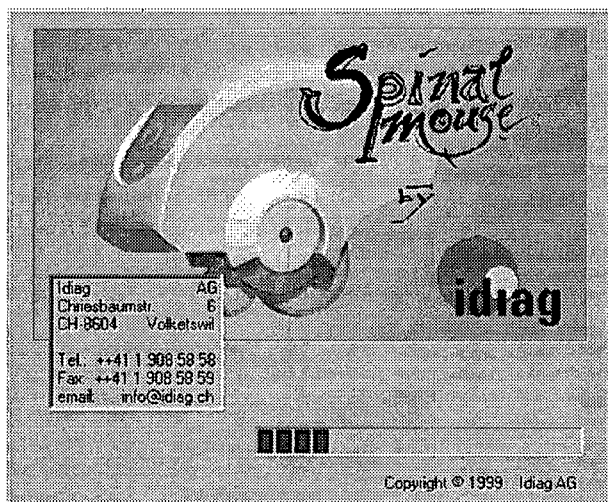
Starting the SpinalMouse® software



Shortcut to
SpinalMouse

To begin with you have to start the SpinalMouse® software. You can do this when you are in the Windows-Explorer by double clicking on the icon «SpinalMouse.exe»

While the program is being loaded, a window will appear with the name of the registered user. Thereafter the dialogue window «Patient Details» will appear.



Registration of Patient Details

When measuring a new patient, begin by entering the patient's details in the spaces provided: (Name, First Name, Date of Birth etc.). It is also possible to complete this information later. Simply enter «control mode» and double click on the patient details.

Clicking on «continue» switches the software to «control mode»



The measurements recorded by the SpinalMouse® are subject to data protection regulations. That means they should be treated confidentially and must not be made available to unauthorized third-parties. Idiag accepts no responsibility for the abuse of data gathered by the SpinalMouse®.

Metric-System

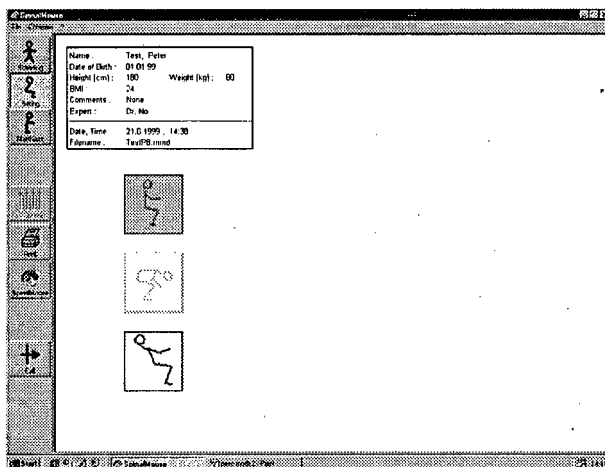
US-System

Choosing the Measurement Mode

Control Mode

The following screen-shot shows the SpinalMouse® software in «Control Mode». In this mode you can enter or change patient details, start a measurement or analyse the results.





You can make all the necessary settings before beginning measurement from in the «control mode». The SpinalMouse® can be used in three different measurement modes. «Standing», «Seated», and «Matthias». Use the PC-mouse to click on the icon for the desired mode.



«**Standing**» mode: Measurements can be taken with the patient upright, bent full forwards and bent right back. Ask the patient to adopt the desired posture. Now consult the chapter **Choice of Measurement Posture**.



«**Seated**» mode: This mode is suitable for patients who cannot maintain the desired position for long enough while standing. These patients can balance better when seated and so feel more secure. The three positions, „Upright“, „Flexion“ and „Extension“ can be measured as normal. Generally the pelvic girdle moves less when seated while the chest vertebrae move more during „extension“.

Note



To ensure good access to the patient's back, use a stool rather than a chair. Ideally, the stool seat should be a touch too small, so that the patient's posterior overhangs a little. This enables the SpinalMouse® to easily reach the Sacrum. Seat height should be adjusted so that both feet are flat on the floor and the patients knees form a right angle.



«**Matthiass**» mode: The Matthiass test is designed to identify postural weakness by comparison of two standing postures. The first is normal and the second is with both arms in the horizontal position. The patient is measured in the first position. Then, after 30 seconds with arms up, the measurement is repeated. Holding the arms horizontally moves the center of gravity forwards, and this stress is often compensated by shifting the whole body back. The pelvic girdle moves forwards and lordosis deepens.

That done, you have completed the settings that need to be made with your computer mouse. Control now passes to the SpinalMouse® and you can turn your full attention to the patient. Lift the SpinalMouse® from the base-station. You are now ready to select the postural position to be measured.



Choosing Measurement Posture

Choosing posture in «Upright» and «Seated» mode.

In these modes you can measure the patient in the following positions.



Standing-Upright



Standing-Flexion



Standing-Extension



Seated-Upright



Seated-Flexion

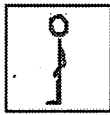


Seated-Extension

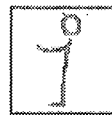
The desired posture can be selected by pressing the „marker“ button on the SpinalMouse® repeatedly. The selection will cycle, with the currently chosen posture-icon being darkened and set back.

Choosing Measurement Posture in «Matthiass Mode»

The patient is measured in two positions.



Matthiass - Upright



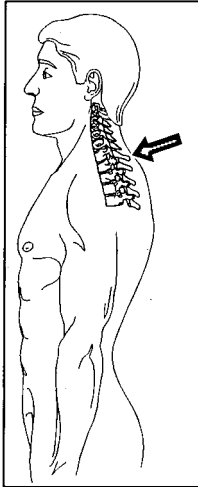
Matthiass-30s Arms Up

The arms up position is held for 30 seconds before the measurement is made.

Procedure for the Matthiass test:

1. First measure the patient in the upright position.
2. Select the „Outstretched Arms“ symbol and re-measure the patient after **30 seconds** with arms up. Patients with weak back-musculature show large differences between the two measurements: Shoulders shift back, hips forwards and lordosis is increased.

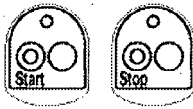
Beginning Measurements



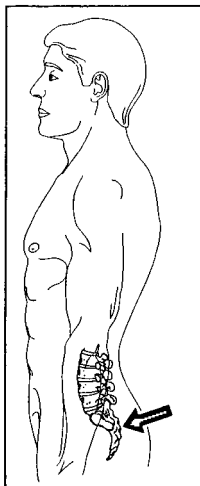
Before you start the measurement check the following chapters:

- Instructions to the patient
- Maintenance (Inspection, Cleaning and Disinfection)

Position the SpinalMouse® on the mark above the C-spine7-process. (cf. instructions to the patient). Make sure that the mark between the two wheels and the mark on the skin coincide. Careful palpation and marking of start point C-spine7-process on the patient's skin is necessary to obtain reliable data.



Begin measurement by pressing the „start“ button on the left. The green LED on the SpinalMouse® will begin to flash. The computer displays the icon of the chosen postural position in color.



Run the SpinalMouse® para-vertebrally along the spinal column (i.e. one wheel's breadth to the side of the processi spinosi as far as the start of Rima Ani (S-spine3). As you run down the patients back, the back curve will be generated real-time on the computer screen.

Note



- Always proceed down the back from C-spine7-process to the Rima Ani. Hold the SpinalMouse® so that your index figure can reach the buttons and the large tracking wheel is downwards. Apply gentle, but even pressure - just enough for the wheels to turn. For the measurement to be valid, both wheels must have skin contact for the whole of the measurement period.
- Try to roll at a constant controlled speed. It should take you about 3 seconds to make the whole measurement from C-spine7-process to S-spine3.

Ending the Measurement

End the measurement by pressing the „Start“ button once you reach the Rima Ani. Once the button is pressed, skin contact is no longer necessary. Check that the measurement looks plausible. Does it match your clinical expectation? Does the back curve look realistic? If in doubt - „delete the measurement“ and try again.
(see: Deleting a measurement)

Instructions to the patient

Note



SpinalMouse® measurements are made by running the device directly over the skin surface.

1. Ask the patient to remove his or her shoes. They affect posture and will prejudice the measurements.
2. Ask the patient to strip to the waist. The whole spinal column from Thorax to Rima Ani (S-spine3) should be accessible. Clothing and underwear will spoil the measurements if they are in the way.

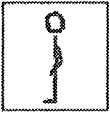


WARNING

For hygienic reasons we recommend you clean and disinfect the skin along the vertebrae with an alcohol based product.

3. To obtain the most accurate measurements the start point must be marked on the skin. Locate the process of C-spine7 and mark the center point with a medical felt-pen. (Ink must be non-irritant).

Marking the starting point significantly improves the accuracy and reliability of the measurements.



Upright: The patient should adopt his usual standing posture. Feet should be slightly spaced (hip-distance) apart. We recommend that you instruct the patient to take up position with a standard instruction: „Please stand as you usually do, not too relaxed, but not too stiff“. Only correct the patients posture when it seems way different from what you expected. α



Flexion: Ask the patient to bend forwards as far as possible. Head and arms should hang loosely. The patient should try to go as far as their hips, chest- and lumbar-vertebrae will allow. N.B. Measurements of standing patients should be made with the knees straight. If the knees are bent, the position of the Rima Ani is hard detect and the hip-sacral angles are falsified.



Extension: Ask the patient to bend back as far as possible. Hands may be placed on hips for stability, but the head should not hang too far back as you need clear access to the start position marked at C-Spine7-process. N.B. Some patients may find very hard to hold this position when standing. Extension in «seated» mode is easier and a viable alternative.

Important Instructions

Note



Downwards:

Always begin measurement at the upper marker and roll down the back to the Rima Ani. The SpinalMouse® is not bi-directional. If you try measurements in the opposite direction the data will be meaningless. α

Even Pressure:

Press the SpinalMouse® against the patient's skin just hard enough for the wheels to turn. Keep the pressure even. 17

Skin Contact:

Both wheels must have skin contact for the whole the measurement period.

Para-vertebral:

Best results are obtained when you run the SpinalMouse® para-vertebrally along the spinal column (i.e. one wheel's breadth to the side of the process spinosi).

Note



Energy-Saver Mode

After a few seconds not being used, the SpinalMouse® enters a power-save mode. (The LEDs switch off.) The Screen displays the message „Power-save mode - press Marker button twice to exit.“ To re-activate the SpinalMouse® press the marker button twice. The green LED will light when the SpinalMouse® is ready to continue.

Changing Patient Details

If you have not entered all the patient details or you need to correct an entry:

1. Double click in the patient data area. The entry mask will appear and data can be modified. Confirm the modification.

Deleting a Single Measurement

Should you decide, while analysing results, that you want to delete a single measurement:

1. Using the PC Mouse, double-click on the SpinalMouse® icon (screen left). When the dialogue appears, select «complete» The program will switch to the measuring mode.
2. Double click on the incorrect measurement. A dialogue window will appear: Confirm that you want to delete this measurement.

Setting Marker Points

Marker points enable you to register the location of clinically interesting points on the patient's back for easy recognition in the analysis.

Begin measurement in the usual manner as described in Chapter 3. Press the „Marker“- button as you pass over the position you wish to mark. You can mark up to 18 positions. To be able to compare marked positions from different measurements ensure that you can recognize the marked point in the data output. (you may want to make notes on the print-out).

End measurement as described in chapter 3, by pressing the „Stop“ button. The marked points will be displayed graphically on the screen with a green cross.

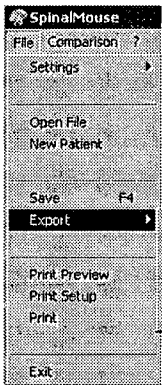
Data Loss

If you have a bad radio-link between the SpinalMouse® and the base-station the chances are that some data will not be transmitted properly. When this occurs, the software will display the message, „Data loss during transmission.“ However, the measurements are not lost - they are still stored in the SpinalMouse®.

To move the data safely to the computer - follow the instructions on the screen. - Hold the SpinalMouse® very close to the base-station and press first the „Marker“-button then the „Stop“-button. The data will be transmitted to the PC while an LED blinks.

Printing the Measurements

Select the „Printer“ icon (screen left) with the PC mouse. This will open the dialogue window for the currently installed printer. Note that the data is printed in landscape format.



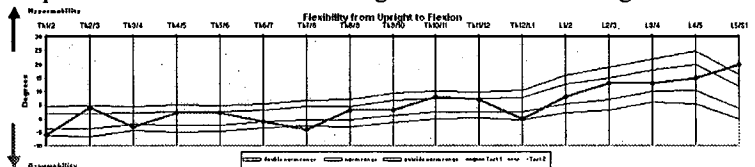
Import/Export and Archiving of Data

In order to be able to compare a series of measurements an export function has been included. To export data:

1. Open the chosen patient data file.
2. Ensure that you are in «Evaluation» mode
3. In the «File» menu, choose «Export » and one of the given options.

• Data to Excel

Transfers your SpinalMouse® data into a given Excel template and shows a graphic comparison between the data of the examined person and standard data same gender and similar in age.



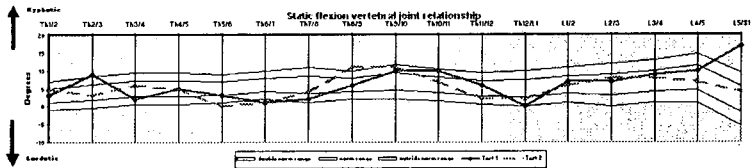
• Comparison of data in Excel



The SpinalMouse® may not be used blind in the sense of an "expert system", in which deviations from the norm are uncritically construed as pathology. The expert makes the assessment, not the measuring system.

Transfers data from two different SpinalMouse® measurements into a given Excel template and shows a graphic comparison between the examination data and standard data same gender and similar in age.

- Please regard the proper succession of measurements
- Open the older data of the two measurements you want to compare
- Click on Comparison of data in Excel
- Select the second measurement



Note More information about „normative values“ see „SpinalMouse® interpretation Manual“.

- **Column Format**

Transfers your SpinalMouse® data into Excel columns

- **Row Format**

Transfers your SpinalMouse® data into Excel rows

Opening an Existing Patient File

You can open and work on an existing patient record at any time. There are several ways to do this.

1. In the «Windows Explorer» find the chosen patient file and double click on it. The SpinalMouse® software will run and display the patient data.
2. If you have already started the SpinalMouse® software, you can select «Patient», «Select Patient». A dialogue window which allows you to choose from the patient list.
3. Under the «File» menu, «Open Patient»

Using two SpinalMice in the same room

It is possible to use two SpinalMice in the same room. All SpinalMice are set to use the same frequency when shipped. To avoid a clash of frequencies and interference between the two devices, it is necessary to change the frequency of one of the SpinalMice. This is easily done:

SPECIAL FUNCTIONS



Frequency switch
(basestation)

1. On the under-side of the SpinalMouse® is a frequency switch.
2. Use a ball-point pen or similar object to switch to the alternative frequency.
3. A second switch is found on the base-station near the cable connections. Flip this switch as well.
4. Do a test measurement to ensure that the radio-link is working. If it isn't you haven't switched both sides.
 - Make sure that both switches are in the same position.
 - Make sure that the two SpinalMice are not interfering with each other.
 - The first SpinalMouse® and base-station should both be switched to position 1. The second SpinalMouse® and base-station should both be switched to position 2.

Setting frequency-channel

Measuring instrument 1

selector receive in position 1
selector basis-station in position 1

Measuring instrument 2

selector receive in position 2
selector basis-station in position 2

Note



Changing the metric system

If you want to enter the patient's data in the US-system instead the metric system choose „Settings“ in the „File“-menu. Remove the tick at „Metric system“. The display changes immediatly to the US-system.

User's address

You may want to have written your name and adress on the printed SpinalMouse® datas. Choose „Settings“ in the „File“-menu, then choose „User's adress“. Enter your adress in the spaces provided.

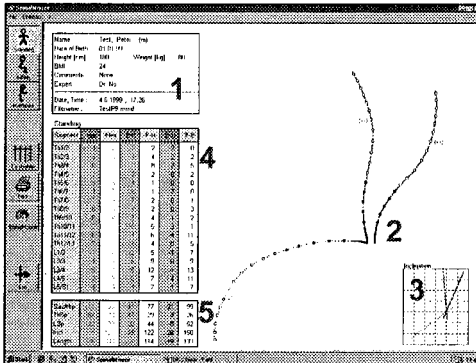
Results



You have now carried out at least one SpinalMouse® measurement on a patient. Place the SpinalMouse® back in its base-station and return to the computer. Using the PC mouse, click on the <<Evaluation>> icon (screenleft).

The Evaluation page presents the following data.

1. Patient data.
2. Graphical presentation of the data.
3. Inclination lines
4. Segmental Angles (tables)
5. Curvature and flexibility of the vertebrae (table)



Patient Data (1)

Experience shows that age, sex, body-size and weight influence the shape and flexibility of the back. The Body Mass Index (BMI) enables an estimate of the patients corpulence.

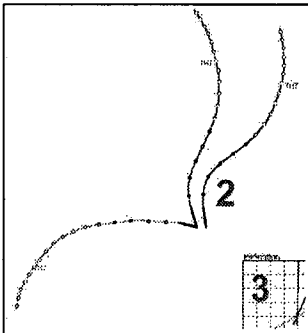
Name	
Date of Birth :	
Height [cm] :	Weight [kg] :
BMI :	
Comments :	<input type="button" value="Add ..."/>
Expert :	
Date, Time :	
Filename :	Default39.mmd

Double click on the patient data at any time to change or add to it.

If you need more space for notes click on „Add ...“ and insert your notes. Your notes will be saved and stored as Word documents. They will be named with the name of the actual SpinalMouse® file with the additional ending "temp.doc"

Graphic Presentation of the Data (2)

The graphic shows the contours of the back in the sagittal plane. The software calculates the position of the vertebrae and displays them (not the spinal processes) as circles projected onto the back surface. Bold circles indicate lumbar vertebrae, normal circles mean thoracic vertebrae. The apparent separation of the vertebrae dependent on curvature is also accounted for (according to Schober, Ott). Thus the program graphic is fully equivalent to the clinical picture of spinal shape.



Note: For easy orientation the lumbar vertebrae and the seventh thoracic spine are marked as bold circles.

Inclination lines (3)

The inclination lines are the shortest distance between start at D-spine1 and L5/S1 - the last flexible segment. They are a measure of the patients postural position - the sum of the total forward or backward motion. A comparable qualitative measure is the floor-finger distance. In practice, inclination change is a frequently used measure - but it does not correspond to the sum of segmental flexibility values as some of these cancel each other out.

◆
◆
◆

Segmental angles and segmental mobility (4)

Segment	Upr	Flex	Ext	F-U	E-U	F-E
Th1/2	4	5	5	-1	1	-2
Th2/3	3	3	3	5	0	5
Th3/4	2	2	7	0	0	0
Th4/5	2	7	7	-3	3	-6
Th5/6	3	7	7	1	5	-3
Th6/7	3	5	5	-2	0	-2
Th7/8	3	7	7	-2	0	-2
Th8/9	10	11	11	1	2	0
Th9/10	10	9	9	3	0	3
Th10/11	10	5	4	-1	5	5
Th11/L1	2	0	0	6	-1	7
Th12/L1	3	2	5	3	5	8
L1/2	4	3	3	5	-4	9
L2/3	10	3	14	19	-4	23
L3/4	10	1	13	13	-2	15
L4/5	10	3	10	8	-1	10
L5/S1	5	7	5	12	0	13

In table (4) the segmental angles and flexibility for all recorded positions are displayed. They should be understood as being analogous to the picture that one usually makes of segmental angles, i.e. the tilt or movement of a pair of vertebra relative to each other. Positive angles correspond to kyphosis or flexion and negative angles mean lordosis or extension.

The upright, flexion and extension columns correspond to the respective positions. The columns ,Upright - (minus) Flexion‘, ,Upright - Extension‘ and ,Flexion - Extension‘ describe the difference between respective positions and are thus a measure of flexibility.

Upright-Flexion (A-F):	Flexibility in Flexion direction
Upright-Extension (A-E):	Flexibility in Extension direction
Flexion-Extension (F-E):	Total Flexibility

Curvature and Flexibility of the thoracis and lumbal spine (5)

Sac/Hip	15	11	5	65	9	75
ThSp	14	70	66	10	8	4
LSp	11	68	69	60	16	78
Incl	1	110	23	119	22	142
Length	1	600	539	136	17	119

The second table (5) summarises the clinically relevant measurements, curvature and flexibility of the thoracis and lumbal spine as well as the sacrum spatial

position and hip joint co-motion. They correspond to the sum of the segmental angles of the corresponding vertebral sections. Once again positive angles mean Kyphosis (flexion) and negative angles Lordosis (Extension). The TH12/L1 segment counts functionally as belonging to the lumbal spine. The difference between the sacral angle and the vertical is the effective mobility of the hip joints because the movement of the sacral-iliac joint is negligible. Condition: The knees must stay fully extended.

Graphic Comparison



The SpinalMouse® may not be used blind in the sense of an "expert system", in which deviations from the norm are uncritically construed as pathology. The expert makes the assessment, not the measuring system.

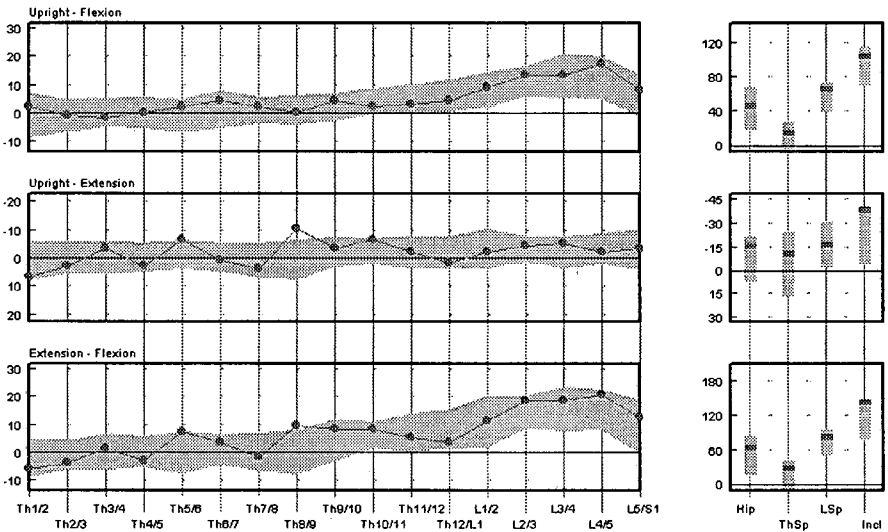
Scientific research has provided normative data for various agegroups. You can directly compare a processed measurement with the norm by double-clicking „Evaluation“.



More information about „normative values“ see „SpinalMouse® interpretation Manual“. Available under www.idiap.ch.

Graphic Comparison with Normative Values:

Standing, Men between 36 and 55 years old



Back to «Control» mode

To get back to the «Control» mode, click on the SpinalMouse® icon. The following choices are available.

1. **New patient:** When you want to measure a new patient.
2. **Repeat:** You want to do a new set of measurements with the same patient. Patient details are written to the new file - but data is not. Choose this option when you want to do a new measurement without having to re-enter patient details.
3. **Complete:** When you want to complete the existing data with new measurements. The analysed data can be supplemented or deleted.



Inspection by the user

Make a inspection of the SpinalMouse® before each measurement. If you suspect that the SpinalMouse® is malfunctioning, do not try to open it. Send it to your local distributor to be repaired. If repairs are necessary they should only be carried out by Idiag or an authorized customer service center.

Faulty components which affect the safety of the Spinal-Mouse® equipment must be replaced by genuine spare parts.

Interval	Scope	Methode
Before each measurement	• Make sure that the wheels turn and the „boat“ moves almost frictionless.	Inspection
	• Make sure that no part of the SpinalMouse® may hurt somebody.	Inspection
	• Make sure that the SpinalMouse® has been cleaned and disinfected.	Inspection
Daily	• Check the lamps, look for damaged components, labels and warning signs	Inspection
Weekly	• Check all cables (damage, breakage)	Inspection



WARNING

- Make a inspection of the SpinalMouse® before each measurement.
- Do not use a SpinalMouse® which has not passed an inspection.
- Do not use a SpinalMouse® that is damaged or does not function properly.
- Do not use a SpinalMouse® which may hurt the patient or user.
- Do not use a SpinalMouse® if a battery leaks.
- Do not open the SpinalMouse® or the Base-Station (except the battery compartment).

Cleaning of the SpinalMouse® and Base-Station

General remarks about cleaning

Please bear the following in mind when choosing a detergent:

To clean plastic surfaces you must never use anything other than soap and water. If other detergents are used (e.g. with high alcohol content) the material will become matt or tend to crack. Never use any corrosive solvent or abrasive detergents or polishes.

When cleaning, please observe the following:

- Before cleaning the SpinalMouse® equipment switch off at the mains.
- Ensure that no water or other liquides can enter the SpinalMouse® equipment. This precaution prevents electrical short-circuits and corrosion forming on the sensitive precision electronics and mechanical components.
- Use a lint free cloth moisted with a mild soap and water solution.
- Clean the SpinalMouse® equipment if required.
- Clean the SpinalMouse® rear tracking wheels after 50 measurements or at least once a month:
 1. Pull the small rear tracking wheel carefully out of the fixation.
 2. Clean the wheel, the axle and the fixation.
 3. Carefully press the wheel back into the fixation until it snaps in place.
 4. Make sure that the wheel turns almost frictionless.
- Clean the Base-Station after 50 measurements or at least once a month.



Disinfection of the SpinalMouse® and Base-Station

The method of disinfection used must conform to the legal regulations and guidelines regarding disinfection and explosion protection.

Apart of disinfect the patient's skin along the vertebra column it is important to disinfect the SpinalMouse®, especially the wheels, before and after each measurement.

Note



- Never use any corrosive, solvent or abrasive disinfectants.
- Never use a disinfectant with a high alcohol content.
- Do not use toluene based solvents.
- Do not sterilize the SpinalMouse® equipment.
- Do not expose the SpinalMouse® equipment to an alcohol based disinfectant for a longer period than 5 minutes.
- Do not bath the SpinalMouse® equipment or parts of it in disinfectants.
- Use a lint free cloth moisted with a disinfectant.
- Use a common disinfectant for plastic surfaces.



DANGER

If you use disinfectants which form explosive mixtures of gases, these must first have evaporated before you switch the SpinalMouse® equipment on again.

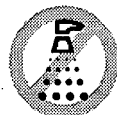
- Before disinfecting the SpinalMouse® equipment switch off at the mains.
- You may disinfect all parts on the SpinalMouse® surface including connecting cables by wiping only.
- Disinfection by spraying is not to be recommended because the disinfectant may enter the SpinalMouse® equipment.



WARNING

Disinfect at least the wheels and the surface of the SpinalMouse® before and after each use.

OPERATING, TRANSPORT AND STORAGE CONDITIONS

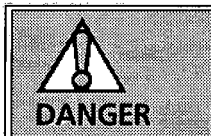


General Conditions and Recommendations

- The SpinalMouse® registers data with highly sensitive precision electronics.
- Shocks and excessive vibration can damage these parts. So don't drop it or handle it carelessly.
- Avoid dropping or jarring the units
- Do not expose to extreme temperatures or direct sunlight.
- Do not expose to water, dampness or high humidity.
- Do not rest heavy objects on the units.
- To maximize battery life and to prevent damage, remove the batteries of the SpinalMouse® if they will not be used for several days / weeks.

Operating Conditions

- Temperature: +10 °C to +40 °C
- Relative Humidity: 30% to 75%
- Atmospheric Pressure: 700hPa to 1060hPa



Equipment not suitable for use in the presence of a flammable (e.g. anaesthetic) mixture with air or with oxygen or nitrous oxide.

- Typical operating environment: Hospital, practice, office, etc.
- Transmitter and receiver must be in the same room - approx. 3m / 10ft apart.
- Store the SpinalMouse® after use on the Base-Station.
- For further information see „General Conditions and Recommendations“.

Transport Conditions

- Temperature: -40 °C to +70 °C
- Relative Humidity: 10% to 100%, including condensation
- Atmospheric Pressure: 500hPa to 1060hPa
- Use only the original SpinalMouse® packaging for transportation.
- Do not cover with heavy objects.
- Take off the batteries.
- For further information see „General Conditions and Recommendations“.

OPERATING, TRANSPORT AND STORAGE CONDITIONS

Storage Conditions

- Temperature: -40 °C to +70 °C
- Relative Humidity: 10% to 100%, including condensation
- Atmospheric Pressure: 500hPa to 1060hPa
- Always store the SpinalMouse® and the base-station in a dry dust-free environment.
- Use only the original SpinalMouse® packaging for storage.
- For further information see „General Conditions and Recommendations“

General

Transmitter and receiver must be in the same room - approx. 3m / 10ft apart

Dimensions

SpinalMouse®: (L x H x B) approx. 140 x 110 x 50 mm /
approx. 5.5 x 4.3 x 2 in

SpinalMouse® Base-station: (B x H x T) approx. 210 x 150 x
110 mm /

Serial Cable-length: approx. 8.3 x 5.9 x 4.3 in
3m / 10ft

Weight

SpinalMouse®: 240g / 8.5 oz (incl. batteries)

SpinalMouse®-Basestation: 600g / 21.2 oz (incl. antenna)

Electrical data

SpinalMouse®:

Operating voltage: SpinalMouse® 2 Batteries, R6P, AAS, 1.5V

Battery-life: approximately 1 month

Idiag recommends: Duracell®-Procell Type
PC1500 LRR Size AA 1.5V.

Base-Satation:

Operating Base-station: 9VAC

Power consumption: 200 mA



External power supply:

Jerome Industries, Model TPHN90-01M

Main voltage required: 115/230VAC 50/60Hz

Output: 9 VAC, 200 mA

Safety Certifications:

CAN / CSA C22.2 No.60 IEC 60601-1
UL 2601-1



Use only with external power supplies noted in this instruction manual.

For North America: Use only with Jerome Industries, Model TPHN90-01M adapter.

Radio Specifications

Radio link range: < 3 m / 10ft

Possible interference sources: PC, radio-telephones, High frequency-therapy-appliances (see „Information regarding interference“)

Frequency channel 1: 27,040 MHz

Frequency channel 2: 27,230 MHz

TECHNICAL DATA

System requirements

Operating system: Windows 95[®], Windows 98[®], Windows NT[®]
Memory: Minimum 10MB on Hard disks and 8 MB RAM
Parallel interface with 16555 compatible components.

Measurement Accuracy

Angle-measurement: +/- 1°
Distance-measurement: +/- 5mm/m / +/-0.6 in/ft

Classifications:

Base Station: Type of protection against electric shock: Class II equipment
Degree of protection against electric shock: Not classified, No applied parts.
SpinalMouse[®]: Degree of protection against electric shock:
Type BF equipment.

Classification according to the degree of protection against ingress of water:
IPXO - Not classified.

Method of sterilisation or disinfection: Sterilization not permitted; refer to page 30 for disinfection instructions

Degree of Safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:

Equipment not suitable for use in the presence of flammable mixtures.

Mode of operation:

Continuous.



Information regarding interference and its avoidance

This equipment has been tested and found to comply with the limits for medical devices in IEC 601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

PROBLEMS AND SOLUTIONS

Program-Error Message	Possible Cause	Solution
Leave energy-saving mode - press Marker button twice.	The SpinalMouse was not used for at least 30 seconds. The mouse is now in energy-saving-mode.	Push the Marker button twice and continue.
Movement too fast. Repeat the measurement.	You exceeded the maximum speed which the mouse can handle.	Repeat the measurement more slowly.
Radio-link communication-error.	A transmission error has occurred.	Check that the curve shown indicates correct measurement. If in doubt, you should discard the data and repeat the measurement.
Data loss during transmission.	Data loss occurred during transmission.	Pressing both SpinalMouse buttons simultaneously causes re-transmission of the data - saving the measurement.
Repeating transmission.	The SpinalMouse is repeating the transmission of the last data.	Wait 3 seconds before proceeding. If this message occurs frequently you should reduce the distance between the SpinalMouse and the base-station.

PROBLEMS AND SOLUTIONS

<p>The SpinalMouse is out of sync. with the program.</p>	<p>The SpinalMouse and the computer have lost track of each other.</p>	<p>Wait 20 seconds before continuing. If this message occurs frequently you should reduce the distance between the SpinalMouse and the base-station.</p>
<p>LED on the base-station does not light-up when the software is launched. Message: No link to base-station.</p>	<p>The program cannot communicate with the base-station.</p>	<ol style="list-style-type: none"> 1. Close the program by choosing <<Quit>>. 2. Check the following: <ul style="list-style-type: none"> • Is the base station connected to a serial port (COM1 or COM2)? • Is the power connected to the base-station? • Is the antenna mounted on the base-station? • Is there another program which is trying to use the COM port? 3. Shut down Windows and restart your computer.
<p>The SpinalMouse® does not react. (LEDs do not light or flash amber).</p>	<p>SpinalMouse® batteries low or empty.</p>	<ol style="list-style-type: none"> 1. Ensure that the battery polarity is correct. 2. Replace batteries.



WARRANTY

Dear Customer,

Congratulations on the purchase of a SpinalMouse® and thanks for your confidence in Idiag. The SpinalMouse® has been designed in Switzerland using the latest scientific discoveries and is produced using the latest manufacturing methods. Reliability and durability are assured by the high-quality components and materials used.

The SpinalMouse® is guaranteed (see below). In the unlikely event of it malfunctioning, please contact us at the following address: Idiag; Postfach; CH-8604 Volketswil, Switzerland,
Tel: 0041 (0)1-908 58 58; Fax: 0041 (0)1-908 58 59

Terms of Warranty

Idiag warrants this product to be free from material defects and workmanship for a period of one (1) year from the date of original retail purchase provided that:

1. The original packing, proof of purchase and date is provided;
2. The purchaser delivers the SpinalMouse® during the warranty period to Idiag or an authorised service facility.

The purchaser shall bear all shipping, packing and insurance costs and all other costs, excluding labour and parts necessary to effect repair, replacement or refund under this warranty.

The warranty excludes:

1. Regular inspections, maintenance and repair or replacement of parts due to normal wear and tear.
2. Risks and costs of transport, which are connected directly or indirectly with this guarantee.
3. Damages to the SpinalMouse® caused by:
 - a. Abuse or misuse of the SpinalMouse®, particularly when the SpinalMouse® has been used for other applications than those described in the handbook.
 - b. Non-observance of the operating and maintenance instructions.
 - c. Unauthorised manipulations of the hardware or software. Defects may only be repaired by the manufacturer or an authorised service center.
 - d. Accidents or environmental factors which lie beyond the control of Idiag e.g. damages by water, fire, intrusions, interference and acid damage.
4. The warranty only applies to parts and appliances which are distributed by Idiag.
5. This guarantee does not limit the purchaser's national legal rights. If the applicable national law does not stipulate anything to the contrary, the rights of the purchaser are limited to this guarantee and Idiag does not take any liability, nor responsibility for direct or indirect damages or losses connected with the use of the SpinalMouse®.

Idiag Software License Agreement

In return for acquiring a license to use the software („Software“) and related documentation, the purchaser agrees to the following terms and conditions:

1. License: This Agreement grants you, the Licensee, a license to:
 - a. use the Software on a single computer system which is used in combination with the SpinalMouse®;
 - b. make a single machine-readable copy of the software solely for back-up purposes, provided you reproduce Idiag's copyright and trademark notices.
2. Restrictions: The SpinalMouse®-Software was designed for exclusive use with the SpinalMouse® device. You may not use the Software for other means except to record, analyse and store data registered by the SpinalMouse®. You may not distribute copies of the Software to others or electronically transfer the Software from one computer to another over a network. You may not use the Software from multiple locations of a multi-user or networked system at any one time. The Software contains trade secrets and in order to protect these, you may not de-compile, reverse engineer, disassemble, or otherwise convert the source code into a perceptible form. YOU MAY NOT MODIFY, ADAPT, TRANSLATE, RENT, LEASE, LOAN, RESELL FOR PROFIT, DISTRIBUTE OVER A NETWORK OR CREATE DERIVATIVE WORKS BASED UPON THE SOFTWARE OR ANY PART THEREOF.
3. Copyright: This licence is not a sale of the software or any other copy. Idiag retains title and ownership of the software and documentation, including all intellectual property rights. No title to the intellectual property in the software is transferred to you.
4. Confidentiality: The Licensee is responsible for the confidentiality of the data gathered by the SpinalMouse® and for the security of the software itself. i.e. The Licensee must take all reasonable precautions to prevent unauthorised access to the PC on which the software is installed and to all copies of the software or data generated by it.
5. Term: This license is effective until January 1, 2042, unless terminated earlier. The purchaser may terminate the license at any time by destroying the Software, including the related documentation, together with all copies or modifications in any form. Idiag retains the right to terminate your license immediately if you fail to comply with any term or condition of this Agreement. Upon any termination, including termination by the purchaser, the purchaser is legally bound [unconditionally agrees to] to destroy the Software, including the related documentation, together with all copies or modifications in any form.

WARRANTY

6. **Limited Warranty:** Iddiag warrants that the media on which the software is furnished will be free from defects in material or workmanship under normal use and service for a period of thirty (30) days from the date of delivery to you. IDIAG DOES NOT AND CANNOT WARRANT THE PERFORMANCE OR RESULTS YOU MAY OBTAIN BY USING THE SOFTWARE OR DOCUMENTATION. EXCEPT FOR THE LIMITED WARRANTY ABOVE, IDIAG MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO NON-INFRINGEMENT OF THIRD PARTY RIGHTS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
7. Some states/countries do not allow the exclusion of implied warranties or limitations on how long an implied warranty may last, so the above limitations may not apply to the purchaser. This warranty gives you specific legal rights and you may also have other rights which vary from state to state or country to country.
Limitation of Liability: IN NO EVENT WILL IDIAG BE LIABLE TO THE PURCHASER OR ANY THIRD PARTY FOR ANY CONSEQUENTIAL DAMAGES, INCLUDING ANY LOST PROFITS, LOST SAVINGS OR OTHER INCIDENTAL DAMAGES, EVEN IF IDIAG HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. Some states/countries do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation or exclusion may not apply to the purchaser.
8. **Limitation of Recourse:** Iddiag's entire liability and the purchaser's rights are limited to:
- a. The replacement of any defective media which is returned to Iddiag under the terms of the warranty;
 - b. If Iddiag or its distributor is unable to deliver a replacement, media which is free of defects in materials or workmanship, the purchaser may terminate this Agreement by returning the Software and the purchaser's money will be refunded.
9. **General:** The purchaser acknowledges that the purchaser has read this Agreement, understands it, and that by opening the package the purchaser agrees to be bound by its terms and conditions. The purchaser further agrees that it is the complete and exclusive statement of the agreement between Iddiag and the purchaser which supersedes any proposal or prior agreement, oral or written.
The purchaser assumes full responsibility for the use of the Software and agrees to use the Software legally and responsibly.
Should the purchaser have any questions concerning this Agreement, the purchaser may contact Iddiag by writing to:
Iddiag, Chriesbaumstrasse 6, Postfach, 8604 Volketswil, Switzerland

Limited warranty

Idiag warrants that the SpinalMouse® software will work according to specifications under the described conditions above. Under any other conditions, especially in combination with other programs, the SpinalMouse® software may not work properly.

Idiag does not and cannot warrant any claims connected with:

- Abusive modification of the SpinalMouse® software by unauthorised third-parties.
- Use alongside and/or combination of the SpinalMouse® software with programs, data or devices which are not distributed by Idiag.
- Loss or damage of any data.
- Any compensation claims based on third party claims.

Legal regulations

Idiag accepts no responsibility for implications or diagnoses and possible consequences which are based on data generated by the SpinalMouse®. SpinalMouse® data is no basis for further medical treatment without the additional examination by a physician. The examining physician is completely responsible for an accurate analysis and interpretation of SpinalMouse® data.

Protection of data privacy

Be aware that personal details and the measurement data generated or stored by SpinalMouse® and its software are subject to data protection legislation. The purchaser must take all reasonable precautions to ensure that data cannot be accessed, copied or used by unauthorised third parties. Idiag does not take any liability for the misuse or abuse of any data created or stored by the SpinalMouse® system.





