

## SpinalMouse<sup>®</sup> frequently asked questions

The questions below were taken from inquiries, interviews and e-mails as made or submitted by interested parties. All of the responses were prepared and presented by Dr. Lucio Carlucci, Director of Medical Research for idiag AG, Switzerland, the manufacturer of the SpinalMouse. Dr. Carlucci is one of the inventors of the SpinalMouse device and he is completely competent to respond to any and all inquiries concerning the SpinalMouse device, its operation, uses or features.

In a few words, please explain what the SpinalMouse does?

*The SpinalMouse is a computer-assisted medical device that can be used to determine the shape and mobility of the spinal column by simply gliding the device manually down the back. From the superficial shape, an intelligent recursive algorithm computes information concerning the relative position of the vertebral bodies of the thoracic and lumbar spine, while taking into account the local curvature (kyphotic or lordotic). An accurate segmental localization of all vertebral bodies as the projection of their midpoints on the superficial contour of the back is obtained as final result.*

Where, when and why was the SpinalMouse system created?

*The idea of a surface measuring device similar to ours had been influenced by a study performed and published in 1994 by Dr. Seichert and Prof. Senn. Both were working at the Clinic of Physical Medicine and Rehabilitation of the Ludwig-Maximilian University of Munich, Germany. They were involved, together with a staff of developers from our company idiag AG, in the development of the first prototype of the SpinalMouse. In 1999 idiag AG launched the first SpinalMouse devices on the Swiss market. The development was mainly motivated by the fact, that so far, there was no methodology or device allowing a non invasive, radiation free, simple and fast, but still reliable and cost effective measurement of shape and segmental mobility of the spine.*

What kind of information do we get from a measurement with the SpinalMouse?

*We get important clinical information that is needed and can be used by the physician and the therapist in order to formulate the best treatment, therapy or overall care-plan for the patient, and to accurately measure the results or outcomes of any treatments or interventions.*

*Just some of the clinical information or data are:*

*Posture (sagittal and frontal shape of the spine)*

- *total back length*
- *sagittal and frontal curvature of thoracic and lumbar spine*
- *angle of inclination relative to a perpendicular line*
- *segmental angles (kyphotic/lordotic relation)*
- *pelvic tilt (mean sacral angle)*

*Mobility, Range Of Motion (ROM)*

- *ROM of the thoracic and lumbar spine*
- *segmental mobility for all segments starting from T1/2 to L5/S1*
- *inclination (total ROM)*
- *flexion and extension mobility of hip joints*

*Stability of the Spine (postural competence)*

- *postural reaction when loaded in functional tests (e.g. Mathiass test)*

Furthermore, the SpinalMouse software provides the physician with indications for spinal dysfunctional posture or mobility and can correlate with physician exam findings.

- indications for non-harmonic curvature (posture)
  - Angle differences, of kyphotic or lordotic relation, from one segment to the next one of more than 7°
  - Assessment of segment integrity
  - Kyphosis instead of Lordosis in the lumbar spine in upright position (“+” instead of “-“ values)
  - Lordosis instead of kyphosis in the thoracic spine in upright position (“-“ instead of “+” values)
  - Lordotic segments in flexed position
  - Kyphotic segments in the lumbar spine in extended position
- indications for non-harmonic mobility (ROM)
  - Differences in motion from one motional segment to the next one of more than 7°
  - Dorsal motion of segments when moving from upright to flexed position (“-“ values in “U-F”)
  - Segmental ROM values smaller than 1 /° (segmental hypo mobility)
  - 0° of ROM of subsequent segments (regional hypo mobility)
  - 0° of ROM of one segment in both directions (“U-F” and “U-E”); rigid segment)

Based on the expert interpretation of the measured data, the SpinalMouse software can recommends exercise interventions for therapy and/or training program.

What is the difference between SpinalMouse and other diagnostic methods such as radiograph and what innovations does it bring to diagnosis and evaluation?

*There are many reasons why and how the SpinalMouse is different. Mainly the SpinalMouse stands out due to an accurate, simple, fast and cost effective measurement procedure; its validity and rater-independent reproducibility are both very high; and it uses no radiation or chemicals which allows SpinalMouse to be free of any contraindications or side effects. SpinalMouse can be used on the same patient as often or as frequently as desired at very little, if any, actual cost. MRI, C-T scans and X-ray measurements are expensive, require the patient to be seen at another location or facility, are sometime limited by contraindication and side effects, and expose the patient to harmful radiation and/or chemical.*

*It must be emphasized, that the SpinalMouse technology is addressing the functional aspects of the spine, derived from the superficial measurement. X-ray, CT scan or MRI in contrast, mainly yields structural information due to tissue and bone penetrating technology and is therefore essential e.g. in fracture or degenerative disease analysis. As a consequence X-ray measurements of functional spine aspects can be replaced by the accurate SpinalMouse measurement. I need to clarify that the SpinalMouse is not an expert system "per se", it takes a medical expert in order to formulate diagnoses.*

What advantages does a patient have when using SpinalMouse for his/her measurement?

*A back patient may obtain fast, valid and reliable information about shape and mobility of the spine in a format that is easy to understand. This leads to a much higher degree of patient cooperation, commitment and compliance with interventions, treatment or therapy regimens. Furthermore, SpinalMouse has the ability to compare a prior SpinalMouse scan or series with a current one, and this allows for useful quality assurance information while providing an accurate means of assessing the effectiveness of any rehabilitation or therapy program by checking the individual patient's progress. By the way, soon to be released SpinalMouse software links the measured indications with effective exercise interventions - thus enabling an even more specific and individual rehabilitation program.*

In how many countries is the SpinalMouse used?

*There are roughly 20 certificated international SpinalMouse distributors covering the range of approximately 40 countries.*

Is there relevant research and peer-review which indicate the scientific and diagnostic value of a measurement with the SpinalMouse?

*There are a number of validation studies as well as studies providing OME evidence regarding the clinical usage of the SpinalMouse. Accordingly, the SpinalMouse delivered consistently reliable values for standing curvatures and range of motion (Post, Leferink 2004, Mannion 2004). The reproducibility of the measurements obtained with the SpinalMouse is markedly better than that of x-ray evaluations in the inter-rater and intra-rater comparison (Schulz 1999). For more literature we suggest to visit our websites at SpinalMouse.com or ldiag.ch*

For what problems or complaints should a patient have a SpinalMouse measurement?

*For any or all of the following:*

- *diagnose: Find Indications for malfunctions and spinal pathologies*
- *follow up of pathology*
- *follow up of treatment*
- *quality assurance of diagnose and therapy*
- *patient communication and education tool*
- *health Insurance (reimbursement)*
- *marketing tool – patient retention*
- *preventative and screening tool (school, industry, science)*

Could somebody without any special problem make a measurement just for precautionary reasons?  
Could this be beneficial for that person?

*The SpinalMouse can provide useful information in so called “screenings” or “wellness checks”. Spine and back related pain and disorders usually have multi-factorial causes and may develop in nebulous and creeping ways. Regular screenings help to establish baseline information and may alert a person to changes. Bringing such information to the attention of that person’s physician can be extremely helpful in preventing further problems or allowing for an early diagnosis of existing ones.*

*The SpinalMouse measurements can also be a part of health education program (e.g. in terms of a correct lifting technique or for adjusting a physiological sitting posture). The soon to be release and integrated checklist for specific exercise interventions forms just the next step in the integral client and patient support. Prophylactic back training tailored according to the individually measured spine helps preventing future spine and back disorders and is one important approach for a healthy and active lifestyle.*

Dr. Carlucci, if possible, in a few word give us your opinion as to why a patient should have a SpinalMouse measurement.

*We know from some studies that surgery is not always the best answer to back pain. We have also learned that conventional and some newly developed physical and training therapy can be very efficient and helpful when performed by a well-trained medical expert such as a physiotherapist or medical doctor. The key appears to be evidence-based medicine. Evidence-based medicine is the future of modern medicine. The concept of "Testing-Treating-Retesting" will in the near future, if not already, be part of every day medicine. A SpinalMouse measurement visualizes the cause of the patient's back pain for the patient, the physician, and the therapist. I strongly believe that by understanding the cause of back pain, the patient will understand the treatment offered by the physician and participate more fully in his own program. The SpinalMouse measurement is fast, easily performed, uses no harmful chemical or radiation, has no side effects or contraindications, can be taken at any time or as many times as desired. SpinalMouse measurements made during treatment or therapy can track the progress of the patient and provide much-needed quality assurance. Ultimately, this will lead to better rehabilitation results for the patient, medical and healthcare providers, and lower costs with less time lost for employer and insurance companies.*