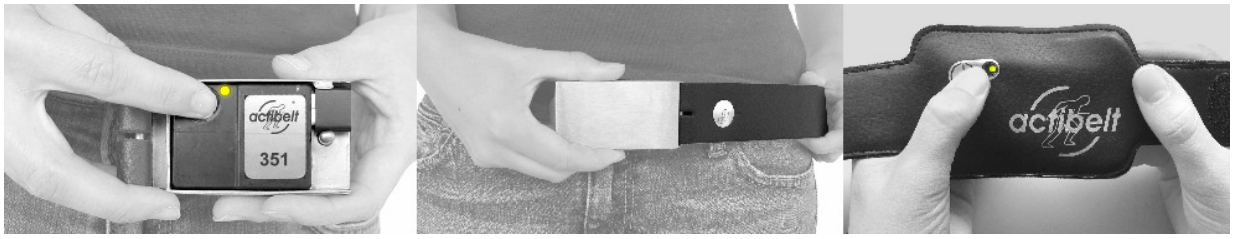
Mobile 3D-accelerometry to objectively quantify walking impairment

actibelt® – a novel platform to capture and analyse human motion



Beyond questionnaires

The level of a patient's walking ability or impairment in the context of controlled clinical trials is usually measured by using questionnaires. Common problems are substantial, uncontrollable bias and high inter- and intra-rater variability. Invalid outcome measures and/or invalid surrogate markers in a variety of chronic disabling diseases are a well-known problem.

Physical activity in general and walking ability (distance, speed, quality) in particular play a major role as potential patient-oriented outcome measures and confounding factors in a broad range of diseases, multiple sclerosis, CAD and COPD being prominent examples. Insufficient assessment of this important variable that may also be a therapeutic option in its own right may lead to unnecessary noise and even bias in the data, thereby diluting and/or diminishing a potential beneficial effect of the treatment.

What is the actibelt® ?

We have developed an integrated platform to objectively assess the physical activity profile of a person using a high-tech 3D-accelerometer hidden in a belt buckle, the "actibelt®". Much like a miniaturised Holter recorder measures long-term ECG, the actibelt® measures high-resolution (noise <0.01 g, 100Hz in three axis) long-term (10x24x7, 512MB) accelerations close to the body's centre of mass.

actibelt® is a joint development of Trium Analysis Online GmbH and SLCMSR e.V., Hohenlindenerstr. 1, 81677 München, Germany
Literature about the actibelt® can be found at www.actibelt.com
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Recharging is done within 2 hours using standard USB chargers at the clinical centre or the central lab. Small weight & size, different belt sizes and styles, options for belt buckles (metal buckle or flex buckle for sleep/sport) allow to reach a very high user acceptance (independent validation study). Usability aspects are of utmost importance for sufficiently long, unbiased recording times.

What does it measure?

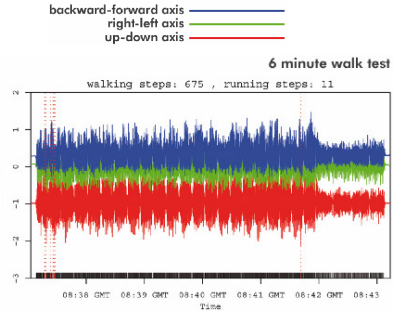
Innovative algorithms allow to extract a variety of relevant and meaningful parameters from the data recorded by the actibelt®. Raw data is stored ("canned activity") to allow novel and/or improved parameter extraction for continuous refinement and validation at any later time.

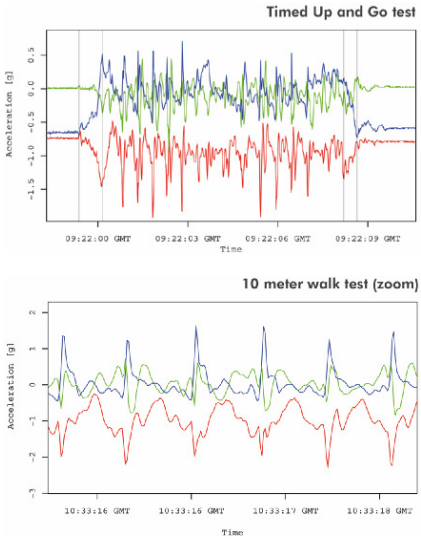
Parameters that can be extracted from a 7-day recording include

- activity count (one mean filtered acceleration value per minute)
- activity regions (high, medium, low)
- activity temperature (mean activity per day)
- number of steps in any given period of time & distribution (high accuracy, also at low speed)
- distance travelled & distribution (less than 15m, 50m, 100m, 200m, 300m, 500m, < 5% accuracy)
- gait speed (high accuracy – >90% of the time accuracy less than 0.2 m/s)
- gait asymmetry (e.g. limping)
- coherence length (measure for gait quality)
- norm step (including gait phases – heel strike, toe off)
- activity pie chart (lying/sleeping, sitting/standing, walking, running)
- exercise induced energy consumption (body weight needed)
- number of falls (online fall detection in preparation)
- changes in altitude/stair climbing (precision <0.5m, in preparation)

The following "rapid tests" have been developed for improved clinical assessment of balance and fall risk using the actibelt®:

- 6MWT
- 25FWT
- Timed up and go test
- Romberg test
- Timed tandem walk
- Chair rise test
- One-legged stance





An easy-to-use **web-platform** supports central data management, analysis, reporting and can be linked to any eCRF-system/eTrial software with standard web-interface (in particular Trium's CT-Engine®).

The actibelt® platform is in use in various international (AU, AUS, CH, CZ, ESP, FI, FR, GER, IT, UK, USA) multi-centre trials and clinical-epidemiological studies in multiple sclerosis, CAD, osteoporosis, lupus, osteoarthritis, Parkinson's disease, depression, schizophrenia, fracture heeling, COPD, sport & space science. Hundreds of patients, including children and elderly people, have been equipped with the actibelt®, more than 25.000 hours of recordings have been stored and analysed. The logistics allows for indivdualized use up to "high throughput accelerometry", e.g. up to 50 patients per day can be equipped with the actibelt® per day per centre.

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