3.6 Safety Aspects

Regarding user safety, there are three aspects that were considered in the system design process:

- *Hazards from supply voltages* in case of short circuits/direct contact
- *Hazards from high NIR light intensities* in case of eye exposure
- *Hazards from tissue heating* during direct contact with the NIR light emitters.

Hazard from supply voltages: As the system is designed for mobility and safety, only low-voltage components were used. At no time, the battery and supply voltages exceed 9V dc, which is in the range of protective extra-low voltage (PELV) and does not pose any danger even in direct contact to the skin over longer time periods.
As the measured data is transmitted via Bluetooth to a computer, no galvanic isolation between instrument and PC is necessary, as it is the case when using a RS232 cable. In the case that the UART-RS232 interface is used with a level converter and cable to the PC (as mentioned in subsection 3.5.3), it is only safe to wear the device in accordance with European medical isolation standards (EN60601-1) when the level converter/connector PCB includes a galvanic isolation between the NIRS instrument and the PC, e.g. by optocouplers. However, for testing and debugging without the need to wear the device, the direct cable connection could be used without galvanic isolation.

As NIRS is an active recording technique depositing energy into the subject and measuring the changes of the reflected energy, the effects of the deposited energy have to be taken into account.
Regarding the *hazards from high NIR light intensities* and *tissue heating*, safety assessments were made by Cope 1991 [21], Strangman 2002 [13] and Bozkurt 2004 [57]:
As there are no safety standards for single wavelengths in LEDs, as it is the case for Lasers (IEC68025), laser standards and the IEC62471 (photobiological safety of lamps and lamp systems) are often used as orientation. Because LED light is not coherent, relatively high intensities compared with laser light still do not pose danger to the eyes.
As NIR light is non-ionizing, it poses no risk of altering genetic information unlike UV radiation. The major concerns are discomfort and damage by tissue heating. According to Strangman [13], the maximum permissible exposure of NIR light on the skin ranges from $0.2\,W/cm^2$ at $630\,nm$ to $0.4\,W/cm^2$ at $850\,nm$ with the exact limits depending on many factors such as wavelength, coherence, duration and area of exposure.
The main potential hazard of NIR light is tissue heating as a result of absorption, as the vast majority of the energy ($> 95\,\%$) is deposited in the scalp [13]. Absorption by blood pigments in deep tissue is not a problem as they are constantly circulating and therefore cannot heat up. According to Bozkurt et al., the limits for tissue heating are set by the propability of cell death which is increasing when cell temperatures are sustained above $41\,^\circ$C. These limits are also applied in pulse oximetry applications. With the mean temperature of the forehead being $35\,^\circ$C, this permits a maximum increase of $6\,^\circ$C during longer usage of the instrument.
Systems using Time-Division Multiplexing (as is the case here) or sinusoidal modulation significantly lower the temperature increase of the scalp resulting from the cooling effect of duty cycles/idle durations [57].