Risk Assessment

Description of the activity: Investigating the electro-cutaneous sensation around the thigh of healthy volunteers
Person(s) undertaking activity: Graham Webb, [redacted] and volunteer test subjects
Person carrying out the assessment: Graham Webb (Centre for Biomedical Engineering) Extension: 9350

Signature: 

Date of assessment: 28th September 2010

Risk / Hazard	**Persons at Risk**	**Control Measures**	**Severity** (see Table 2)	**Likelihood** (see Table 3)	**Risk rating** (see Table 3)
1. Inappropriate electrode use. For example: Removal of electrodes whilst stimulator is on, incorrect placement of electrodes	Test subjects and experimenters	Experimenters are trained in the correct operation of electrical stimulation and will apply the electrodes to the test subjects according to pre-defined position marks.	2	1	2
2. Skin irritation caused by reaction to electrodes	Test subjects	The study duration will be short. The stimulator is designed to use bi-phasic waveforms. Electrodes incorporate a hydrogel layer to minimise high current densities.	2	2	4
3. Falling due to trailing wires	Test subjects	All wires will be attached to the patient by a waistband prior to any walking.	2	1	2
4. Temporary localised pain at skin surface due to application of high current	Test subjects	Hardware stop button provided for the test subjects. Software emergency stop button provided for the experimenter. Maximum current provision limited to 100mA.	2	2	4

In addition to the Faculty of Engineering and Physical Sciences risk management guidance, the Wandsworth Primary Care Trust Risk Management Strategy was used to evaluate the scale of risk. Because the strategy uses a risk severity rating developed by the National Patient Safety Agency which is suited to evaluating studies of this nature. The strategy classifies risks as either Acceptable or Unacceptable. An acceptable risk is "one which has been accepted after proper evaluation and is one where appropriate controls have been implemented. The risk must not only be identified, but also quantified to the maximum practicable, analysed and communicated to the appropriate level of management" (Caulfeild-Stoker, 2002). Action should be taken to reduce any unacceptable risks to an acceptable level. All acceptable risks are measured according to their likelihood (or frequency) and severity (or consequences) and entered into a risk matrix (Table 1). The acceptance of a risk should therefore represent an informed decision to accept the consequences and likelihood of that risk. Table 3 shows the risk severity descriptors and Table 3 shows the descriptors used to quantify risk likelihood.

Table 1 Risk Matrix

Likelihood (frequency)	Severity (consequences)				
	1 (Insignificant)	2 (Minor)	3 (Moderate)	4 (Major)	5 (Catastrophic)
5 Certain	5 Y	10 Y	15 R	20 R	25 R
4 Likely	4 G	8 Y	12 Y	16 R	20 R
3 Possible	3 G	6 Y	9 Y	12 Y	15 R
2 Unlikely	2 G	4 G	6 Y	8 Y	10 Y
1 rare	1 G	2 G	3 G	4 G	5 Y

- Green risks are regarded as low / acceptable, to be investigated by local managers
- Yellow risks are regarded as medium to be investigated by a Senior Manager / Head of Services or equivalent and acted upon where appropriate, including producing an action plan
- Red risks are regarded as high or significant and must be reported at Associate Director level for an action plan to be agreed and implemented, as quickly as possible

Evaluation of Risk: **All risks in this activity are deemed low / acceptable**

Table 2 Risk severity levels identified by the National Patient Safety Agency

Description	**Impact on individual**	**Impact on organisation**	**Person affected at any one time**	**Financial Impact Complaint Litigation**
1 Insignificant	No injury	No risk No impact on service No impact on environment	None	Theft/loss up to £1k Complaint unlikely Litigation risk remote
2 Minor	First Aid Minor Injury or Minor illness up to 1 month	Minimal risk Slight impact on service Slight impact on environment	Very few 1-2	Theft/loss between £1k - £5K Complaint possible Litigation <£50K
3 Moderate	Temporary incapacity. Short term monitoring. Additional Medical treatment required up to 1 year	Some service disruption. Potential for adverse publicity Moderate impact on environment	Small numbers 3 - 15	Theft/loss £5k - £25k Complaint expected Litigation possible >£50k - £500k
4 Major	Major Injury (reportable) major clinical intervention Permanent incapacity	Service restriction Adverse publicity Loss of reputation Major impact on environment	16 – 50	Theft/loss £25k – £200k Litigation >£500 - £1m expected
5 Catastrophic	Death	National Media Interest. Severe loss of confidence	50+	Theft/loss over £200k Litigation >£1m

Table 3 Likelihood (frequency or probability) or risk occurring or repeating.

SCORE		**DESCRIPTION**
1	RARE	Do not believe will happen, one off. Exceptional circumstances
2	UNLIKELY	Not expected but possible. Could occur at some time
3	POSSIBLE	May/should occur at some time
4	LIKELY	Will probably occur.
5	ALMOST CERTAIN	Likely to occur on many occasions. A persistent issue