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Electrical surgical instrument design principles

This article examines difficulties in analysing antecedent medical device technology used in modern medicine against new or evolving regulations, considering *state scientiae* elaborated in contemporary clinical background but where technology has advanced very little or is stagnant, evidence-based medicine inconsistent with contemporary levels and specific regulations or technical standards are either imprecise or inexistent.

Absence, too, of fundamental design principles, including human factors and useability engineering for such older technology, coupled with plethora of mimics – notably because of the ease of producing so-called substantially-equivalent iterations, means that for an indefinite yet vast number of medical devices, fitness for purpose cannot be easily determined or compared scientifically.

In the case of certain medical-electrical equipment, for instance, disposable devices including applied parts within the meaning of §4.6 EN IEC 60601-1 in context of consumables applied as accessories for use with a medical-electrical equipment, these deficiencies could be regarded as unacceptable.

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Notwithstanding regulatory status of a consumable medical-electrical such as an electrical-surgical instrument to be used with an electro-surgical generator, considering European medical device regulations set and in Council Directive 93/42/EEC and imminently Regulation (EU) 2017/745, such an instrument is extremely noteworthy as an example of a product technology that has not benefitted from proper, property-based scientific design and scrutiny over the years. Despite prodigious use in surgery and innumerable medical publications on surgical outcome and so on, pitiful technical research is published concerning fundamental design principles. Most research, for obvious reasons, concentrates on electro-surgical generators and official, albeit voluntary, technical standards likewise.

Consequently, manufacturers and notified bodies alike cannot easily equate to obligations of fulfilling *state scientiae* specified by European legislation; instead, conformity assessment predisposes to electrical-safety standards which it is opined are ill-suited for such consumables used with generators.

Electrical-surgical instruments

Electrical-surgical instruments used in conventional electro-surgery are available in an array of models and configurations. Typically, they consist of conductive core insulated by plastics polymers, proximal connexions and distal energy delivery point. Some models are equipped with control functions.

Design is generally simple and readily reduced to fundamentals properties.

Overall functions and performance (disregarding clinical effectiveness) are dictated by the electro-surgical generator on which an electrical-surgical instrument is used.

Coupled with comparatively-simple methods of construction and volume manufacture conduciveness, such a device is a good example to use when exploring intricacies of design principles in regulatory conformity assessment.

General properties

This article is not an electrical-surgical instrument engineering specification or design-guide. Instead, it elaborates relevant medical-device

regulatory conformity assessment issues a specialist encounters when evaluating antecedent product.

Electrical-surgical instruments conduct and deliver energy from an external source to body tissue in the form of heat. Thermal output depends on electrical wave-form, allowing effects from dissection to coagulation to vaporisation.

Heat disposal or spray produces blended (or dual) effect of dissection and coagulation (fulguration).

Thermal output produces minimal-maximal haemostasis. As with other electrical equipment producing or delivering heat to an object, rate of heat generated and heat distribution profile determines effect, *eg*, if waveform vaporises or coagulates.

As with other electrical equipment, magnetic fields are generated.

General deficiencies

Electrical-surgical instruments were invented decades ago. Design principles were never elaborated, however and very little thematic or phenomenological research is published on this subject. Further, electrical-surgical instrument design is static overall and stagnant for most proprieties and characteristics thereof. Most interactions are incremental and none, hitherto, revolutionary or fundamental. Furthermore, evidence reveals commercially-available iterations are poorly scientifically-described and equally poorly-designed, although important exceptions do exist, many manufacturers supply iterations replicating specifications of unknown provenance and in numerous cases, without any or with only limited scientific knowledge of electrical-surgical design requirements. Functional safety is largely un-defined and no official requirements exist. Reasons for the *status quo* are conjectured but excluded from this discussion.

State scientiae

State scientiae (state-of-the-art) of electrical-surgical instruments is static or even stagnant. Grounded-theory and thematic research does not reveal fundamental research in this area.

Problems

Electrical-surgical instruments are ubiquitous in and integral to electro-surgery but design is emergent and spontaneous rather than scientific and fundamental. Critically, this obnubilates as electrical-surgical instruments as poor and unfit. Undesirable properties and characteristics manifest as:

- inefficient surgical outcomes
- complications
- danger (to patient, user and others)
- increased sacrifice
- increased injury
- accidents
- increased medical costs
- user impairment, notably, repetitive strain
- unconsidered psychological effects
- unintuitive competence and know-how (un-proficiency)
- subjective surgical outcomes

Resolution

Fundamental electrical-surgical instrument properties to achieve efficient function and clinical performance, require proper, scientific characterisation and research. This seems important to ensure objective surgical outcomes and electrical – surgical instrument clinical evidence - base.

Electrical-surgical instrument patient design factors

Practitioners and medical device manufacturers in the field are well-acquainted with electrical-surgical effects constituting clinical *state scientiae*, *viz*, dissection, haemostasis (coagulation) and vaporisation, applied in a manner dictated by the surgeon. This is static and unlikely to change, despite only very limited scientific treatise and research on relevant tissue thermal properties, effects thereof on surgical outcome and electro-surgical treatment efficiency. Rather, phenomenological evidence-base deduced from surgical outcome research and retrospection predominates.

Accepting external generator design and construction are better understood and defined, it is argued that it is electro-surgical instrument design principles that are lacking.

Resolution

Electrical-surgical instruments design principles may be distinguished by the following factors:

a) electrical properties,
b) thermal performance, pursuant to basic thermal design principles and rules,
c) surgical performance, including surgical outcomes,
d) functional safety,
e) bio-mechanical properties, accommodating optimum tool design principles,
f) ergonomics, accommodation optimum tool design principles,
g) miscellaneous human factors engineering, including inter-operability, useability, psychology and cognition.

General electrical-surgical instruments design concepts are a), b) and g); whereas functional design concepts are c) - f). It is on these premisses that fundamental electrical-surgical instrument principles can be formulated.

Electrical-surgical instrument optimum design

Once desired electrical properties of an electrical-surgical instrument will present are decided, thermal performance pursuant to basic thermal design principles and rules can be established and analysed, for example, if an instrument will perform dissection, haemostasis or fulguration, further range of performances desired, *eg*, minimal and maximal haemostasis. In the absence of defined, accepted parameters for such instruments, a designing manufacturer would be expected to specify relevant properties and characteristics, including:

- heat distribution
- waveform response
- suitable tissue/ body fluid in which an instrument might be used

Functional safety requirements should be defined accordingly, subsequently, instrument engineering translation can be reduced and proceeded.

An optimum electrical-surgical instrument should achieve basic tool design, considering bio-mechanical properties such as grip, posture deviation, inherent hand/wrist flexor strain, strength requirements, handling properties, handedness (dexterity requirements), activation and control ease (manipulation) and positive configuration (eg, contour versus functional safety). Instruments should not be heavy or bulky. Various inter-operability and useability properties and characteristics are relevant. Further, incorporation of indicator, alarm and record functions should be considered. Wherever possible, electrical-surgical instrument design should be adoptive. Preferably, electrical-surgical instrument should be mono-manual/uni-manual.

Regarding ergonomics, electrical-surgical instruments require basic properties and characteristics, *eg*, not hold or cold, avoid unnecessary sharp edges and surfaces also possess optimum centre of gravity *versus* local, ensure minimal ulnar artery pressure for instance, avoid sustained grip fore even when not applying force. Further, gloved operation must be considered. Point control is crucial. Psychological factors, including cognition should be defined essentially. Where important, handle incorporation and sleekness should be considered.

Considering conformity assessment requirements specified by Council Directive 93/42/EEC | Regulation (EU) 2017/745, assessment of antecedent device technology tends to be lax, experience revealing inadequate or ill-defined endeavours to ensure subject devices constitute *state scientiae*. Too often, relaxation of required standard is evident, whereby notion of established or referent devices and know-how is accepted by manufacturers and notified bodies, contrary to obligations toward advancement.

Economics of updating antecedent technology to fulfil advancing *state scientiae* would, of course, prohibit treatment availability, however, without clearer or preferably categorical assessment of design principles, conformity assessment adequacy and device fitness for purpose, remain uncertain.

Summary

Conventional electrical-surgical instrument design requirements are un-elaborated. Deficiently, commercially-available models embody convention because fundamental principles are either un-elucidated or receive insufficient attention during design. Absence of official specifications or voluntary technical standards confounds. It is likely internal product specifications devised by manufacturers of such instruments necessarily must compensate.

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