Safety procedures for Non-ionizing radiation (the role and responsiblities of Medical Physicist)

ΤΕΧΝΟΛΟΓΙΚΟ
ΕΚΠΑΙΔΕΥΤΙΚΟ
ΙΔΡΥΜΑ
ΔΥΤΙΚΗΣ ΕΛΛΑΔΑΣ

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Objective

To describe from occupational safety viewpoint:

- Risks and accidents from EMF radiation
- Current status on Short & Micro Wave diathermy units (S & MWD) quality control practices
- Need for S & MWD maintenance and QC

Meeting of ICRP and IDNIRP: "*Ionizing radiation can cause stochastic and deterministic effects, while most effects due to exposure from non-ionizing radiation appear to be deterministic… For ionizing radiation there is a greater emphasis on optimization of protection even at low levels of exposure, whereas for non-ionizing radiation there is a greater emphasis on keeping exposures below thresholds (RLs) for observed effects*"

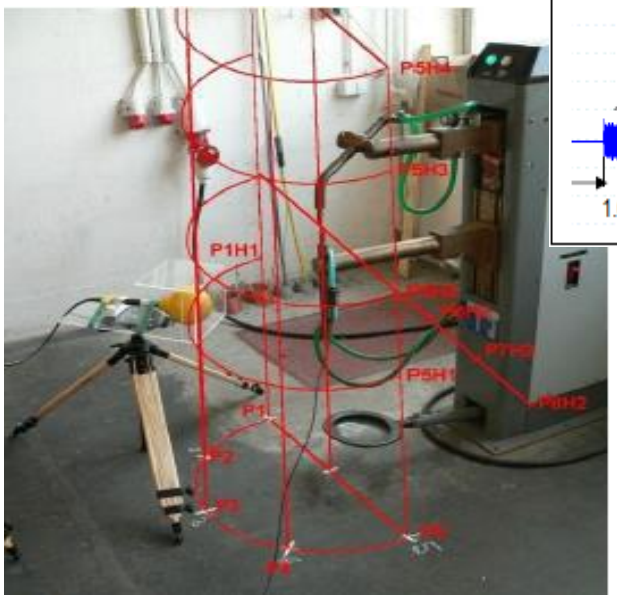
[ICNIRP 2017]

Outline

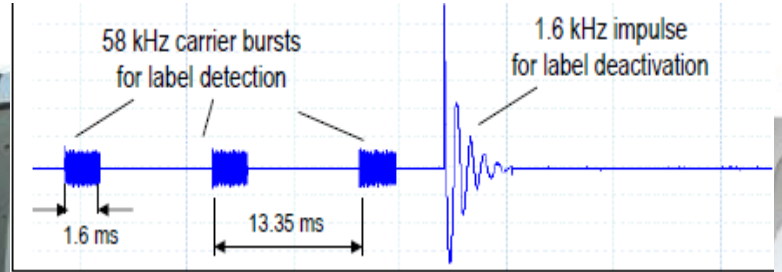
1. Workplace specific exposure assessment and dosimetry
2. Safety procedures for S & MWD
3. The necessity for QCs
4. Conclusions

“Specific” Devices and Close “Distances”

1. Workplace specific exposure assessment and dosimetry [Schmidt G 2012]



Welding (arc welding / resistance welding): DC – kHz



EAS Deactivators (1.6 kHz, 58 kHz, 8.2 MHz)

1. Workplace specific exposure : Diathermies' risks

Equipment that use EM sources, emitting energy in radio (RF) and microwave (MW) frequency spectra. EM radiation induce heat inside patient's body is used in Physiotherapy Units

- wound rehabilitation (**dia**thermia)

..other

- cancer treatment to allow chemotherapy to work better (**hyper**thermia)
- increase direct ablation of tumors (**thermal ablation**) [Riadh W et al 2006].

Diathermy units in Physiotherapy

Therapeutic approaches based on the transfer of thermal energy in the body are called **thermotherapy**.

Equipment that use EM sources emitting energy in shortwave (SW) and microwave (MW) frequency spectra, are called **diathermies**.

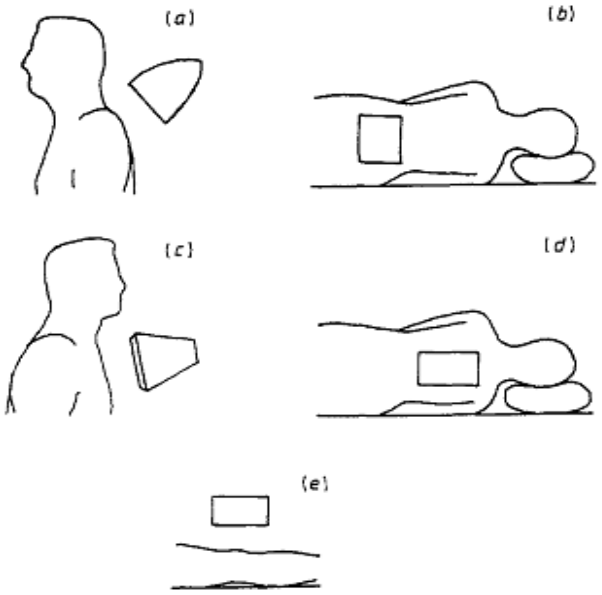
MWD which is a type of medical equipment that utilizes EM radiation to induce heat inside patient's body are used in Physiotherapy Units

Shortwave Pulse and Continuous Mode Diathermies

- Diathermy (27.12 MHz, 433.9 MHz, 2.45 GHz)

2.45 GHz MWD unit

Rehabilitation Protocols



Example: 20 minutes, 150 Watt, pulse mode (rectangular), 2.45 MHz

RF Exposure accidents

RF Exposure in the vicinity of these machines has been found higher than permissible levels [Shields et al, 2003, 2007, Koutsojannis, 2009, 2012, Karpowitz et al , 2013]

Associated with adverse effects for physiotherapists' health:

- spontaneous abortion,
- stillbirth,
- congenital malformations,
- low birth weight
- alteration to the gender ratio,
- local aching, heart problems …
- bone ache, and low iron concentration

[Lerman Y et al 2001, Cromie J 2002, Israel M et al 2007, Di Nallo A 2008, Maccà I et al 2008, Garcia PA & Toledo BM 2009] and

- *Our results are indicative of a stress activated phenomena of monocytes upon MWD radiation, which could lead or trigger potential hazardous cellular outcomes due to thermal and/or bystander effects* (submitted)

Outline

1. Workplace specific exposure assessment and dosimetry

2. Safety procedures for S & MWDs

2. Safety procedures

- In Greek Radiation Protection legislation, there is no recommendation for health and safety guidelines for diathermy users as for Base Station antennas or more recently Magnetic Resonance Imaging systems.
- Safe use of diathermy devices is already underpinned by professional standards, safety codes and guidelines delineating their safe use and practices and procedures in a number of countries (Canada, Great Britain, Australia) [CSP 1997a, CSP 1997b, CSP 1998, CSP 2000].

Safety procedures (manuals)

This includes:

- training in the safe use of equipment, (fire hazards)
- determination of the safe distance, (from 50 cm to 2 or 3 m ?)
- use of a non-metallic treatment couch or chair,
- determination of an appropriate size for the treatment cubicle,
- avoidance of electromagnetic interference,
- some instructions for pregnant physiotherapists,
- various instructions for patient safety (skin temperature, low blood pressure, pacemakers, etc)

[NHMRC 1985, HC Safety Code 25 1983, HC 1999, HMSO 1974, HMSO 1992].

Safety...

Safe use of therapeutic diathermy in clinical practice requires procedures in compliance to international professional safety guidelines and regulations [Goats GC 1990, Osepchuk J and Petersen R. 2001, Kitchen R 2001, Shah SG and Farrow A 2013, Martin DJ and Sutton DG 2015, Andrikopoulos A at al 2017].

Outline

1. Workplace specific exposure assessment and dosimetry
2. Safety procedures for S & MWDs
3. The necessity for QCs

3. QC : Mechanical safety

Proper care of equipment, ensure that no damages exist in mechanical condition (as in case, arms, breaks, electrodes, control panel) that would adversely affect patient or operator safety. All features that must be inspected are covered with NHMRC 1985, IEC 60601-2-3 2007, IEC 60601-2-6 2012.

Timer accuracy digital stopwatches can be used [DHW 1983].

QC Procedure

QC protocol	TEST SECTION	INCLUTED TESTS	CRITERIA				REFERENCE
	Safe use guidelines of operation exposure		Control of operation exposure				
			*frequency**	acceplable	desirable	*units*	
Care of equipment	*Mechanical Tests*	Secure casing	*b*	All panels in good condition, Access to internal components only with tools			NHMRC (1985)
		Functioning castors	*b*	Unit is portable			
		Operatinf castor breakes	*c*	Breakes immobilize uints			
		Movable treatment arms	*c*	Securely attached and freely movable			
		Treatment arms lock	*b*	Lock in place			
		Interchangable electrodes	*c*	Lock in place, Range available			
		Condition of electrodes	*c*	No signs of damage, Air-space adjastable, Rubber on pad electrodes not broken down			
		Functioning control	*c*	Lamps and controls operational, Dials are fixed and click at correct interval			
		Operation of patient circuit braker	*b*	Power output stops when operated			
		Timer accuracy	*b*	Unit only operate with timer Output switches off when timer is zeroed < 5 min : 30 sec 5-10 min: 10 % > 10 min: 60 sec	 15 sec 5% 30 sec	 *sec* *sec* *sec*	IEC 60601-2-3 (1991) DHW (1993)
		Linearity		30%			
Use of equipment	*Output tests*	Stability	*a*	Max power output < 500 W	250	*w*	IEC 60601-2-3 (2007)
		Reproducibility	*a*	20%	10%	*w*	
		Waveform analysis	*a*	20% 2445 - 2475 MHz Pulse Frequency: 30 % Pulse width: 30 %	10% 2455-2465 MHz	*w* *Hz* *Hz* *w*	IEC 60601-2-6 (2012)
	Electrical Safety	Visual Inspection	*c*	Physical damage ruled out			IEC 60601-2-3 (2007)
		Earthing tests	*a*	200 mΩ	200 mΩ	*Ω*	
		Insulation Tests	*a*	> 50 MΩ	> 50 MΩ	*Ω*	
		Leakage current tests	*a*	Earth: < 1000 μA Enclosure: < 500 μA Patient (AC): < 500 μA Patient (DC): <50 μA	500 μA 100 μA 100 μA 10 μA	*A* *A* *A* *A*	IEC 60601-2-3 (2007)
		Auxillary current tests	*a*	AC: <0.1 mA DC: < 0.05	0.1 mA 0.01 mA	*A* *A*	IEC 60601-2-3 (2007)
Enviroment of equipment	*Environmental Survey*	Furniture	*c*	Beds and chairs non-metallic			NHMRC (1985), ENRAF NONIUS (1997), DHW (1993), APA (1992), CSP (1992), CSP (1994)
		Treatment area layout	*c*	Metal objects > 3m Mains filter present	> 5m	*m*	DHW (1983), APA (1992) NHMRC (1985), ENRAF NONIUS (1997)
		Warning Signs	*c*	No use of mobile phones Danger for patients with pacemakers			IEC 60601-2-6 (2012)
		Other modalities in area	*c*	Other electrotherapy units > 3 m	> 5 m	*m*	CSP (1992), CSP (1994)
	RF Radiation Measurements	Isotropic probe, frequency analysis Maximum averaging over 6 min	*a*	E-field : 61 V/m H-field: 0.16 A/m	61 V/m 0.13 A/m	*V/m* *A/m*	ICNIRP (2004)
		Distance 0.5 m, 1 m, 1.5 m , 2 m, 2.5 m. 3.0 m, 3.5 m, 4.0 m, 4.5 m, 5 m, 6 m		SAR: 0.4 W/Kgr	0.08 W/Kgr	*W/Kgr*	IEC 61786 (1998), IEEE Std C95.3 (2002), CEPT Revised ECC/REC/(02) (2004), ETSI EG 202 373 V.1.1.1 (2005)
		Height 1.1 m, 1,5 m, 1.7 m Angle 0, +45, +90, +135, -45, -90, -135 degrees					

QC: Safe use-output safety tests

Analysis of the output waveform from MWD can be performed using a digital oscilloscope with a scope probe attached that acted as a basic antenna. The parameters tested are proposed be pulse frequency and pulse width.

Output stability can be measured over a 20 min period, as this is representative of an average treatment session

[Robertson V et al 2006].

QC : -Electrical safety

- MWD units can be categorized as Class I type BF electrical equipment and are subject to compliance with the relevant IEC 601-2-6 that specifies minimum requirements considered to provide for a practical degree of safety in the operation of microwave therapy equipment.

QC : -Electrical safety

- This particular standard amends and supplements IEC 60601-1 (third edition, 2005 and amendment 1 2012). The second edition cancels and replaces the first edition of IEC 60601-2-6, published in 1984.
- This edition constitutes a technical revision and has been aligned to the third edition of IEC 60601-1:2005+A1:2012 [IEC 60601-2-6 2012].

QC Procedure

QC protocol	TEST SECTION	INCLUTED TESTS	CRITERIA				REFERENCE
	Safe use guidelines of operation exposure		Control of operation exposure				
			*frequency**	acceplable	desirable	*units*	
Care of equipment	*Mechanical Tests*	Secure casing	*b*	All panels in good condition, Access to internal components only with tools			NHMRC (1985)
		Functioning castors	*b*	Unit is portable			
		Operatinf castor breakes	*c*	Breakes immobilize uints			
		Movable treatment arms	*c*	Securely attached and freely movable			
		Treatment arms lock	*b*	Lock in place			
		Interchangable electrodes	*c*	Lock in place, Range available			
		Condition of electrodes	*c*	No signs of damage, Air-space adjastable, Rubber on pad electrodes not broken down			
		Functioning control	*c*	Lamps and controls operational, Dials are fixed and click at correct interval			
		Operation of patient circuit braker	*b*	Power output stops when operated			
		Timer accuracy	*b*	Unit only operate with timer Output switches off when timer is zeroed			IEC 606O1-2-3 (1991)
				< 5 min : 30 sec 5-10 min: 10 % > 10 min: 60 sec	15 sec 5% 30 sec	*sec* *sec* *sec*	DHW (1993)
Use of equipment	*Output tests*	Linearity	*a*	30% Max power output < 500 W	250	*w*	IEC 606O1-2-3 (2007)
		Stability	*a*	20%	10%	*w*	
		Reproducibility	*a*	20%	10%	*w*	
		Waveform analysis	*a*	2445 - 2475 MHz Pulse Frequency: 30 % Pulse width: 30 %	2455-2465 MHz	*Hz* *Hz* *w*	IEC 60601-2-6 (2012)
	Electrical Safety	Visual Inspection	*c*	Physical damage ruled out			IEC 606O1-2-3 (2007)
		Earthing tests	*a*	200 mΩ	200 mΩ	*Ω*	
		Insulation Tests	*a*	> 50 MΩ	> 50 MΩ	*Ω*	
		Leakage current tests	*a*	Earth: < 1000 µA Enclosure: < 500 µA Patient (AC): < 500 µA Patient (DC): <50 µA	500 µA 100 µA 100 µA 10 µA	*A* *A* *A* *A*	IEC 60601-2-3 (2007)
		Auxillary current tests	*a*	AC: <0.1 mA DC: < 0.05	0.1 mA 0.01 mA	*A* *A*	IEC 60601-2-3 (2007)
		Furniture	*c*	Beds and chairs non-metallic			NHMRC (1985), ENRAF NONIUS (1997), DHW (1993), APA (1992), CSP (1992), CSP (1994)
Enviroment of equipment	*Environmental Survey*	Treatment area layout	*c*	Metal objects > 3m Mains filter present	> 5m	*m*	DHW (1983), APA (1992) NHMRC (1985), ENRAF NONIUS (1997)
		Warning Signs	*c*	No use of mobile phones Danger for patients with pacemakers			IEC 60601-2-6 (2012)
		Other modalities in area	*c*	Other electrotherapy units > 3 m	> 5 m	*m*	CSP (1992), CSP (1994)
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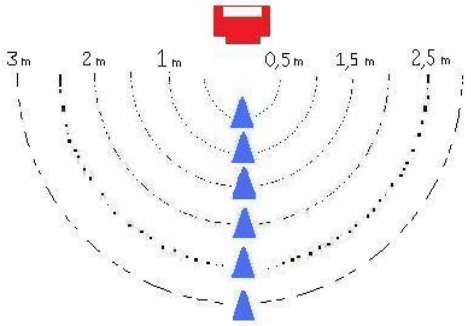
		Distance 0.5 m, 1 m, 1.5 m , 2 m, 2.5 m. 3.0 m, 3.5 m, 4.0 m, 4.5 m, 5 m, 6 m		SAR: 0.4 W/Kgr	0.08 W/Kgr	*W/Kgr*	IEC 61786 (1998), IEEE Std C95.3 (2002), CEPT Revised ECC/REC/(02) (2004), ETSI EG 202 373 V.1.1.1 (2005)
		Height 1.1 m, 1,5 m, 1.7 m Angle 0, +45, +90, +135, -45, -90, -135 degrees					

QC:-RF radiation measurements

From radiation protection viewpoint and according a number of studies there have to be recorded values at different distances

(1 to 6 m with 0,5 m step) and angles (0 to +135, -135 degrees with 45 degrees step) for 6 minutes and at three levels above ground (1.1 m, 1.5 m, 1.7 m) in the room of the physiotherapy unit when it radiates at maximum output value

[ICNIRP 1998, IEEE 2002, Shah SG and Farrow A 2013, Koutsojannis C 2009, NHMRC 1985].



QC : RF radiation measurements

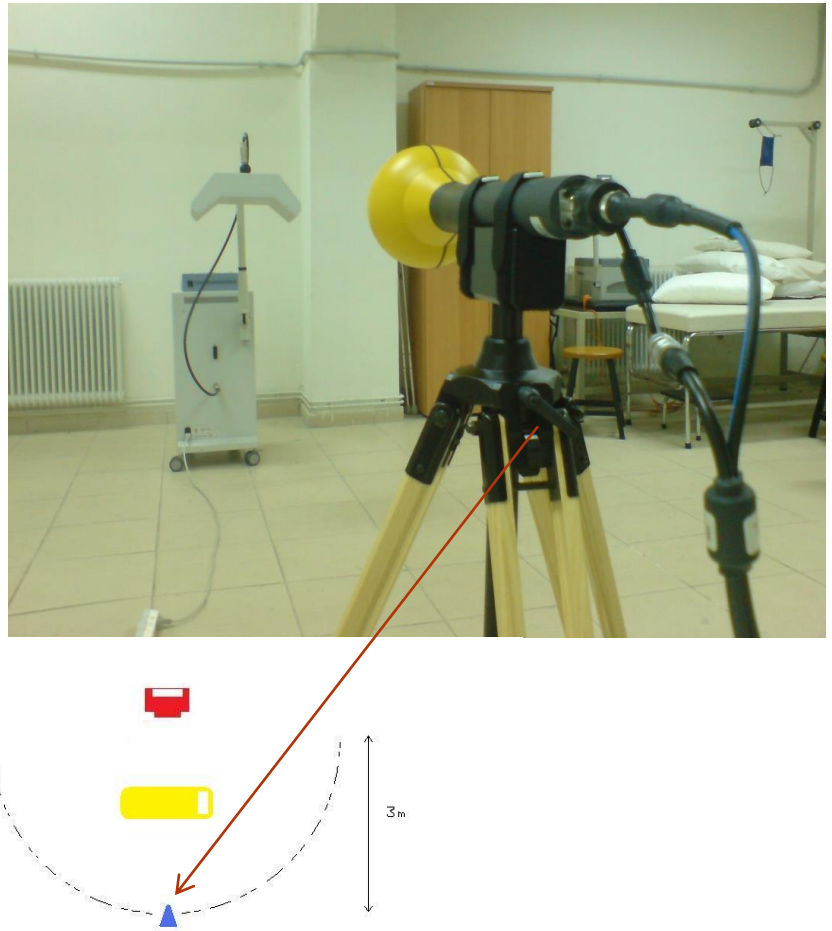
For upper limps radiation protection of the operator detailed field distribution near the MWD unit needs to be measured with sufficiently small probes.

Peak values are also relevant and not only RMS values [Koutsojannis C et al 2018, Schmidt G 2012].

Additionally it must be noted that ICNIRP provides basic restrictions for Central Nervous System (CNS) and peripheral tissues [Schmidt G 2012]. Consequently further studies and guidelines for exposure just for peripheral body parts needs to be considered.

QC: RF radiation measurements

- Measurements may have to be repeated including objects between transmitting and measuring devices such as beds and chairs in different formations [Shields N et al 2003, NHMRC 1985, Li CY & Feng CK 1999, Shah SG and Farrow A 2013, Andrikopoulc et al 2017, Koutsojannis et al 2018].



QC Procedure

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		Stability	*a*	20%	10%	*w*	
		Reproducibility	*a*	20%	10%	*w*	
		Waveform analysis	*a*	2445 - 2475 MHz Pulse Frequency: 30 % Pulse width: 30 %	2455-2465 MHz	*Hz* *Hz* *w*	IEC 60601-2-6 (2012)
	Electrical Safety	Visual Inspection	*c*	Physical damage ruled out			IEC 60601-2-3 (2007)
		Earthing tests	*a*	200 mΩ	200 mΩ	*Ω*	
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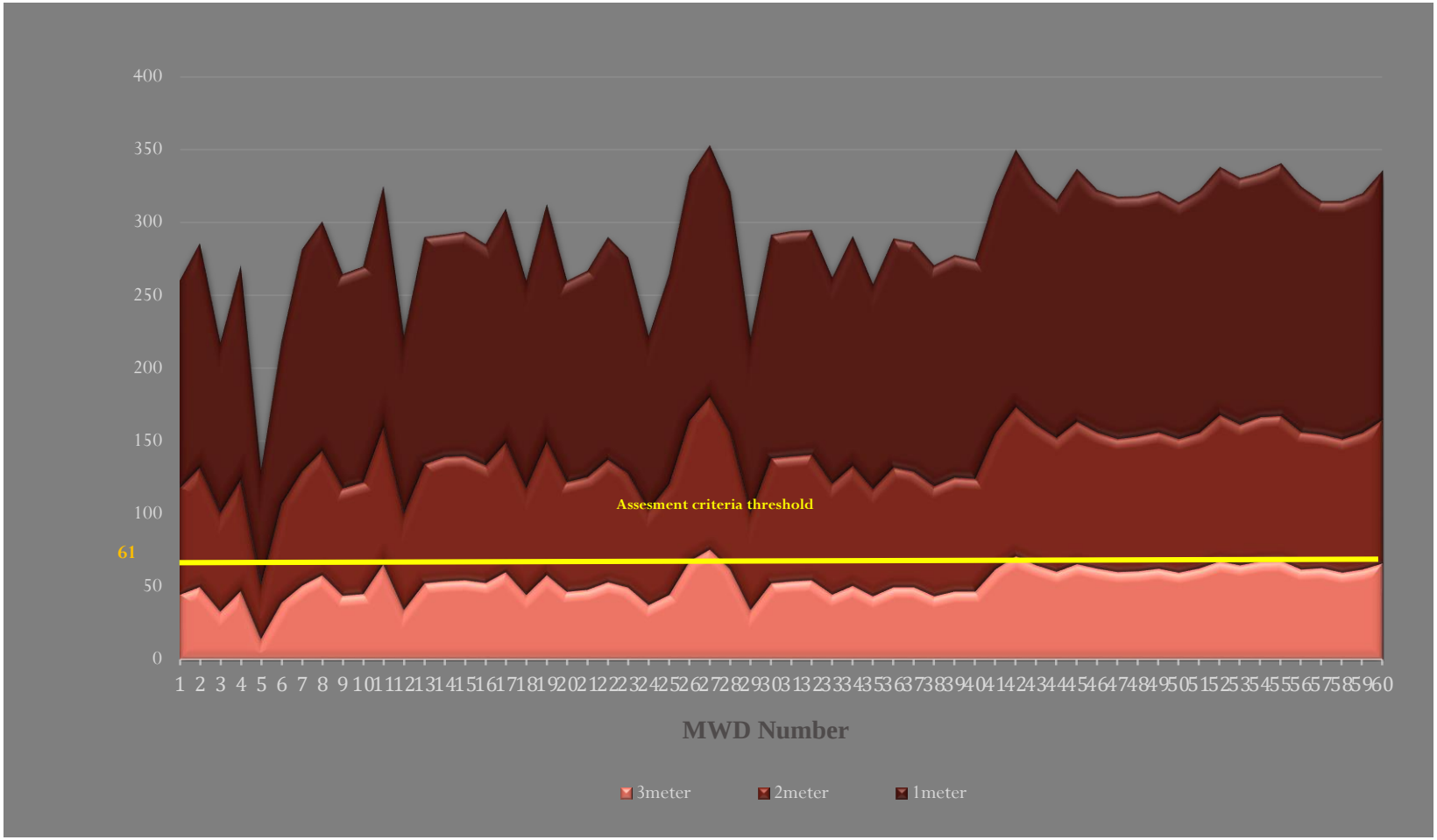
		Distance 0.5 m, 1 m, 1.5 m , 2 m, 2.5 m. 3.0 m, 3.5 m, 4.0 m, 4.5 m, 5 m, 6 m		SAR: 0.4 W/Kgr	0.08 W/Kgr	*W/Kgr*	IEC 61786 (1998), IEEE Std C95.3 (2002), CEPT Revised ECC/REC/(02) (2004), ETSI EG 202 373 V.1.1.1 (2005)
		Height 1.1 m, 1,5 m, 1.7 m Angle 0, +45, +90, +135, -45, -90, -135 degrees					

QC : … an example

RADAMED 950+, 200 watt, continuous mode, 1-3 m, 1,7 m, free 60 $m^{2,}$

	0°	45° +	45° -	90° +	90° -	Simulation at 0°	greek limit
0,5	310,00	114,70	176,70	124,00	46,50	496,00	51
1	213,80	79,11	121,87	85,52	32,07	124,00	51
1,5	133,75	49,49	76,24	53,50	20,06	55,11	51
2	75,00	27,75	52,75	30,00	11,25	31,00	51
2,5	62,50	23,13	35,63	25,00	9,38	19,84	51
3	55,04	20,36	31,37	22,02	8,26	13,78	51

[Koutsojannis C, 2012, 2013]


400
350
300
250
200
150
100
61
50
0
Assesment criteria threshold
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60
MWD Number
3meter
2meter
1meter

QC : -Environmental survey

The treatment environment have to be assessed to ensure that stray radiation from S & MWD units caused no interference with nearby equipment and that objects in the area would not cause a concentration of radiation

[Shields N et al 2003, NHMRC 1985, HC Safety code 25, Del Pizzo V and Joyner KH 1987].

QC : -Environmental survey

Metal objects can also constitute a fire hazard, as the concentration of RF fields can increase the temperature of that object and induce burning in nearby materials. Therefore the presence of any such objects near the MWD treatment area must be noted or replaced from others constructed with plastic or wooden parts [Koutsojannis C 2009, Shields N et al 2003, Del Pizzo V, Joyner KH, 1987].

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	Electrical Safety	Visual Inspection	*c*	Physical damage ruled out			IEC 606O1-2-3 (2007)
		Earthing tests	*a*	200 mΩ	200 mΩ	Ω	
		Insulation Tests	*a*	> 50 MΩ	> 50 MΩ	Ω	
		Leakage current tests	*a*	Earth: < 1000 µA Enclosure: < 500 µA Patient (AC): < 500 µA Patient (DC): <50 µA	500 µA 100 µA 100 µA 10 µA	*A* *A* *A* *A*	IEC 60601-2-3 (2007)
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	RF Radiation Measurements	Isotropic probe, frequency analysis	*a*	E-field : 61 V/m	61 V/m	*V/m*	ICNIRP (2004)
		Maximum averaging over 6 min		H-field: 0.16 A/m	0.13 A/m	*A/m*	
		Distance 0.5 m, 1 m, 1.5 m , 2 m, 2.5 m. 3.0 m, 3.5 m, 4.0 m, 4.5 m, 5 m, 6 m		SAR: 0.4 W/Kgr	0.08 W/Kgr	*W/Kgr*	IEC 61786 (1998), IEEE Std C95.3 (2002), CEPT Revised ECC/REC/(02) (2004), ETSI EG 202 373 V.1.1.1 (2005)
		Height 1.1 m, 1,5 m, 1.7 m Angle 0, +45, +90, +135, -45, -90, -135 degrees					

QC : Environmental survey

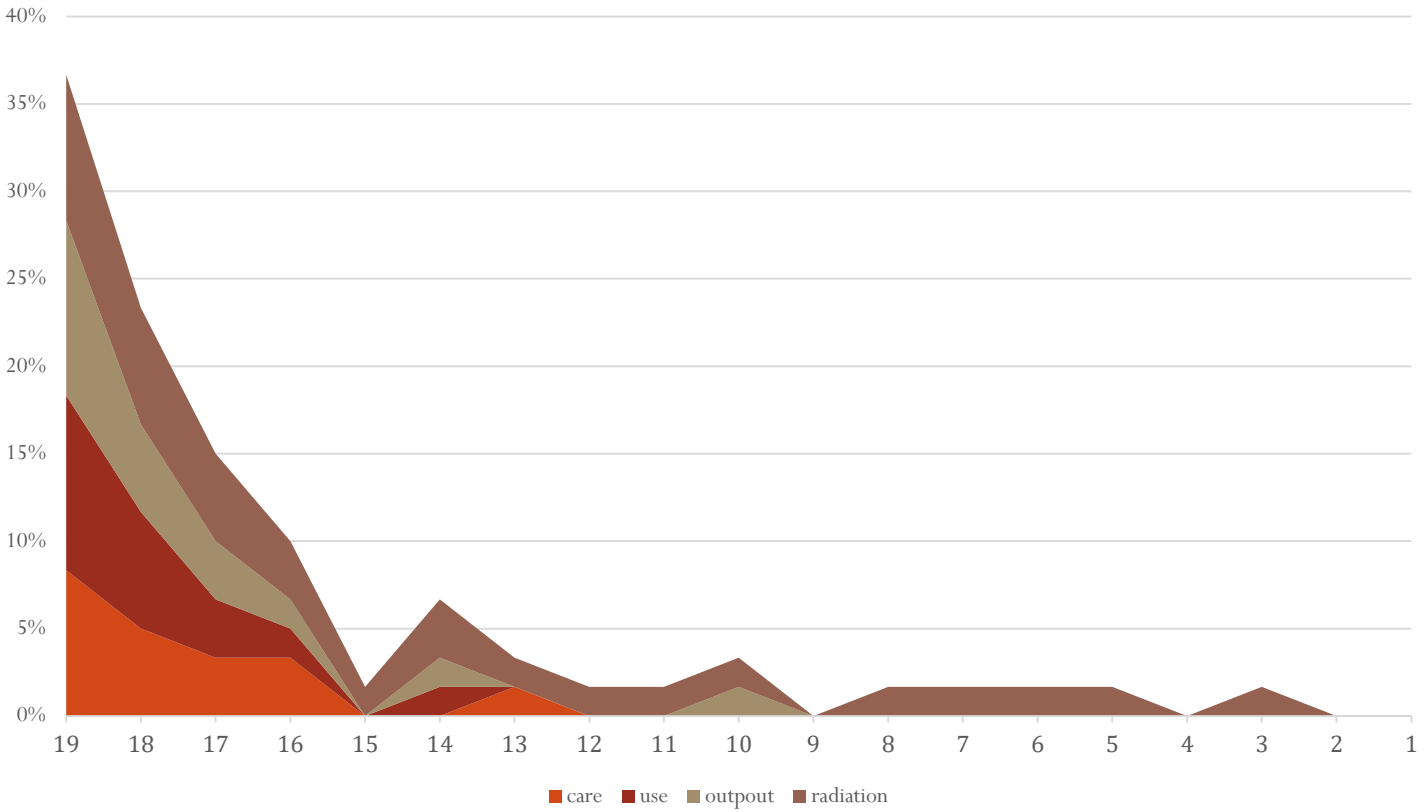
The Chartered Society of Physiotherapy in Britain, recommends that equipment must be tested every 6 months

[CSP 1997a, CSP 1997b , CSP 2000].

Introducing modification of IEC 601-2-6 Standard, we suggest to perform the proposed mechanical tests, the output power, the electrical safety and RF measurement tests, every 6 months

[IEC 60601-2-6 2012].

Lack of maintenance



QC : Challenges

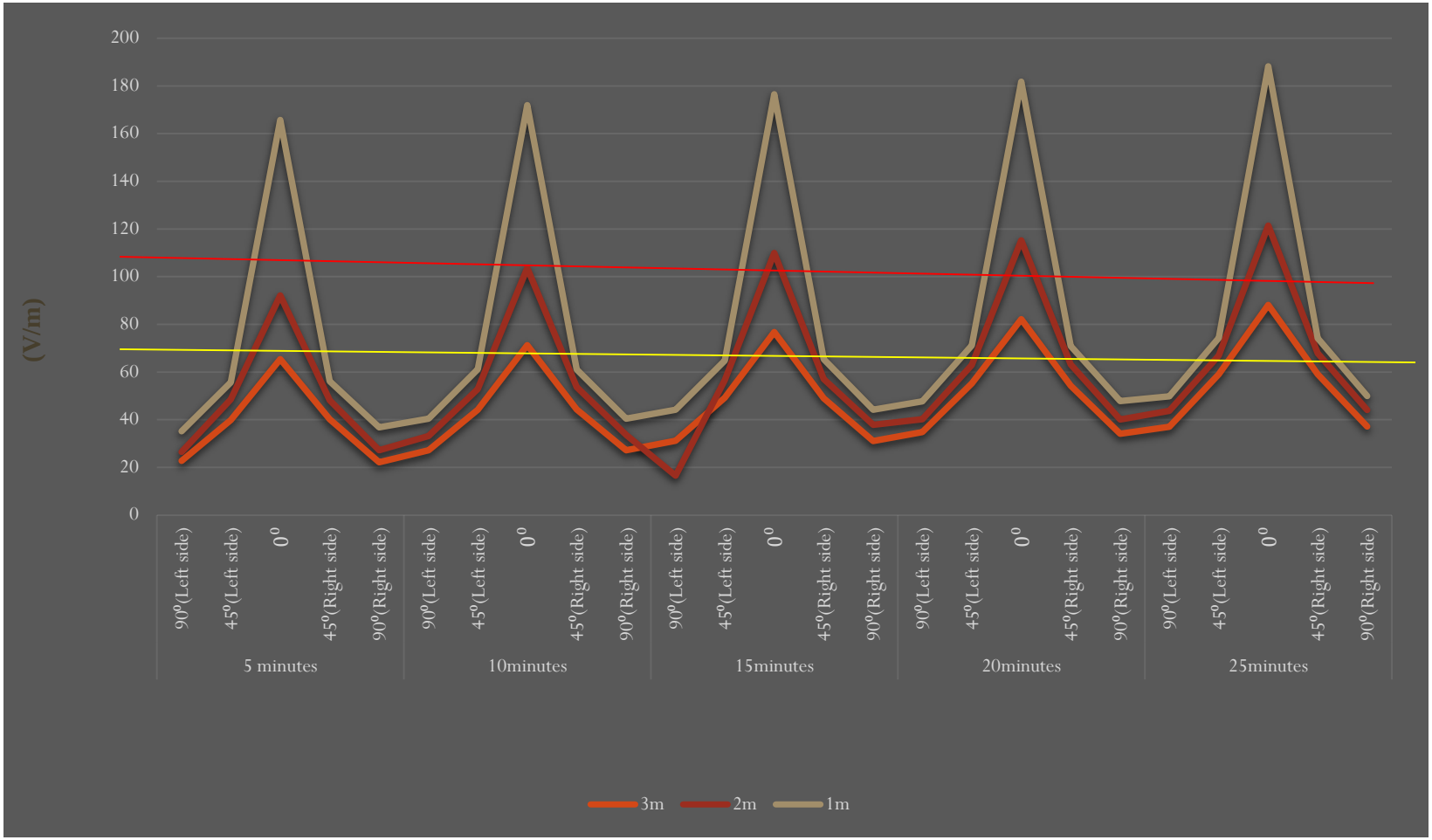
- Additional research in the areas of dosage, physiological change from treatment and risk assessment will enable these criteria to be refined as today there is no totally accepted method for measuring patient dosage , even various methods (as thermocouple measures of tissue temperature or phantom temperature) have been suggested [Lloyd, J. and Evans, J. 1988, Shields N et al 2003].
- Developing a reliable method of measuring patient dosage => the treatment is accurate and reproducible (major problem for double-blind research approaches in rehabilitation) .

QC : Challenges

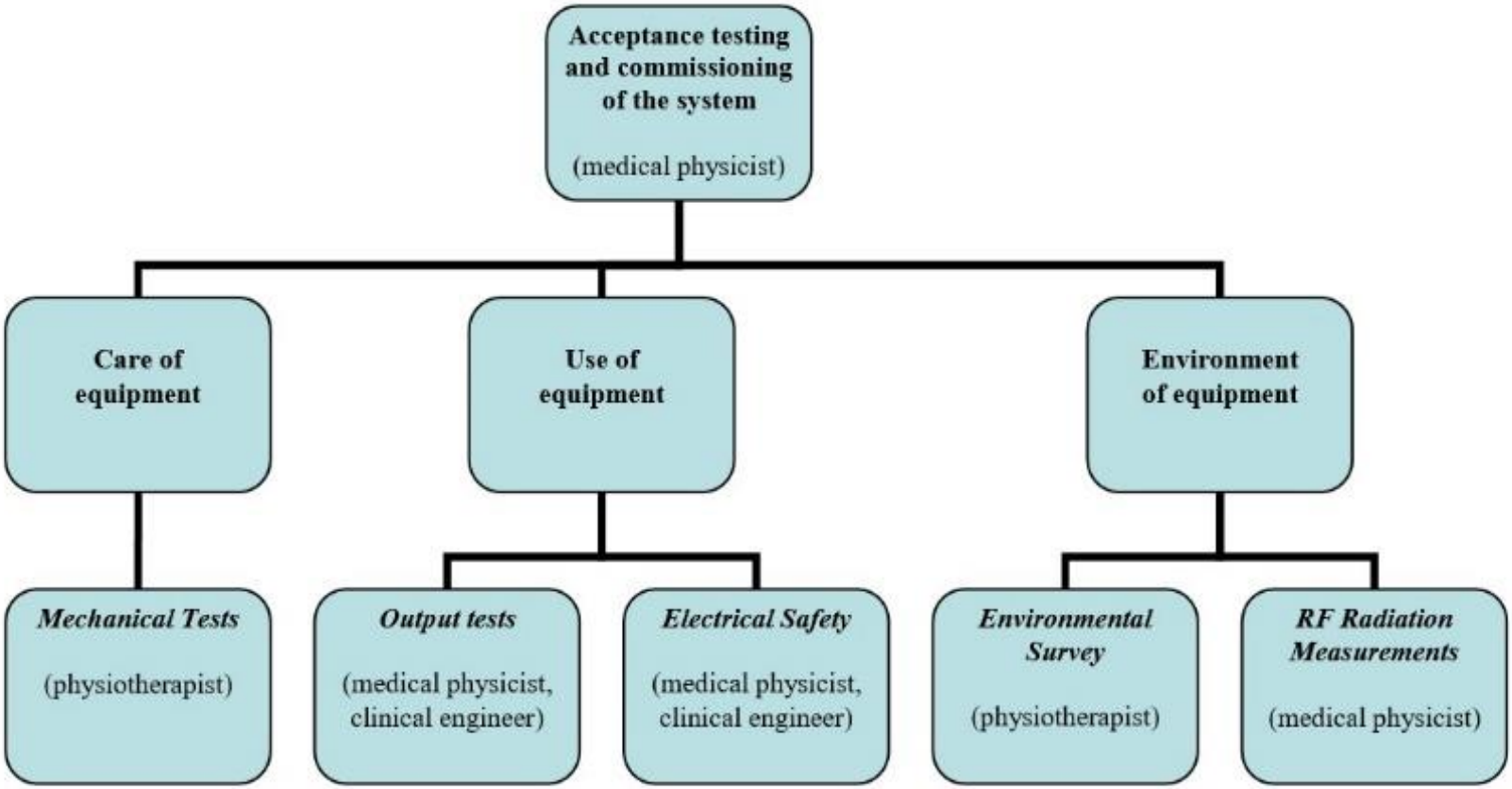
Finally under current safety restrictions no department operating S & MWD equipment is obliged to have a RF-screened room using fixed or removable materials.

This facility could be the most important, in ensuring that other people in the vicinity of operating equipment are not exposed to excess amounts of stray radiation, as directed by international guidelines [IRPA 1988].

Time inhomogeneity…



Responsibilities



Outline

1. Workplace specific exposure assessment and dosimetry
2. Safety procedures for Microwave diathermy units (MWDs)
3. The necessity for QCs
4. Conclusions

4. Conclusions

The QC procedure can be used to verify whether a unit is functioning within normal limits and also after periodic reviews of a unit's performance, in this way, those operating such equipment can be assured of reproducible treatments.

Equipment analysis is important, as the use of faulty equipment in electro- and thermo-therapy treatment can cause adverse effects [Koutsojannis et al 2018].

Conclusions

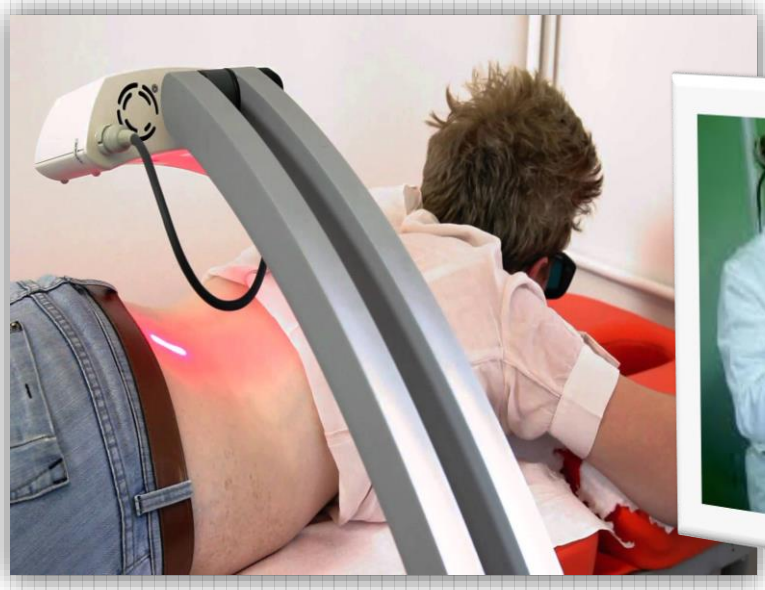
- National and International Professional bodies have to develop directives for non-ionizing radiation exposure in Physiotherapy Units, including strict regulations in order that all units that do not conform acceptance or functioning criteria, should be immediately repaired or replaced, as introduced in other fields of medical application of electromagnetics [Lin J 2011,2012].
- International commissions as ICNIRP evaluate the state of knowledge about the effects of NIR on human health and to provide science-based advice and recommendations on protection against harmful effects of NIR [Koutsojannis et al 2018].

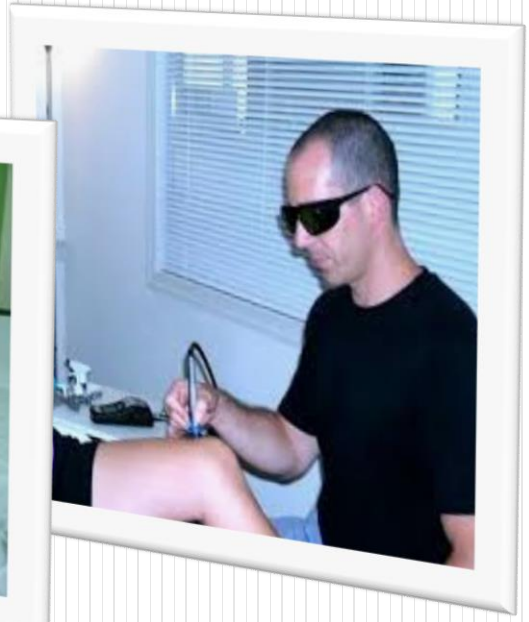
Conclusions

- The advantages of such procedures for occupational safety of health care professionals in rehabilitation could also be modified and used for cancer treatment with MWD units. Taking account that these units work with much higher power output the QC procedure must be extrapolated and appropriate EM shielding has to be introduced [Riadh W et al 2006].

What else ?

Magnetotherapy*, Lasers*, Infra-Ultra-Blue Light, etc





Thank you for your attention