

**Regulation of “Medical Devices” in Hong Kong
Consultation Document**

(July 2003)

**Department of Health
Government of the Hong Kong Special Administrative Region**

Joint Submission By :

**Hong Kong Chiropractors Association
(HKCA)**

**Chiropractic Doctors Association of Hong Kong
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DETAILED DOCUMENT

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Submission

Members of the chiropractic profession welcome the proposed legislation to regulate potentially dangerous devices in the interest of public safety.

The chiropractic profession, represented in this submission by the **Hong Kong Chiropractors' Association (HKCA)** and the **Chiropractic Doctors Association of Hong Kong (CDAHK)**, are genuinely concerned that the proposed regulation of medical devices may hinder the practice of chiropractic and it feels that it treats the chiropractic profession unfairly.

The use in the English title of the generic term 'medical' rather than 'health' can lead to misunderstanding. An article in the September issue of the *Medical Tribune* is an example: quote “ ... no supervision of the use of a specific medical device by non-medical professionals, ...” The proposed legislation is aimed at devices that are used by a number of professionals in both the health and beauty fields. We suggest that the term **'HEALTH DEVICES'** is more appropriate and in line with the Chinese translation.

The main thrust of our concern is that the status of the Chiropractors Regulation Ordinance Cap 428 (CRO) and the Chiropractors Council have been ignored. The Medical Registration Ordinance Cap 161 and The Dental Registration Ordinance Cap 156 and their relevant Councils have been recognised as having **statutory incidental control** for the use of medical devices, by registered medical doctors and dentists. Our review of the Medical and Dental Ordinances does not reveal any particular reference to the use of devices. Control of practice comes within the relevant profession's Code of Practice. Therefore, this privilege should be extended to registered chiropractors.

The use of devices, either specifically chiropractic devices or other health-related devices, by chiropractors is controlled and regulated by the Chiropractors Council in accordance with its Code of Practice. In order to qualify for registration as a chiropractor in Hong Kong, as elsewhere, a chiropractor has had to complete a full degree course equivalent to their medical and dental colleagues. This training qualifies the chiropractor to use those devices that are necessary for him to function as a chiropractor. For the proposed legislation to treat chiropractors differently to medical doctors and dentists is unreasonable and unfair.

Chiropractors are highly trained in the operation and use of X-ray machines as well as the interpretation of X-ray films. Unlike many GHTK constituent countries, an anomaly exists in Hong Kong law, which prohibits chiropractors from operating X-ray machines. This is a matter that the chiropractic profession wishes to rectify in the near future.

In conclusion we would like to emphasise that the chiropractic profession should be given the same consideration as that given to the medical and dental professions.

Our profession looks forward to further correspondence from the Department of Health in regards to this consultation document, and other aspects of review on Health Care Reform in Hong Kong SAR.

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Introduction

Our Concerns

The Hong Kong chiropractic profession is genuinely concerned that the proposed regulation of so-called medical devices may hinder the practice of chiropractic.

Our survey results (refer to page 11; appendix 1) show that all chiropractors in Hong Kong do use such devices in their day to day consultations and treatment of their patients.

Since chiropractors routinely use certain medical devices, the consultation document and proposed regulation makes no mention as to how the use of such devices, by Doctors of Chiropractic (DC's), would be regulated.

Our colleagues feel that the proposed legislation treats the chiropractic profession unfairly. Fellow chiropractors in the USA, Canada, United Kingdom, Australia and New Zealand have government authorization and licensure to use such devices as qualified health professionals.

Although the Chiropractors Registration Ordinance Cap 428 (CRO) is now fully implemented, the proposed regulation does not recognize its parallel role in regulating the use of medical devices by chiropractors.

The proposed regulation only mentions the statutory incidental control that is provided under the Medical Registration Ordinance Cap 161 and the Dentists Registration Ordinance Cap 156 for the use of medical devices by Medical Doctors and Dentists. Our review of these Ordinances does not reveal any particular reference to the use of devices any more than the Chiropractic Registration Ordinance.

At present, Chiropractors, although qualified in many of the GHTF constituent member countries, are not allowed to use and operate X-ray equipment in Hong Kong.

International Status of Chiropractic

In January 1997, the World Health Organization (WHO) recognized Chiropractic as an "Alternative Medicine Therapeutic discipline". It is one of two disciplines to hold this status; the other is Acupuncture.

The World Federation of Chiropractic (WFC) became a non-government organization (NGO) in official relations with the WHO. (1)

The WFC's definition of Chiropractic includes :

" A health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments including spinal manipulation or adjustment." (2)

Education Standards

Chiropractors must complete four to six years at an accredited chiropractic college. The complete curriculum includes a minimum of 4,800 hours of classroom, laboratory and clinical experience.

Country	Subject Area (Years of Study)				
	General Science	Chiropractic Science	Clinical Science	Internship	Total Years of Study
Australia		3	2	1*	6
UK		3	2	1	6
USA	2	4*			6
Canada	2	4*			6

* Most chiropractic colleges in the United States, Canada and Australia have their internship concurrent with their last year of study.

Table 1: Length of Accredited Chiropractic School Programmes in Various Countries

The Council on Chiropractic Education (CCE) is a US Government Agency and is internationally recognized as the "gold standard" of accreditation for chiropractic colleges. And it has reciprocal or equivalent accrediting bodies in Australasia, Canada, the United Kingdom, and parts of the European Union. The Hong Kong Chiropractic Council fully recognizes the CCE's stature.

Approximately 555 hours are devoted to learning about adjustive techniques and spinal analysis in colleges of chiropractic. Within these adjustive technique disciplines, there are particular techniques which use equipment and/or devices that may be unique to chiropractic. The proposed legislation, through its definition, would encompass such chiropractic devices.

In the US, those intending to become Chiropractors must also pass the national board exam and all exams required by the state in which the individual wishes to practice. The individual must also meet all individual state licensing requirements in order to become a doctor of chiropractic. Equivalent regulations are required in Australasia, Canada, the United Kingdom, and parts of the European Union, and now in Hong Kong, SAR.

An individual studying to become a doctor of chiropractic receives an education in both the basic and clinical sciences and in related health subjects. The intention of the basic chiropractic curriculum is to provide an in-depth understanding of the structure and function of the human body in health and disease. The educational program includes training in the basic medical sciences, including anatomy with human dissection, physiology, and biochemistry. Thorough training is also obtained in differential diagnosis, radiology and therapeutic techniques. This means, doctors of

chiropractic can both diagnose and treat patients, which may discern them from non-physician status providers, like physical therapists. According to the CCE chiropractors are trained as Primary care Providers.

Table 2 lists eleven(11) subject disciplines that are common to undergraduate programmes in medicine and chiropractic. This reflects the common clinical aspects of the two healthcare professions.

Of note, under the heading of X-ray, most chiropractic colleges include instruction in the use of x-ray equipment; proceeding to competencies for licensure in various state or government authorities. And, Radiography is taught in tandem with Radiology.

The discipline of Electrical Physical Therapeutics, which can include the understanding and clinical application of ultrasound, heat and cold, low-level lasers, TENS, interferential current, etc. are common to all chiropractic colleges and are taught as adjunctive modalities to manipulative therapy. (refer to Table 3).

	Medical College	Chiropractic College
Human Anatomy	508	520
Physiology	326	420
Pathology	401	205
Biochemistry	325	300
Microbiology	114	130
Diagnosis	324	420
Neurology	112	320
X-ray	148	217
Psychiatry	144	65
Obstetrics&Gynaecology	198	65
Orthopaedics	156	225
Total no. of Hours	2,756	2,887
Grand Total Class Hours (including other basic subjects)	4,248	4,485
Others: D.C. ² :- Chiro. Adj.	Manipulation, Kinesiology,	And subjects for specialty.
M.D. ³ :- Pharmacology,	Immunology, General Surgery,	And subjects for specialty.

¹ The cited study hours were compiled following a review of the curriculum catalogues of 22 medical schools and 11 chiropractic colleges, and updated with statistics from the National Health Federation Bulletin and other publications.

² Other required subjects in the Chiropractic Curriculum include Chiropractic Technique, Electrical Physical Therapeutics, Human Biomechanics, Human Nutrition, Radiography, and subjects related to the subspecialties.

³ Other required subjects in the Medical Curriculum include Histology, Immunology, Internal Medicine, General Surgery, and subjects related to the subspecialties.

Table 2: Comparison Between Chiropractic and Medical Curriculum ¹

Chiropractic School ¹	Country	*Subject Name (or equivalent) HOURS OF TUITION		
		Electrical Physiological Therapeutics	Radiography	Radiology
Anglo-European Chiropractic College	U.K.	40	112	196
Canadian Memorial Chiropractic College	Canada	41	243 ²	
Southern California University of Health Sciences	U.S.A.	150	165	195
National University of Health Sciences	U.S.A.	61	51	215
Life Chiropractic College West	U.S.A.	110	66	231
Palmer College of Chiropractic	U.S.A.	60	82	75
Royal Melbourne of Technology University	Australia	65	104	39
Macquarie University	Australia	204	133	168
AVERAGE PER SUBJECT DISCIPLINE (HOURS)		90	104	155
¹ selected chiropractic schools where Hong Kong registered chiropractors have graduated from ² where two subjects overlap in their teaching course design				

Table 3 : Summary of Subject Hours for Three Chiropractic Disciplines*

Sources: Websites of the above Schools (@2003); Direct correspondence with Department Heads (September 2003)

Suggestion on Term Used

The GHTF's definition of *medical devices* is quite broad and far ranging. The Consultation Document has adopted this same definition and its use in the English title of the generic term 'medical' rather than 'health' can lead to misunderstanding.

A definition of *medical* does imply “of the science of medicine (viz. the science of preventing and curing illness and disease)” (3). This appears to limit the scope of the Consultation Document and may be inconsistent with the Chinese translation.

A definition of *health* includes “the state of being well and free from illness in body or mind”(3).

The proposed legislation is aimed at devices that are used by a number of professionals in both the health and beauty fields.

We suggest that the term '**HEALTH DEVICES**' is more appropriate and in line with the Chinese translation.

Incidental Control Under the Chiropractic Registration Ordinance (CRO Cap 428)

The Chiropractors' Council of Hong Kong, founded in 1993, has worked with the government to draft the rules, codes of practice, registration qualifications and fee schedules required for chiropractic registration.

In 1998 there were 32 chiropractors – all of whom have graduated from CCE affiliated tertiary chiropractic institutions either in Australia, Canada, United Kingdom and the USA. As yet, there is no recognized tertiary institution for chiropractic in HKSAR. Presently, there are about sixty chiropractors licensed to practice in Hong Kong.

On June 8, the Chiropractors' Rules (Registration and Disciplinary Procedure) made by the Chiropractors' Council under the Chiropractors' Registration Ordinance, were published in the *Gazette*. *The Gazette is a publication of the Hong Kong special administrative region of the People's Republic of China*. The Chiropractic Rules detail registration and disciplinary procedures applicable to chiropractors in Hong Kong.

Registration of Hong Kong Chiropractors began on September 1, 2001. (4)

With the full operation of the CRO through its government appointed Council, the chiropractic profession has full legitimacy and accountability in the Hong Kong community. Within the

Council's Code of Practice, the Scope of Practice helps conceptualizes what chiropractic is and how chiropractors should function as healthcare professionals.

For the purpose of this submission, the Scope of Practice states :

- that registered chiropractors are trained to diagnose with “*diagnostic imaging and laboratory examinations*”;
- that ‘*The practice and the procedures which may be employed by the registered chiropractor include the use of diagnostic and therapeutic procedures based on the academic and clinical training received in and through accredited chiropractic institutions or post-graduate chiropractic studies.*’;
- and that chiropractors can use “*physiological therapeutic procedures designed to assist in the restoration and maintenance of neurological integrity and homeostatic balance.*”

This may be interpreted as giving Incidental Control for registered chiropractors for the use of health devices. And, with the government appointed Chiropractors' Council, provides mechanisms to ensure the safe and appropriate treatment of chiropractic patients and the public at large.

CRO's Scope of Practice

“Chiropractic is a distinct health care system. It is not a part of orthodox medicine. Chiropractic is a discipline of the scientific healing arts concerned with the pathogenesis, diagnostics, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and disturbances, pathomechanical states, pain syndromes and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis.

To reach a proper diagnosis of a condition, chiropractors apply their knowledge in chiropractic diagnosis, motion palpation, human biomechanics and kinesiology together with diagnostic imaging and laboratory examinations. Proper clinical diagnosis is stressed to distinguish the conditions between those that can be treated by the registered chiropractor and those that cannot. The registered chiropractor should refer any condition that needs alternate care to the appropriate health care practitioner.

The practice and the procedures which may be employed by the registered chiropractor include the use of diagnostic and therapeutic procedures based on the academic and clinical training received in and through accredited chiropractic institutions or post-graduate chiropractic studies.

Patient care is conducted with due regard for environmental, nutritional and psychotherapeutic factors, as well as first aid, hygiene, sanitation, rehabilitation and physiological therapeutic procedures designed to assist in the restoration and maintenance of neurological integrity and homeostatic balance.” ... (6) ref. Chiropractors Council of Hong Kong – Code of Practice, page 4

Chiropractors' Use of Medical Devices – high device-dependent practice

SURVEY RESULTS ON THE USE OF MEDICAL DEVICES BY HONG KONG REGISTERED CHIROPRACTORS

Introduction

In response to the consultation document and proposed legislation, the chiropractic profession surveyed its members to clarify three areas of contention:

1. Their use of medical devices – whether these devices are essential or not
2. Medical devices they presently use – countries from where these devices are purchased
3. Risk Levels of chiropractic/medical devices

There are presently sixty-five (65) chiropractors registered with the Chiropractors' Council; 3 of whom are practicing overseas. Of consequence, there were 32 in 1998 - this represents a 100% increase in five years.

Fifty-four surveys were distributed in Hong Kong by e-mail or fax. Thirty-three responses were received by 23 September, 2003. This represents a 65% response rate.

Results

Section 1 of the survey shows 32 of 33 (97%), of respondents, do use medical devices, and 30 of 33 (91%) state that medical devices are essential to their practice. 32 of 33 respondents state that they are qualified or certified to use such devices; their qualifications are mainly from USA(17); Canada(9); Australia(8) and UK(3).

Section 2 shows that the 21 respondents have 10 or less medical devices in their clinics. Only 1 respondent reported having 25 or greater such devices. The devices were mainly purchased from the USA(27); Hong Kong(13); Canada(10); Australia(8) and Europe (5); and Singapore registered 2 items.

Section 3 shows that 30 of 33 chiropractors have used and are qualified to use X-ray either in USA(15); Canada(8); Australia(8); UK(3). With this in mind (i.e. X-ray machines as an example of "Medium to High" Risk), chiropractors rated most of their devices as Low(20); Low-Medium(5); Medium to High(3); and no responses in the High Risk (Class IV) category.

Discussion

The sample of Hong Kong chiropractic profession reports (91%) that medical devices are an essential part of their practice and that they are qualified or certified (from a number of

countries) to use them. This is not surprising as Hong Kong registered chiropractors must gain their qualification from an accredited chiropractic schools in the USA, Canada, Australia, or UK.

A majority of chiropractors appear to use some 10 or less devices in their clinics which are purchased mainly in the USA, although, Hong Kong is listed as the second most common source of purchase. Our survey did not ask for the types of medical devices used, and, most respondents rated them in the “Low” Risk category.

In addition, most respondents have used and have qualifications in X-ray machines from either the USA, Canada, Australia, and UK. This is a significant factor in assessing chiropractors’ status for access to the types of medical devices. The abovementioned countries grant limited licenses to chiropractors to operate X-ray machines. Our survey shows that 30 of 33 (91 %) are qualified to use X-ray. If the proposed legislation is to be enacted, then Hong Kong registered chiropractors may be considered to have access to medical devices from Class I, II, and III (i.e. up to Medium to High Risk).

Conclusions from the Survey

The results of this survey show that a significant part of the Hong Kong chiropractic profession considers the use of medical devices essential their clinical practice. That their qualifications are from the USA, Canada, Australia, UK, and that these devices are mainly purchased for the USA and Hong Kong. Although most respondents classify their devices as Low Risk (Class I), Hong Kong registered chiropractors have qualification to use X-ray machines (Class III).

Examples of devices used by and unique to bonafide Chiropractors

Chiropractors, with their training as primary care practitioners (with grounding in orthopaedics, neurology, diagnosis, radiography, radiology and first aid), are qualified to use those devices which are common to Medical Doctors in general practice. A limited list of health devices is provided in Appendix 2.

Moreover, chiropractors are perhaps uniquely qualified to use particular devices in their general practice. A selection of those devices can be viewed at the websites below. It is noted that there are particular techniques, which require training from an accredited course in order to be proficient (and safe) at that technique. Postgraduate training in technique (with their diagnostic and analytic criteria) is not uncommon.

The proposed legislation, through its definition, would encompass such chiropractic devices.

<http://www.chirotables.com/newtables/loydtable.htm>

<http://www.dcproductsreview.com/chiropractic/tables.html>

<http://www.chiropractictables.com/history.html>

<http://www.coxtechnic.com/>

Chiropractors' Use of X-ray Equipment

Principles of Practice (5)

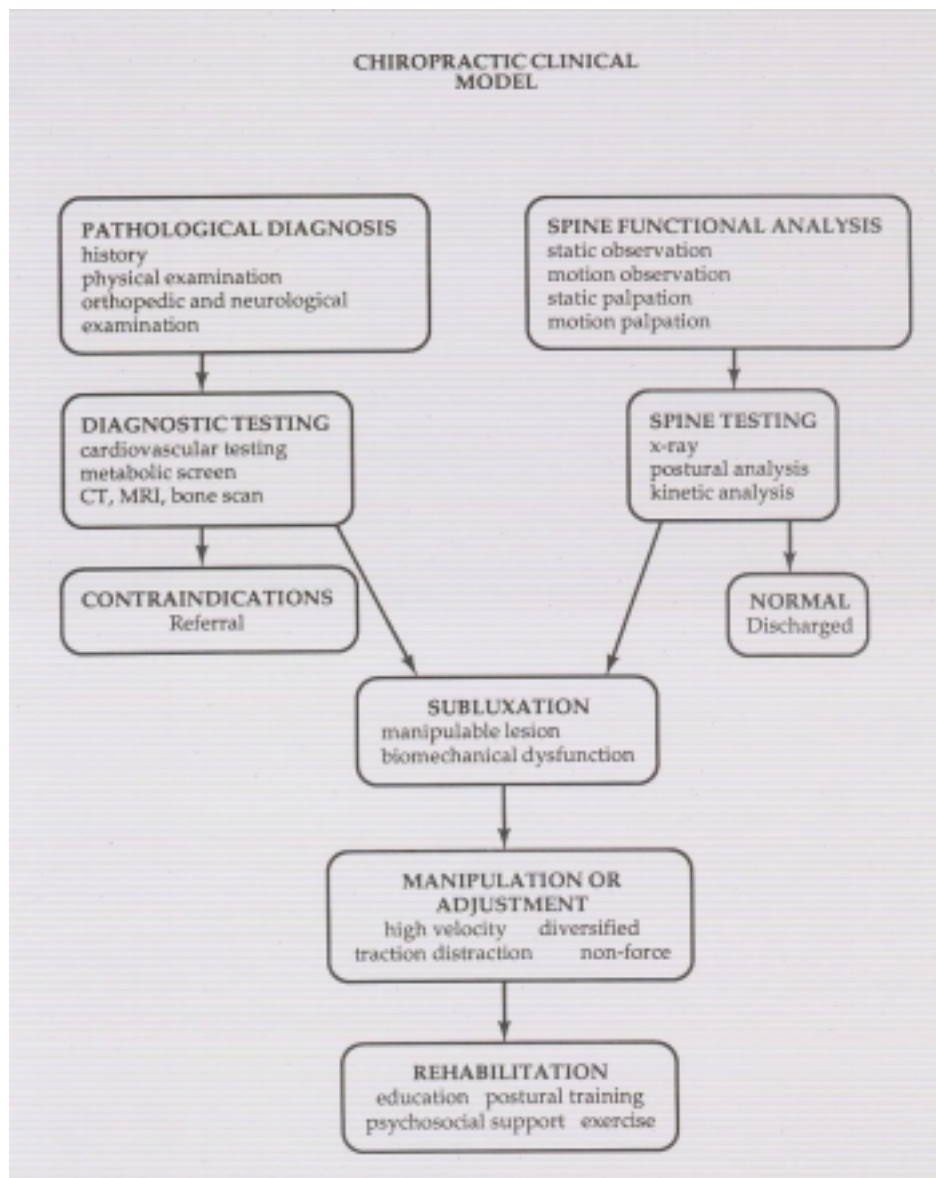
Patients typically visit a chiropractor for the first time through a personal reference or a referral of another health care specialist. At their first visit, you can expect the chiropractor to complete a thorough consultation which includes:

- **Patient History**
- **Physical Examination**
- **Diagnostic Studies**
Diagnostic studies are helpful in revealing pathologies and identifying structural abnormalities that more accurately diagnose a condition. They may or may not be necessary based upon the results of the history and examination. The most common diagnostic studies include:
 1. X-ray
 2. MRI (Magnetic Resonance Imaging) scan
 3. Laboratory tests

Many chiropractors are licensed and can do basic x-rays in their office, but an MRI scan and more extensive images may be referred to an outside center for which an appointment is needed.

- **Diagnosis:** The culmination of the history, examination and diagnostic studies is a specific diagnosis. Once the diagnosis is established, the chiropractor will determine if the condition will respond to chiropractic care.
- **Treatment Plan:** Most chiropractors begin treatment on the first visit, although some may wait until the next appointment. Treatment recommendations may include some or all of the following:
 1. Adjustments (manipulation) to key joint dysfunctions
 2. Modalities to improve soft tissue healing and pain control (egs.ultrasound, electrical stimulation and traction)
 3. Exercises to improve muscles balance, strength, and coordination
 4. Patient education to improve posture, ergonomics and motor control
 5. Other treatments may be included, such as massage, heat/cold application, and nutrition education.

The DC's role, as a primary care provider, in any cost-effective healthcare system, will necessitate them to use diagnostic testing to accurately determine a diagnosis. Access to diagnostic devices by a qualified DC is essential to a synergistic relationship between chiropractic and other health professionals, and provides an efficient means of determining whether the patient is contraindicated to chiropractic care. This is paramount to any clinician's decision-making as to when to, and when not to, refer to other health professionals for assessment.



Source: Principles and Practice of Chiropractic - 2nd ed. (1992) Haldeman S

Conclusions

- The Chiropractic profession is both internationally recognized by the World Health Organization, and locally legitimized in Hong Kong through the Chiropractors' Registration Ordinance (CAP 428). The latter, via the government appointed Chiropractors' Council, provides mechanisms to ensure the safe and appropriate treatment of chiropractic patients.
- Doctors of Chiropractic, registered in Hong Kong, attain their basic qualifications from college/university programmes that are accredited by the Council on Chiropractic Education, or its equivalent, in the US, UK, Canada, and Australia. (These countries are members of the Global Harmonisation Task Force.)
- Undergraduate college/university programmes requires competencies in the use of diagnostic studies to determine a specific diagnosis for the safe and effective treatment of their patients. These will include the use of medical/health devices in the Department of Health's classification I, II, and III.
- The Doctor of Chiropractic's role, as a primary care provider, in any cost-effective healthcare system, will necessitate them to use diagnostic testing to accurately determine a diagnosis. Unencumbered access to medical/health devices is essential to any chiropractic practice.
- This submission would like to emphasise that the chiropractic profession should be given the same consideration as that given to the medical and dental professions.

References:

1. Chapman-Smith D - ed. (1998) "The Chiropractic Report" January 1998 Vol.12
2. www.wfc.org
3. Oxford Advanced Learner's Dictionary of Current English – 5th ed. (1995) edited by Crowther J, et al. Oxford University Press
4. www.chiroweb.com - "Doctors of Chiropractic(DC) are recognized health care professional in Hong Kong"
5. www.spine-health.com - [Peter J. Schubbe, DC](#) May 22, 2000
6. Chiropractors Council of Hong Kong – Code of Practice, page 4

Appendix 1

SURVEY RESULTS ON THE USE OF MEDICAL DEVICES BY HONG KONG REGISTERED CHIROPRACTORS (September 2003)

Total number of surveys distributed : 32(HKCA) 22(CDAHK)

Total number of respondents : 20 13

Section 1: Your Use of Medical Devices

1.1 Based on the definition (of medical devices), do you use any in your clinic 19xY 1xN 13xY

1.2 Are the use of medical devices essential to your clinical practice 18 2 12 1

1.3 Do you feel qualified or certified to use the devices in your clinical practice 19 ? 13

1.3.1 Where did you obtain your qualification or certification for the use of such devices

a. undergraduate college/university 7 2

b. postgraduate seminar/programme 3 4

c. a. and b. 10 7

1.3.2 In which country(ies) did you receive these qualifications a. USA 8 9 e. Australia 5 3

b. UK 3 0 f. Japan 0 0

c. Europe 0 0

d. Canada 7 2

g. Other: Hong Kong 1 0

Section 2 : Medical Devices You Presently Use

2.1 Can you estimate and based on the above definition, how many medical devices you presently have in your clinic

a. 0-10 11 10 b. 11-15 3 2 c. 16-20 3 0 d. 21-25 1 0 e. >25 2 0

2.2 Where did you purchase such devices : a. USA 18 9

b. UK 2 0

c. Europe 5 0

d. Canada 7 3

e. Australia 5 3

g. Japan 1 0

h. Other: 10 3 (Hong Kong) 2 0 (Singapore)

Section 3: Risk Levels of Chiropractic/Medical Devices

3.1 Based on the example of an X-ray machine being rated as a "Medium to High" Risk (or Class III), how would you rate the devices you presently use :

a. Low 10 10 b. Low-Medium 4 1 c. Medium to High 2 1 d. High 0 0

3.2 Have you ever used an X-ray machine? 19 Y ? 11 Y 1 N

3.2.1 Are you qualified to use X-ray? 19 Y ? 11 Y 0 N

3.2.2 Where are you qualified to use X-ray? a. USA 6 9

b. UK 3 0

c. Europe 0 0

d. Canada 6 2

e. Australia 5 3

f. Japan 0 0

g. Other: 1 1 (Hong Kong)

Comments : Chiropractors are fully qualified to own and operate X-ray machines. Why not in HKSAR? What is the reason behind it.

Appendix 2

A limited list of medical / chiropractic / physiotherapeutic modality and appliances that may be used in a chiropractic clinic.

This would include (but not limited to) items such as:

- ultrasound - diagnostic and therapeutic
- microcurrent stimulation
- Muscle stim
- tens machines
- interferential stimulation
- laser stimulation
- combination stim machines / stim and ultrasound machines in one
- Knee braces or other braces such as AFOs, wrist, elbow, ankle, or collars.
- foot orthotics / custom footwear
- G-5 (vibration)
- hot packs
- taping / bracing
- pillows and supports including neoprene and elastic supports
- ergonomic aids
- lotions and linaments
- inversion machines
- drop piece tables *
- flexion / distraction tables *
- hylo tables *
- Activator *
- infrared therapy
- Surface EMG
- X-Ray machines
- X-Ray view box
- Bone densityometer
- Spinal decompression / traction units
- Ozone generators
- Air purifiers
- Fit balls and other exercise apparatus such as rubber tubing
- diagnostic scales and Spinal Postural assessment machines
- Stretching apparatus
- SOT blocks *
- Stop Watch or watch to check heart rate
- Sphygmomanometer, oto/ophthalmoscope, reflex hammer, pin wheel, tongue depressor, cotton ball
- Hyperbaric chambers
- Wobble boards
- Magnets
- Rubber gloves

*** Health Devices which require Accredited Chiropractic training to order to be proficient**