

HIGH-VOLTAGE ELECTRIC FIELD THERAPY



**HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA**

020/07



Prepared by:

Dr Harishah binti Talib,
Final Year,
Masters of Public Health (Epidemiology),
Faculty of Medicine,
University of Malaya,
Kuala Lumpur.
November 2007.

Reviewed By:

Datin Dr Rugayah Bt Bakri,
Deputy Director,
Health Technology Assessment Unit,
Ministry of Health Malaysia,
November 2007

www.ww.high-voltage-therapy.com
www.monkon.net

EXECUTIVE SUMMARY

This review was requested by the Disease Control Division, Ministry of Health Malaysia. The objective was to determine the safety, effectiveness and cost effectiveness of high-voltage electric field therapy unit [REDACTED] for treatment of patients with headache, muscle pain, insomnia, chronic constipation, and lumbago.

[REDACTED] is a product from [REDACTED]. [REDACTED] is a high-voltage electric field therapy unit that stimulates the entire body with a maximum voltage of 9000 V (peak value). It is used to treat patients with headache, muscle pain, insomnia, chronic constipation, and lumbago. The treatment can be administered to the patient either when they are lying on a bed or sitting on a chair. Three selectable output levels and three treatment programmes are provided.

There was no retrievable scientific evidence on the safety, effectiveness as well as cost-effectiveness aspects of [REDACTED] high-voltage electric field therapy. The price of the device is about [REDACTED]. This device is not recommended to be used in any health care facilities in Malaysia at the moment. Clinical research on the safety and effectiveness of this device is much warranted.

www.wv.high-voltage-therapy.com
www.monkon.net



1. INTRODUCTION

██████████ is a high-voltage electric field therapy unit that stimulates the entire body with a maximum voltage of 9000 V (peak value). The unit is used primarily to treat headache, muscle pain, insomnia, chronic constipation, and lumbago.¹ This review was requested by the Disease Control Division, Ministry of Health Malaysia.

2. OBJECTIVES

To determine the safety, effectiveness and cost effectiveness of high-voltage electric field therapy unit ██████████ for treatment of headache, muscle pain, insomnia, chronic constipation, lumbago and other diseases.

3. TECHNICAL FEATURES

██████████ is a product from ██████████. This company has been operating since 23 years ago.² The device is about 390mm width, 320mm depth and 170mm height with 6.5kg weight. The power supplies are 110V or 220V with 50 or 60 Hz. The rated power consumption is 13.5W. The output voltages are 3000V, 6000V or peak value of 9000V. The standard accessories provided are two mattress electrodes (with a 2-meter cord), one point electrode and seven insulating spacer. Other accessories are insulating sheet, and footrest.³

Therapy can be administered in any posture. Since a mattress electrode is used for the administration of therapy, patient can either lie on a bed or sit on a chair and relax while receiving treatment. The output level, a timer, and whole-body/local treatment can be set using a simple, one-touch button. Three selectable output levels are provided: 3000V, 6000V, and 9000V. There are three treatment programs which can be selected. The output changes every minute to prevent the body from accommodation to the stimulation, resulting in more effective treatment. The unit uses a mattress electrode for the treatment of the entire body and a point electrode for a local treatment. The treatment time can be selected from duration of 30 minutes, one hour, two hours, four hours, till eight hours. The remaining treatment time is displayed in minutes.¹



FIGURE 1: BIOS 9000

4. METHODOLOGY

4.1 SEARCH METHODS

Literature were searched through electronic databases, which included Pubmed, OVID, Proquest, Ebscohost, EBM Reviews for controlled trials, Cochrane database on systematic review, Cochrane Clinical Trial Registry, Science Direct, Springer Link, and General Databases Such as Google and Yahoo.

The search strategy used the terms, which were either used singly or in various combinations: “XXXXXXXXXX” OR “high voltage electric field” OR “electric field” OR “electric mattress” OR “mattress electrode” OR “high voltage electric field therapy XXXXXXXXXX”, “safety” OR “safe” OR “adverse effect” OR harm* effect*” OR “toxicity”, OR “cost effectiveness” OR “cost analysis” OR econom*.

Further information from the importer/distributors of the device was attempted by calling the head office as well as the five branches, however, none were contactable⁴. Further clarification regarding the safety of the device was also sought from the Electrical Engineering Division, Ministry of Health, Malaysia.

www.ww.high-voltage-therapy.com

4.2 SELECTION OF STUDIES INCLUDED/EXCLUDED

No limitation to the search was instituted. Personal communication was also carried out by telephone calls.

5. RESULTS AND DISCUSSION

5.1 SAFETY

No retrievable evidence on the safety aspect of this device. There were articles stating that it is contraindicated in pregnant mothers, cancer patients and patients with inserted pacemakers.² There was no evidence of safety approval by US FDA,⁵ International Electrotechnical Commission (IEC), International Conference on Harmonisation (ICH)⁶ or TUV product services.⁷ Personal communication with Engineering Division of Ministry of Health Malaysia also confirmed that there was no FDA or European Certificate (CE) marking approval. However, based on our verbal communication with one of the user, he mentioned that he felt slight dehydration on using this device for the first time, but he felt better afterward (anecdotal claim).

5.2 EFFECTIVENESS

There was no retrievable evidence on evaluation of the effectiveness of using this technology.

5.3 COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of using this technology. However, the price is about [REDACTED].⁸

6. CONCLUSION AND RECOMMENDATION

Since there was no retrievable scientific evidence on the safety, effectiveness as well as the cost effectiveness on BIOS 9000, this device is not recommended to be used in any health care facilities in Malaysia at the moment. Clinical research on the safety and effectiveness on this device is much warranted.

www.ww.high-voltage-therapy.com
www.monkon.net

7. REFERENCES

- 1 Ito Co. ltd. Internet communication at tolator.co.jp/english/products/cat05.html - 19k on 28.10.2007
- 2 Rawatan Therapy Bios 9000. Internet communication at devali.multiply.com/reviews/item/11 - 14k on 12.11.07
- 3 BIOS 9000 (Just beauty enterprise, Brunei Darussalam). Internet Communication at
- 4 HOME. Internet communication at <http://www.high-voltage-therapy.com> on 18.11.2007
- 5 US Food and Drug Administration. Internet communication at www.high-voltage-therapy.com on 17.11.2007
- 6 International Conference on Harmonization (ICH). Internet communication at
- 7 TUV Product Services Limited internet communication at <http://www.monkon.net> on 18.11.2007
- 8 10 DUN Terima Mesin Fisioterapi at www.high-voltage-therapy.com
www.monkon.net

