



**■ ANDULLATION THERAPY SYSTEM**

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**DISCLAIMER**

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has not been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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## **DISCLOSURE**

The authors of this report have no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia

## **EXECUTIVE SUMMARY**

### **Introduction**

Massage is the manipulation of superficial and deeper layers of muscle and connective tissue to enhance function, aid in healing process, and promote relaxation and well-being. Massage involves acting on and manipulating the body with pressure - structured, unstructured, stationary, or moving-tension, motion, or vibration, done manually or with mechanical aids. Andullation is claimed to be a totally new massage method which treats various complaints that arise from organs functioning 'poorly' or 'inadequately' with a combination of mechanical vibrations that arouse a resonance in the cell and waves of infrared electromagnetic heat. This technology review was conducted following a request from the office of the Deputy Minister of Health following a request from a company to introduce ■■■ Andullation Therapy System to be used in hospital and One Malaysia clinic.

### **Objective/aim**

The objective of this systematic review was to assess the safety, efficacy / effectiveness and cost-effectiveness of ■■■ Andullation Therapy System for treatment of medical conditions such as persistent muscles tension and hardening (Myogelosis) in the shoulders, neck and lower back, stress, metabolic disturbances, circulatory disturbances, lymphatic complaints, rheumatic pains and spinal disc herniation.

### **Results and conclusions**

There was no retrievable evidence on the safety, efficacy / effectiveness and cost-effectiveness of ■■■ Andullation Therapy System from the scientific databases. However, there were few English language summaries of studies on Andullation Therapy System which were retrieved via Google and from the document submitted by a company. The full text articles of the studies were in German language.

From the review, there was limited evidence to suggest the efficacy / effectiveness of Andullation Therapy System for treatment of non specific acute lower back pain, chronic back pain, reduction of stress and lymphoedema of the lower limbs. However, there was no retrievable clinical trial on the safety and the cost-effectiveness of ■■■ Andullation Therapy System.

### **Methods**

Electronic databases were searched through the Ovid interface which included Medline, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-Cochrane database of systematic reviews, EBM Reviews - HTA Databases. Searches were also run in PubMed, Horizon Scanning databases, MHRA and FDA website for published reports. Google and Google scholar were used to search for additional web-based literature. There was no limit in the search. Additional information was also retrieved from the document submitted by a company.

# ■■■■ ANDULLATION THERAPY SYSTEM

## 1. INTRODUCTION

Massage is the manipulation of superficial and deeper layers of muscle and connective tissue to enhance function, aid in healing process, and promote relaxation and well-being. Massage involves acting on and manipulating the body with pressure - structured, unstructured, stationary, or moving-tension, motion, or vibration, done manually or with mechanical aids. Target tissues may include muscles, tendons, ligaments, fascia, skin, joints, or other connective tissue, as well as lymphatic vessels, or organs of the gastrointestinal system. Massage can be applied with hands, fingers, elbows, knees, forearm and feet.<sup>1</sup>

Andullation is claimed to be a totally new massage method which treats various complaints that arise from organs functioning ‘poorly’ or ‘inadequately’ with a combination of mechanical vibrations that arouse a resonance in the cell and waves of infrared electromagnetic heat.<sup>2</sup> The ■■■■ Andullation Therapy System also known as the medical ■■■■ andullation therapy is claimed to be the first certified medical product made in Germany to employ andulling massages with thermal infrared deep heat. It is mainly used to relieve symptoms from specific and non specific back problems but it is also claimed to relieve the symptoms of stress, fibromyalgia, osteoarthritis and many others. It is used in the rehabilitation centres, clinics, health centres and professional application of the massage system is also possible at home. It is claimed to be used in many countries such as Europe, Germany, United States of America, Australia, Canada, England, France and Malaysia.<sup>2-3</sup>

This technology review was conducted following a request from the office of the Deputy Minister of Health following a request from a company to introduce ■■■■ Andullation Therapy System to be used in hospital and One Malaysia clinic.

## 2. OBJECTIVE/AIM

The objective of this systematic review was to assess the safety, efficacy / effectiveness and cost-effectiveness of ■■■■ Andullation Therapy System for treatment of medical conditions such as persistent muscles tension and hardening (Myogelosis) in the shoulders, neck and lower back, stress, metabolic disturbances, circulatory disturbances, lymphatic complaints, rheumatic pains and spinal disc herniation.

## 3. TECHNICAL FEATURES

■■■■ is the developer behind the therapy “Andullation”. The ■■■■ Andullation Therapy System is used to treat medical conditions such as:<sup>2</sup>

- Persistent muscles tension and hardening (Myogelosis) of the musculature situated in the shoulders, the neck and the lower back
- Stress and insufficient relaxation

- Digestion problems
- Circulatory disturbances in the deep muscle area
- Metabolic disturbances
- Lymphatic complaints
- Spinal disc herniation
- Rheumatic pains
- Various pains
- Sciatica
- Migraine
- Insomnia
- Arthritis

### 3.1. The **Andullation Therapy System components and specifications<sup>2</sup>**

The Andullation Therapy System consists of:-

- Foldable massage system
- LED hand held control with 16 different therapeutic massage programmes in reference to Dr. Roland Stutz (P01 to P16)
- Infrared deep heat for the neck and back region
- Infrared legs
- The heart balance pillow (BBP) which ensures the optimum elevation of the legs in relation to the position of the heart
- Andullation belt which is claimed to be ideal for fat reduction
- Optional accessories such as the carrier bag and the base

The device is about 194 cm in length, 61 cm width and 8.5 cm height and weighs 9.6 kilogram. The power supply is 100-240 Volts (V) AC with 50 Hz or 60 Hz. The standard program time is between 15 and 30 minutes.





### 3.2. Mechanism of action (claimed).

The Andullation massage with infrared deep heat generates a stimulation, which expands the blood vessels and results in better blood circulation in the respective tissue. The term Andullation denotes the use of exciting vibrations that can be applied to different cellular tissues of the body, especially the locomotor system, the muscular and the nervous system and body fluids like blood or lymph. The aim of Andullation is to restore the body's natural metabolic processes, to maintain and optimise their function. It is claimed to be achieved by the application of specific sympathetic vibrations in a broad frequency range. By doing this, blockades and insufficient blood flow can be released and a reduced metabolism can be stimulated. For this to occur, it is necessary to apply vibrations with different frequencies to the body to accommodate the different tissue structures.

This form of treatment is an innovative massage method that causes vibrations (20 to 80 Hz) which result in mechanical changes in tissue at skin level. Specific sensory nerve endings, the Pacini neccano receptors, respond very rapidly to this mechanical skin deformation and can register up to 700 vibrations per second. The mechanical vibration energy detected, after conversion into electrical nerve impulses, is generally 'sent through' specific nerve vessels at a speed of 30 to 60 m/sec. At their endings these nerve vessels are in direct contact with the muscle cells of an organ where at the level of the cell membranes the electrical impulses are converted into chemical stimuli.<sup>2,4</sup>

## 4. METHODS

### 4.1. Searching

Electronic databases were searched through the Ovid interface: Medline – In-process and other Non-Indexed citations and Ovid MEDLINE (R) 1948 to present, EBM Reviews - Cochrane Central Register of Controlled Trials-3<sup>rd</sup> Quarter 2011, EBM Reviews - Cochrane database of systematic reviews - 2005 to August 2011, EBM Reviews - Health Technology Assessment - 3<sup>rd</sup> Quarter 2011. Searches were also run in PubMed, Horizon

Scanning database (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham), MHRA and FDA website for published literature. Google and Google scholar were used to search for additional web-based materials and information. There was no limit in the search. Additional articles were identified from reviewing the bibliographies of retrieved articles. Additional information was also retrieved from the document submitted by a company.

The search strategy used the terms which were either used singly or in various combinations; “Andullation therapy”, “Andullation therapy system”, “■■■■ anddullation therapy system” and safe\*.

#### 4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection.

The inclusion and exclusion criteria were:

##### Inclusion criteria

Population	Patients with medical conditions such as persistent muscles tension and hardening (Myogelosis) in the shoulder, neck and lower back, stress, digestion problems, circulatory disturbances, metabolic disturbances, lymphatic complaints, rheumatic pains, various pains, sciatica, migraine, insomnia, arthritis and spinal disc herniation
Interventions	■■■■ Andullation Therapy System
Comparators	1. No comparator 2. Usual care 3. Placebo
Outcomes	Effects on medical conditions, adverse events, cost, cost-effectiveness
Study design	Health Technology Assessment, Systematic reviews, Randomised controlled trial, Cross sectional studies
Type of publication	English full text articles and English summaries (abstracts)

##### Exclusion criteria

Study design	Studies conducted in animals and narrative reviews
Type of publication	Non-English full text article or non-English summaries (abstracts)

Relevant full text articles were critically appraised using Critical Appraisal Skills Programme (CASP) and evidence graded according to US/Canadian Preventive Services Task Force (Appendix 1).

## 5. RESULTS AND DISCUSSION

There was no retrievable evidence on the safety, efficacy / effectiveness and cost-effectiveness of ■■■■ Andullation Therapy System from the scientific databases.



However, there were few English language summaries of studies on Andullation Therapy System which were retrieved via Google and from the document submitted by a company. The full text articles of the studies were in German language.

## **5.1. SAFETY**

There was no clinical trial reporting on the adverse events related to the use of the Andullation Therapy System retrieved. Based on the document submitted by a company, the Andullation Therapy System has CE mark and is endorsed by TUV Rheinland Group Product Safety and the German Olympic Sports Federation.<sup>2</sup> There was no retrievable evidence on United States Food and Drug Administration (U.S. FDA) approval for the Andullation Therapy System. However, there was a 510(k) premarket notification for Massage Mattress VM9100RM.<sup>2</sup> The Andullation Therapy System is contraindicated in patients with thromboses.

## **5.2. EFFICACY / EFFECTIVENESS**

Since there were no English full text articles retrieved, six English abstracts of studies related to the use of Andullation Therapy System for medical conditions were included in the review.

The influence of Andullation Therapy System on non-specific acute lower back pain was studied by Stutz R. He conducted a randomised controlled trial on 40 top sportsmen and women with non-specific acute lower back pain. They were divided randomly into two equal groups. Each subgroup of 20 patients was treated with one specific kind of massage. The first group underwent an andullation therapy for 15 minutes in accordance with an established standard programme. The second group (placebo group) was also massaged for 15 minutes with a normal massage treatment. Four factors were examined before and after the massage; subjective feeling of pain, mobility of the spinal column, presence of cramps in the dorsal muscles and lymph drainage. He found that 92.0% of patients treated with the andullation therapy system had reduction of subjective feeling of pain, 88.0% had increased in mobility of the spinal column, 96.0% had reduction of dorsal muscle cramps and 90.0% had stimulation lymphatic system versus 8.0%, 12.0%, 4.0% and 10.0% respectively in the placebo group.<sup>5</sup>

Oberbillig *et al.* conducted a multicentres cross sectional study to investigate the effect of Andullation Therapy System on 99 patients with chronic back complaints (longer than 6 months) which were due to degenerative disorders of the spinal column. The study included 76 women and 23 men with an average age of 57 years (range, 33-85 years). The found that after 10 treatments with andullation therapy (15 minutes per treatment) a considerable improvement was observed when carrying out less heavy activities such as such as moving a table. After the treatments, 46.6% of the patients experienced a reduction in muscular cramps in the lower back region. They also reported an improvement in subjective pain, 30.0% reduction in intake of painkillers and 57.4% of patients reported an improvement of sleep patterns.<sup>6</sup>

The effect of andullation therapy on the known physiological stress parameters was investigated by Nazarov *et al.* A total of 415 spa guests who were found to have increased stress parameters were included in the study. The average age of the spa guests of both sexes was 62.4 years. All the individuals were treated for 15 minutes with the P05 programme on the Andullation Therapy System. The programme was adjusted to produce a deep level relaxation. The investigation concentrated on the effect of andullation therapy on stress parameters in the echocardiogram. The authors reported a 44.0% stress reduction after 15 minutes treatment with andullation therapy.<sup>7</sup>

Gerlach U conducted a study to investigate the influence of Andullation Therapy System on electroencephalogram (EEG) and the ability to relax. During a period between May and August 2004, andullation therapy was tested on 50 subjects. The investigation recorded for each person the brain activity before, during and after the andullation therapy, both using the 1-channel and 2-channel EEG. The measurement results in six important brain frequency fields were documented in a frequency band trace diagram. Each person was also given a questionnaire in order to evaluate their subjective well-being, their feeling of relaxation and their subjective feelings about stress. He found that in each subject, the 15 minutes andullation therapy on the Andullation Therapy System gave rise to a significant rest phase in the EEG. After the treatment each person also experienced a very positive effect in their general feeling of well-being. The capability of relaxing faster and better was also improved when the andullation treatment was additionally employed regularly thereafter.<sup>8</sup>

Klein F and Felder H conducted a study to evaluate the effect of andullation therapy on patients with oedematous lower limbs. Twenty patients were divided at random into two groups. None of the patients had venous oedema, varicose veins or suffering from heart condition. The study group consisted of ten patients who were treated for 15 minutes with andullation therapy via the special medically established combination programme P03, 'lymph system stimulation'. The ten patients from the control group were treated for the same period with a placebo system without vibrations and without infrared radiation. The participants were checked for four variables; subjective feelings of pain using the Visual analogue scale for pain, swelling of the lower limb using the Principle of Kuhnke's "4cm disk model", presence of oedema (body composition) using Body composition Analyser Inbody 3.0 Biospace and mobility of the knee joint using "Cybex" measurement of the mobility inflexion / extension. They reported greater reduction of subjective feeling of pain, greater reduction in swelling of the lower limb, greater reduction in lymphoedema and greater increased in mobility of the knee joint after andullation therapy compared to placebo.<sup>9</sup>

Another similar study was conducted by Stutz R in 40 outpatients suffering from lymphatic congestions treated in a dedicated rehabilitation centre. The patients were randomly distributed into two groups; 20 in the intervention and 20 in the control group. The intervention group was subjected to a 20 minutes application of the lymphatic drainage programme, while the placebo group spent the same amount of time on a massage bed that superficially appeared identical to the real device. They were not informed about the supposed effect of the treatment and the supervisor of the treatment

was also not informed about the immediate effect of the placebo-mat. The circumference of the leg, the subjective sensation of pain, the flexibility of the knee-joint and the composition of the body were measured and combined. Subsequently, the patients were subjected to the appropriate treatment in accordance with the randomisation plan and afterwards the parameters were re-measured. He found that applying the lymphatic drainage programme of the ■■■ massage bed to patients suffering from lymphatic congestions of the lower extremities leads to a significant reduction of the fluid volume in the afflicted leg, improves flexibility of the knee joint, and influence the sensation of pain in the positive manner.<sup>10</sup>

### **5.3 COST / COST-EFFECTIVENESS**

There was no retrievable evidence on the cost-effectiveness of Andullation Therapy System. The price of the ■■■ Andullation Therapy System is around ■■■■■■■■■■ (via personal communication with ■■■■■■■■■■ representative).

### **5.4 LIMITATIONS**

This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English articles were included in this report. There were no English full text articles available. The full text articles are in German language. Hence, the review included English summaries (abstracts) of the clinical trials only. Therefore, the methodological quality of the studies cannot be assessed. The English abstracts that were available consist of cross sectional studies and randomised controlled trials with very small sample size only.

### **6. CONCLUSION**

There was limited evidence to suggest the efficacy / effectiveness of Andullation Therapy System for treatment of non specific acute lower back pain, chronic back pain, reduction of stress and lymphoedema of the lower limbs. However, there was no retrievable clinical trial on the safety and the cost-effectiveness of ■■■ Andullation Therapy System.

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## **8. APPENDIX**

### **8.1 Appendix 1**

#### **DESIGNATION OF LEVELS OF EVIDENCE**

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-I Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

**SOURCE:** *US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris S2001)*