

# Intended Use

## 1. Intended Use

### ***Applies to All Devices***

This low-voltage device provides a therapeutic massage; this type of therapy is called cycloid vibration therapy (CVT). This device reduces interstitial oedema fluid whether the cause is lymphatic or vascular, may increase local area blood flow and may assist in the reduction of musculoskeletal pain. The device may assist in the treatment of wounds, cellulitis and pressure ulcers where an improvement in local circulation is a factor and may also increase joint mobilisation.

## 2. Contraindications

### ***Lymphoedema Treatment***

The following general contraindications may cause complications to lymphoedema treatment for the following individuals:

- Those who suffer from acute inflammatory episodes such as cellulitis, erysipelas, influenza or active tuberculosis.
- Those with acute thrombosis.
- Those with cardiac insufficiency, superior vena cava obstruction, chronic inflammation, asthma, thyroid dysfunction and history of thrombosis.
- Those with advanced cancer.
- Those whose lymph nodes have not been cleared prior to device use.
- Those individuals with complex aetiology including cutaneous tumour infiltration, occlusion of venous blood flow resulting from deep abdominal or pelvis tumours, ascites and untreated hypoalbuminaemia may receive may receive poor response to these techniques.

### ***Chair and Thermo Cyclopad only***

The heater function should be used with caution in patients with diabetes mellitus, multiple sclerosis, poor circulation, spinal-cord injuries, and rheumatoid arthritis because it may cause disease progression, burns, skin ulceration, and increased inflammation.

The heater application time should be restricted as infections of the skin, urinary tract, and pulmonary system have been associated with the use of heating modalities at a high intensity level.

### **3. Cautions**

#### ***General***

No user-serviceable parts inside. All servicing and repairs should be performed by Niagara or an approved service agent.

The device is supplied non-sterile.

Do not submerge the device in water.

Do not use the supplied AC adaptor if it is damaged.

Take care to prevent string, hair, pins etc from entering any of the device's ventilation slots during use.

All electronic equipment (including batteries) contains printed circuit boards which when disposed of are considered to be hazardous waste. Contact Niagara or an approved agent for assistance in disposing of this equipment.

The following environmental requirements shall be adhered to during normal operation: – 4 to 30 Deg C with 30 – 95% relative humidity non-condensing.

Ensure that the appropriate power supply is connected to the device before connecting to and switching the mains power supply on. Switch the mains supply off before disconnecting the appropriate power supply from the device.

If the device appears to not operate as expected, please contact Niagara.

#### ***Bed and Chair Only***

The load capacity of the Bed is 250kg.

The load capacity of the Chair is 120kg.

The Chair and Bed have a battery back-up system, which enables you to restore the Bed and/or Chair to the preferred position in the occurrence of a mains power outage.

When in use, the Wand Timer LED back light will be illuminated to indicate there is power to the chair. The battery icon on the Wand LED will pulse from left to right to indicate the battery needs charging.

When not in use, keep Chair and/or Bed in closed position.

Prior to re-locating the Chair and/or Bed, release the castors.

Prior to installation ensure the chair is set to zero position.

The chair and bed must be positioned to allow easy access to the power point into which it is plugged.

The method used to isolate from the mains is by disconnecting from the mains power outlet.

Prior to transporting the bed/chair, the item must be shut down in a predetermined sequence (different from the Owner's Manual) to ensure that it cannot inadvertently operate whilst in transit.

#### ***Bed and Thermo Cyclopad Only***

Replace the battery in the remote control should the low-battery indicator illuminate.

#### ***Hand Unit only***

Use only the supplied TR30RAM120-23E11 AC Adapter with the Hand Unit.

Do not bend or tightly wrap cables as this may cause permanent damage.

### ***Thermo Cyclopad only***

Use only the supplied TR60M12-23E13 AC Adapter with the Thermo Cyclopad.

Never use the Thermo Cyclopad without adequate ventilation, for example do not use under a blanket.

Prior to storing, allow the Thermo Cyclopad to cool.

Do not bend or tightly wrap cables as this may cause permanent damage.

## **4. Warnings**

### ***General***

These operating instructions should be carefully read prior to use.

Ensure that there are no objects under the bed and/or chair before lowering. Keep hands and feet away from all moving mechanisms.

Children using the device should be supervised by an adult.

Use only as directed and if symptoms persist, see your doctor.

The device's efficacy is reliant on regular and proper use.

It is recommended the device is used for approximately 3 x 20 minute sessions per day.

Minor and infrequent side effects may occur through the use of the device; these include nausea, light headedness/dizziness, headaches, increased pain, joint soreness/discomfort/aching, continued tingling or vibration feeling, skin itching, teeth chattering and/or an agitated feeling.

It is recommended to drink a glass of water after each treatment.

User shall not modify the device.

### ***Hand Unit and Thermo Cyclopad only***

If you have a **Pacemaker** and / or **Defibrillator** maintain a 15cm (6 inch) distance between the Niagara Therapy motor and your pacemaker / defibrillator. Do not place the Niagara Therapy motor directly over your pacemaker / defibrillator (e.g. chest area, or directly behind your shoulder blades).

When using the Thermo Cyclopad behind your back, the motor must be positioned on your **lower** back only.

### ***Cancer***

There are studies that state that improving circulation in ways such as with gentle massage techniques like lymphatic massage and exercising are not thought to increase the risk of the spreading of cancer cells as this spread is thought to be due to the individual properties of the cancer cells themselves and not to the improved circulation. It would be prudent however for each cancer patient to discuss the effect of receiving gentle massage therapies and the improvement in circulation gained from the Niagara equipment with their individual medical practitioners.

### ***Chair and Thermo Cyclopad only***

Due to the heater function, the Thermo Cyclopad and/or Chair may have a hot surface; under normal use a maximum of 45 degrees Celsius may be reached. Individuals sensitive to heat must exercise caution when using the Thermo Cyclopad and/or Chair.

Do not use the heat device on an unsupervised helpless person or infant.

## **5. Cleaning Instructions**

The device should be cleaned regularly.

Use a vacuum cleaner to remove any build up of foreign matter from the device (including the ventilation slots).

Niagara recommends cleaning small marks on upholstered surfaces with warm water. For larger marks on upholstered surfaces, the device can be professionally steam cleaned.

Niagara recommends cleaning hard surfaces with a damp soft cloth with warm non abrasive and a water solution.

Ensure no liquid or moisture enters the device ventilation slots.

Periodically inspect the power/wand leads for excessive wear or damage. Contact Niagara or an approved service agent should any components of the device require repair or replacement.

## **6. Technical Information**

### ***Electrical Safety***

The devices comply with the electrical safety requirements as defined by IEC 60601-1. Please contact Niagara for further information.

### ***General***

The devices comply with the applicable electromagnetic compatibility requirements (EMC) as defined by IEC 60601-1-2. The electromagnetic compatibility tables for Niagara devices can be found at [www.niagara.com.au/emc.php](http://www.niagara.com.au/emc.php)