

# LTU-904 Portable Laser Therapy Unit

## Low Level Laser Therapy

Low Level Laser Therapy or LLLT is the treatment of various conditions using laser to effect a photochemical reaction at a cellular level. The laser light penetrates into tissue where it is absorbed by cells and converted into energy that influences the course of metabolic process. The LTU-904 does not heat tissue.

The LTU-904 Laser Therapy Unit is a hand-held battery powered treatment device, is non-thermal and delivers a controlled series of 200ns bursts of pulses of 904nm laser beam, which is in the near infrared spectrum that is invisible to the human eye.

The LTU-904 is an infra-red laser operating at a wavelength of 904 nanometers. This invisible wavelength penetrates up to 2 cms (3/4 inch) into tissue.

The LTU-904 is classified as a Class I Laser according to USA FDA 21 CFR 1040.10, 1040.11 regulations.

The Packaged LTU-904 unit contains:-

- Carry Case
- LTU-904 unit
- Battery charger and power lead
- Infrared detector card

## Clinically Tested

Flinders Medical Center (Adelaide, South Australia) has completed a clinical trial using the LTU-904 to treat post mastectomy lymphedema. This trial is believed to be the first scientifically controlled (double blind, randomized, placebo controlled, crossover) study of a physical lymphedema treatment.



## Lymphedema Results

1. Reduced arm volume (by 200 mL or more), maintained at 3 months after treatment, for 20-31% of patients (only 4% of placebo patients had the same arm volume reduction)
2. Reduced extra-cellular fluid in the affected arm
3. Halting of tissue hardening, in comparison with placebo

The LTU-904 can be used in conjunction with manual lymph drainage ultra-sonic therapy, physiotherapy, chiropractic therapy and many other therapies. Full details of treatment methods are provided in the comprehensive owner's manual, which is included with the unit.

The safety and effectiveness of LTU-904 treatment of lymphedema following mastectomy in pregnant woman or children under 18 years has not been established.

## Treatment Procedure

Treatment using the LTU-904 is usually in contact with the skin, directly on the lymph nodes area.

Time and frequency of the treatment for lymphedema is two x 3 week treatment blocks. (A total of 6 weeks treatment). Clinical studies are available from Riancorp.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

## Ease of Use

1. The LTU-904 is a Class I Laser (according to the USA FDA 21CFR 1040.10 and 1040.11 regulations) and therefore considered not hazardous to the eye by most regulatory authorities.
2. Treatment is non invasive.
3. Protective glasses are not required for patient or therapist.
4. The outstanding feature of the LTU-904 is its strength and portability. The unit is designed to be used as easily in the field as in the clinic.
5. The small portable package is hand-held with rechargeable batteries that last up to 5 hours of continuous use between charges.
6. The digital timer monitors treatment time.

## The Unit

The LTU-904 has a self-contained power supply of rechargeable nickel metal hydride batteries. Each unit comes with a charger, instruction manual, infrared detector card and carry case. The whole package weighs less than 4 pounds.

The LTU-904 features an in-built digital timer, an audible warning sound when the unit is operating and two power settings.

## Specifications

Laser Type:	Gallium Arsenide Laser Diode (Ga-As)
Laser Wavelength:	904 nanometers
Peak Power:	5 Watts
Maximum Average Power:	5 milliwatts
Laser Class:	Class I laser to USA FDA 21CFR 1040.10 and 1040.11 regulations

## Scientific Data

Please contact RianCorp for clinical trial and research information

### Indication for Use

The LTU-904 is indicated for use as a tool as part of a therapy regime for the treatment of post mastectomy lymphedema.

### Contraindications

None known

### Warnings

Discontinue laser treatment immediately if the patient:-

- Develops any infections in their affected limb
- Develops metastatic cancer. Seek guidance from patient's medical specialist.

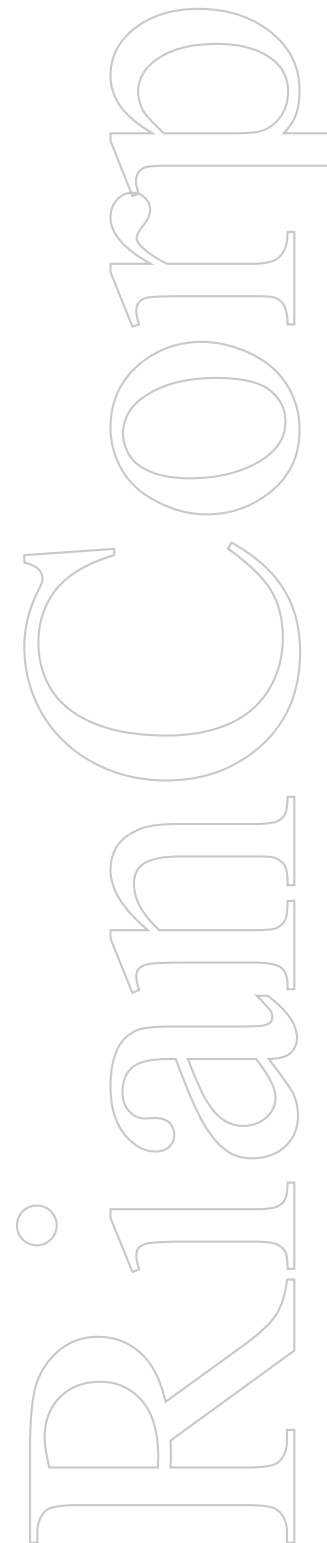
Reduce treatment and seek specialist medical guidance if the patient reports:-

- Dizziness or nausea. (No patients reported dizziness or nausea during the clinical study of the LTU-904.)
- Increased discomfort (pain or heaviness of the limb) (No patients reported increased discomfort during the clinical study of the LTU-904.)

### Precautions

As with any clinical modality for treatment of lymphedema, treatment only should commence after consultation with the patient's oncologist or appropriate medical specialist.

The clinical trial used to support marketing did not evaluate the safety or effectiveness of the device beyond two treatment blocks (i.e., two cycles of treatment administered every 2 days (three times a week) for three weeks. Increasing the amount of treatment time or frequency of treatment will not necessarily improve the results.



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