

Complaint to TGA: Polarbare Club Whole Body Cryotherapy

Acknowledgement:

This complaint was prepared by a 2018 Monash University Summer Vacation Scholarship student, then checked, edited and submitted by Assoc Prof Ken Harvey.

Summary:

The JUKA Cryosauna medical device is promoted by Polarbare Club Cryotherapy Pty Ltd (ABN 46 610 671 559) but is NOT included on the Australian Register of Therapeutic Goods (ARTG).

We allege this is a 'critical' priority complaint due to a breach of s.42DL(12) of the Therapeutic Goods Act 1989 and also many breaches of the Therapeutic Goods Advertising Code 2015. The latter include s.4(2)(i), claimed 100% safe, and s.5(2), claimed to improve acne, psoriasis, eczema and autoimmune diseases.

The U.S. FDA has warned consumers about these devices, so should the TGA.

We also note that searching the ARTG for medical devices is problematic (Appendix I). This needs to be fixed.

Cryotherapy refers to the use of extreme cold in surgery or other treatments. Whole-body cryotherapy involves exposing the whole-body (the head may or may not be exposed depending on the chamber used) to dry air of typically -110 to -160 degrees Celsius for a duration of 2-3 minutes.

A medical device is defined in s 41BD(1)(a)(iii) of the Therapeutic Goods Act 1989 as¹:

Any instrument, apparatus, appliance, material or other article, intended to be used for human beings, for the purpose of one or more of the following:

- i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
- ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- iii. investigation, replacement or modification of the anatomy or of a physiological process;

We allege that the JUKA Cryosauna fits the above definition due to the claims made and the changes that consumers believe will happen to their bodies after one or more sessions of whole-body cryotherapy.

With the current concern surrounding medical devices,² it is important to ensure that the medical devices and treatments marketed and advertised to consumers are included on the ARTG and providers make appropriate claims with good quality scientific evidence in support of them.

Polarbare Club Cryotherapy Pty Ltd extrapolate from limited scientific evidence, including studies with vastly different devices and protocols, to make many unsubstantiated claims.

We allege breaches of the Therapeutic Goods Advertising Code 2015; s.4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(i) and 7(3).

Complaint detail:

Product name: JUKA Cryosauna made in Poland.³ GMDN 45140 Cryotherapy set.

Advertiser: Polarbare Club Cryotherapy ABN 46 610 671 559

Australian distributor: Griffiths Cryotherapy Pty Ltd, ABN 85 626 039 049, P: 08 9468 7219.⁴

Advertisement type: Internet

¹ <https://www.tga.gov.au/what-medical-device>

² <http://www.medreach.com.au/?p=2985>

³ <http://kriogenika.juka.com.pl/en/o-nas/>

⁴ <https://www.griffithscryotherapy.com/cryosauna-machine>

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Where did it appear:

- <http://www.polarbareclubcryo.com.au/benefits/>
- <http://www.polarbareclubcryo.com.au/wholebodycryotherapy/>

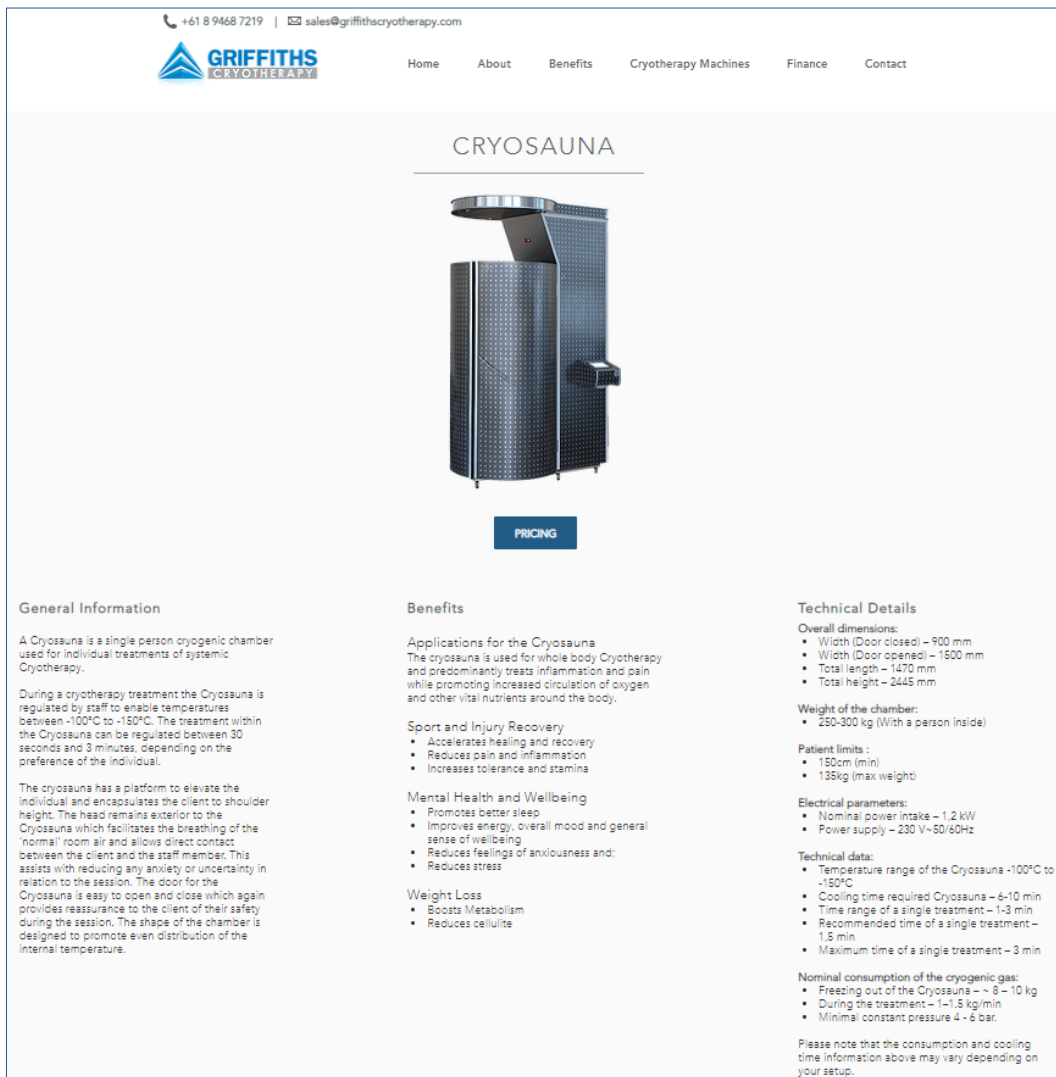
Date seen: December 3, 2018

Claims:

1. Weight loss (burn up to 800 calories per session).
2. Reduce muscle soreness, relieve pain naturally and instantly, speed up injury recovery, 3 minutes in the Cryo chamber, 48 hours shaved off recovery time.
3. Slows down the ageing process.
4. Improves skin disorders such as acne, psoriasis & eczema, can help with autoimmune diseases.
5. Cryotherapy is 100% safe for anyone who's NOT pregnant or suffering from a heart condition.

Advertisement type: Internet

Screen shots:



The screenshot shows the Griffiths Cryotherapy website. At the top, there is a navigation menu with links for Home, About, Benefits, Cryotherapy Machines, Finance, and Contact. The main heading is "CRYOSAUNA" with a large image of the machine. Below the image is a "PRICING" button. The page is divided into three columns of text: General Information, Benefits, and Technical Details.

General Information

A Cryosauna is a single person cryogenic chamber used for individual treatments of systemic Cryotherapy.

During a cryotherapy treatment the Cryosauna is regulated by staff to enable temperatures between -100°C to -150°C. The treatment within the Cryosauna can be regulated between 30 seconds and 3 minutes, depending on the preference of the individual.

The cryosauna has a platform to elevate the individual and encapsulates the client to shoulder height. The head remains exterior to the Cryosauna which facilitates the breathing of the 'normal' room air and allows direct contact between the client and the staff member. This assists with reducing any anxiety or uncertainty in relation to the session. The door for the Cryosauna is easy to open and close which again provides reassurance to the client of their safety during the session. The shape of the chamber is designed to promote even distribution of the internal temperature.

Benefits

Applications for the Cryosauna
The cryosauna is used for whole body Cryotherapy and predominantly treats inflammation and pain while promoting increased circulation of oxygen and other vital nutrients around the body.

Sport and Injury Recovery

- Accelerates healing and recovery
- Reduces pain and inflammation
- Increases tolerance and stamina

Mental Health and Wellbeing

- Promotes better sleep
- Improves energy, overall mood and general sense of wellbeing
- Reduces feelings of anxiousness and:
- Reduces stress

Weight Loss

- Boosts Metabolism
- Reduces cellulite

Technical Details

Overall dimensions:

- Width (Door closed) – 900 mm
- Width (Door opened) – 1500 mm
- Total length – 1470 mm
- Total height – 2445 mm

Weight of the chamber:

- 250-300 kg (With a person inside)

Patient limits :

- 180cm (min)
- 135kg (max weight)

Electrical parameters:

- Nominal power intake – 1.2 kW
- Power supply – 230 V-50/60Hz

Technical data:

- Temperature range of the Cryosauna -100°C to -150°C
- Cooling time required Cryosauna – 6-10 min
- Time range of a single treatment – 1-3 min
- Recommended time of a single treatment – 1.5 min
- Maximum time of a single treatment – 3 min

Nominal consumption of the cryogenic gas:

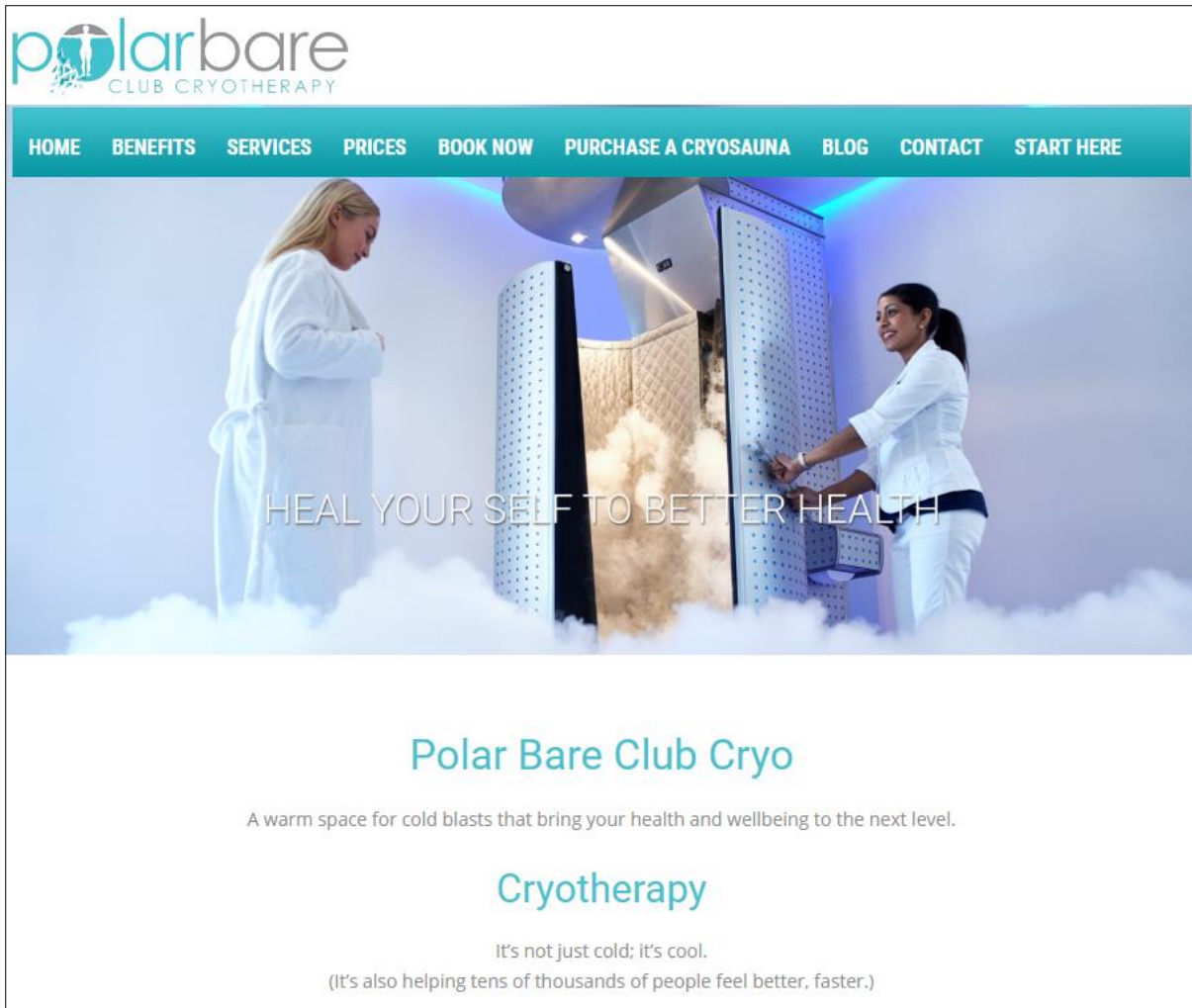
- Freezing out of the Cryosauna – ~ 8 – 10 kg
- During the treatment – 1-1.5 kg/min
- Minimal constant pressure 4 - 6 bar.

Please note that the consumption and cooling time information above may vary depending on your setup.

The Australian distributor of JUKA Cryosauna

<https://www.griffithscryotherapy.com/cryosauna-machine>

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polarbare
CLUB CRYOTHERAPY

HOME BENEFITS SERVICES PRICES BOOK NOW PURCHASE A CRYOSAUNA BLOG CONTACT START HERE

HEAL YOUR SELF TO BETTER HEALTH

Polar Bare Club Cryo

A warm space for cold blasts that bring your health and wellbeing to the next level.

Cryotherapy

It's not just cold; it's cool.
(It's also helping tens of thousands of people feel better, faster.)

<http://www.polarbareclubcryo.com.au/>

After years of research of the latest technology and recovery we couldn't look past the Juka Cryosauna. The Juka Cryosauna is a single person chamber used for individual sessions of WBC. During a session clients wear minimal protective clothing. The temperature is regulated by the automated system, but can also be adjusted within a range of -110°C to -150°C.

The unit is equipped with an electric lift used to adjust a client's height in the chamber so that the body is submerged in the hypercooled air up to neck while the head remains above. This enables the client to be in continuous communication with the technician, which improves the client's overall comfort.

For added safety, the Juka Cryosauna comes standard with a non-locking pivoting door that can be opened at any time. The unit features a heated ventilating system to minimize moisture residues and to vent out used nitrogen gasiform air. The geometric design of the inner cabin optimizes convection of cryotherapy temperatures for improved session results.

<http://www.polarbareclubcryo.com.au/about/purchase-a-cryosauna/>

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BENEFITS OF CRYOTHERAPY



WEIGHT LOSS & FITNESS

If you're someone who lives and breathes the active lifestyle, look no further as Cryotherapy can help you:

- ✓ Burn up to 800 calories per session
- ✓ Enhance your performance
- ✓ Release endorphins
- ✓ Increase your recovery times
- ✓ Increase your energy
- ✓ Reduce muscle soreness
- ✓ Reduce fatigue
- ✓ Reduce inflammation
- ✓ Increase metabolism
- ✓ Boost blood circulation
- ✓ Speed up injury recovery



RECOVERY & HEALTH

If you've tried everything to get rid of those aches and pains that come with age and stress, Cryotherapy to:

- ✓ Relieve pain naturally and instantly
- ✓ Decreases inflammation
- ✓ Relieves stress and anxiety
- ✓ Boosts production of "feel good" chemicals
- ✓ Improves sleep quality
- ✓ Strengthens immune system



ANTI AGING & BEAUTY

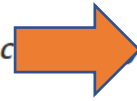
Cold therapy has been used for decades to slow down the aging process, achieve tighter and smoother skin, plus:

- ✓ Stimulates Collagen Production
- ✓ Eliminates toxins found in deeper layers of skin
- ✓ Reduces the appearance of Cellulite
- ✓ Balances skin tone
- ✓ Improves skin disorders such as acne, psoriasis & eczema
- ✓ Healthier, fuller, luscious hair

<http://www.polarbareclubcryo.com.au/benefits/>


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Can You Spare 3 Minutes?

 **: Burn up to 800 calories per session, have unstoppable energy, kiss stress and anxiety goodbye and achieve pain relief with Cryotherapy from Polar Bare Club.**

BOOK NOW

Thinking of trying Cryotherapy? Dare to bare and freeze yourself to optimal health.

 Cryotherapy, is a state of the art therapy using exposure to low temperatures to stimulate your body's metabolism, boost your immune system, relieve stress and anxiety and slow down the aging process or simply recover from an intense workout.

Imagine stepping into our personalized facility and top of the line cryosauna for up to 3 minutes whereby a cool mist begins to engulf your body in a refreshing and safe manner.

As the temperature drops, your body starts responding to the cold by sending immune boosting and energy producing nutrients that leave you feeling like you've never felt before — renewed, refresh and recovered.

 3 minutes in the Cryo Chamber	 48 hours shaved off recovery time*	800 calories burned
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*Let's not even talk about years of your life back...


<http://www.polarbareclubcryo.com.au/wholebodycryotherapy/>

What can Cryo help with?

Cryotherapy can help with a variety of ailments, such as...

- Muscle tension & pain
- Headaches
- Strains & sprains
- Sports injury & rehabilitation
- Eczema
- Cellulite
- Skin disorders
- Slow metabolism
- Excess weight
- Fine lines & wrinkles
- Bloating
- Fatigue
- Swelling
- Stress & anxiety
- Insomnia
- Mental foginess
- Autoimmune diseases
- Surgical recovery
- Aging

Is it safe?

 Yup! Cryotherapy is 100% safe for anyone who's NOT pregnant or suffering from a heart condition. Everyone else... what the freeze are you waiting for?

<http://www.polarbareclubcryo.com.au/starthere/>

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Claims disputed and rationale:

1. Weight loss (burn up to 800 calories per session)

There is evidence that localized application of cold (cryolipolysis) can produce spot reduction of adipose tissue as an alternative to liposuction. Although this procedure is popular, the body of scientific evidence is limited.⁵ However, localised cryolipolysis is very different to whole-body cryotherapy.

A study by Filliard et al. (2016) used Dual Energy X-ray Absorptiometry (I-DXA General Electric) to measure fat and lean mass in 14 male subjects before and after 10 WBC sessions at -110°C twice a day for 5 days. They found no significant statistical differences between the measures for weight, fat mass or lean mass, before and after 10 WBC treatments.⁶

In addition, we could find no evidence to support the claim that 3 minutes in a JUKA Cryosauna burns 800 calories. Even if it did, that would result in a loss of only around 0.1 kg.

We allege that this claim breaches the Therapeutic Goods Advertising Code 2015 s4(1)(b), 4(2)(a) and 4(2)(c). We also allege an additional breach of s 7(3) of the Code because this advertisement does not have an appropriate balance between the claims and references to a healthy energy-controlled diet and physical activity.

2. Reduce muscle soreness, relieve pain naturally and instantly, speed up injury recovery, 3 minutes in the Cryo chamber, 48 hours shaved off recovery time.

A 2015 Cochrane review concluded there was insufficient evidence to determine whether whole-body cryotherapy (WBC) reduced self-reported muscle soreness, or improved subjective recovery, after exercise compared with passive rest or no WBC in physically active young adult males.⁷ Four studies found were all judged to be of low-quality. There was no evidence on the use of this intervention in females or elite athletes. They noted that lack of evidence on adverse events was important given that the exposure to extreme temperature presents a potential hazard. Further high-quality, well-reported research in this area is required and must provide detailed reporting of adverse events.

The following studies assess the effects of whole-body cryotherapy on pain as a result of medical conditions (rheumatoid arthritis, frozen shoulder and chronic low back pain). While these are not relevant to a product marketing to healthy individuals, they do highlight the lack of quality evidence on this topic.

Gizińska et al. (2015) reported a study of postmenopausal women who had been diagnosed with rheumatoid arthritis in which 25 patients receiving whole-body cryotherapy while 19 received traditional rehabilitation.⁸ It was not clear how the two groups were chosen. Regardless of the treatment used, there were comparable significant improvements in the severity of pain, duration of morning stiffness and other parameters.

May et al. (2013) conducted a single-blinded randomized trial involved 30 patients with adhesive capsulitis of the shoulder ('frozen shoulder') randomly assigned to physical therapy modalities and passive joint mobilization with or without active range of motion.⁹ After treatment, all participants reported a clinically meaningful and statistically significant improvement in measured active range of motion of the shoulder, pain and function but whole-body cryotherapy

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4444424/>

⁶ https://bjsm.bmj.com/content/50/Suppl_1/A38

⁷ https://www.cochrane.org/CD010789/MUSKINJ_whole-body-cryotherapy-preventing-and-treating-muscle-soreness-after-exercise

⁸ <https://www.ncbi.nlm.nih.gov/pubmed/26576422>

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/22850489>

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conferred added benefit to joint mobilization. This study had several limitations including the lack of a control group for comparison of results, a small study group, and no data on long-term outcomes of the intervention.

Nugraha et al. (2015) randomised 64 patients with chronic low back pain into treatment with whole-body cryotherapy (-67 °C) or a sham cryotherapy chamber (-5 °C).¹⁰ Results showed similar effectiveness in pain reduction in both groups, indicating that the cryotherapy at lower temperature was not superior to the control group treated with the sham cryotherapy chamber.

We allege that these claims breach the Therapeutic Goods Advertising Code 2015 s.4(1)(b), 4(2)(a) and 4(2)(c).

3. Slows down the ageing process

We found no evidence to substantiate these claims.

We allege that this claim breaches the Therapeutic Goods Advertising Code 2015 s4(1)(b), 4(2)(a) and 4(2)(c).

4. Improves skin disorders such as acne, psoriasis & eczema, can help with autoimmune diseases.

We found no evidence to substantiate these claims. In addition, these claims refer to serious diseases. **The U.S. FDA has warned consumers about misleading claims made for these devices, so should the TGA.**¹¹

We allege breaches of the Therapeutic Goods Advertising Code 2015 s4(1)(b), 4(2)(a), 4(2)(c) and 5(2).

5. Cryotherapy is 100% safe for anyone who's NOT pregnant or suffering from a heart condition.

The 2015 Cochrane review noted that lack of evidence on adverse events given that the exposure to extreme temperature presents a potential hazard. Further high-quality, well-reported research in this area is required and must provide detailed reporting of adverse events.

We allege that this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(2)(i).

Previous complaints:

Searching 'cryotherapy' in the Complaints Register yielded 0 results, but there have been 3 justified complaints regarding cryolipolysis devices.¹²

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13 December 2018

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/25296740/>

¹¹ <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm508739.htm>

¹² http://www.tgacrp.com.au/complaint-register/?_search=cryo

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APPENDIX 1 Attempts to ascertain if this device was included on the ARTG.

We searched the ARTG for 'cryotherapy' with the following results:¹³

ARTG, PI and CMI results

[Query: Cryotherapy -- Documents: 8 fully matching plus 0 partially matching]

1. [The Hassall Australia Trust - Cryo-Fit - Cryotherapy set](#)
 - **ARTG ID:** 306763
 - **Product name:** Cryo-Fit - Cryotherapy set
 - **Sponsor:** The Hassall Australia Trust
 - **Manufacturer:** GTG Wellness Co Ltd
2. [The Hassall Australia Trust - Cryo-V - Cryotherapy set](#)
 - **ARTG ID:** 306542
 - **Product name:** Cryo-V - Cryotherapy set
 - **Sponsor:** The Hassall Australia Trust
 - **Manufacturer:** GTG Wellness Co Ltd
3. [Minus110 Pty Ltd - Cryotherapy set](#)
 - **ARTG ID:** 272678
 - **Product name:** Cryotherapy set
 - **Sponsor:** Minus110 Pty Ltd
 - **Manufacturer:** Przedsiębiorstwo Produkcyjno -Handlowe Juka
4. [Big Green Surgical Company Pty Ltd - Cryotherapy set](#)
 - **ARTG ID:** 224583
 - **Product name:** Cryotherapy set
 - **Sponsor:** Big Green Surgical Company Pty Ltd
 - **Manufacturer:** Galil Medical Ltd
5. [Big Green Surgical Company Pty Ltd - Cryotherapy set](#)
 - **ARTG ID:** 223036
 - **Product name:** Cryotherapy set
 - **Sponsor:** Big Green Surgical Company Pty Ltd
 - **Manufacturer:** Galil Medical Ltd
6. [Medical Industries Australia - MedGyn Cryotherapy System -...](#)
 - **ARTG ID:** 219261
 - **Product name:** MedGyn Cryotherapy System - Cryosurgical unit, general-purpose
 - **Sponsor:** Medical Industries Australia
 - **Manufacturer:** Medgyn Products Inc
7. [Getz Healthcare Pty Ltd - Cryotherapy set](#)
 - **ARTG ID:** 174582
 - **Product name:** Cryotherapy set
 - **Sponsor:** Getz Healthcare Pty Ltd
 - **Manufacturer:** Wallach Surgical Devices Inc
8. [Medtronic Australasia Pty Ltd - Cryotherapy set](#)
 - **ARTG ID:** 166580
 - **Product name:** Cryotherapy set
 - **Sponsor:** Medtronic Australasia Pty Ltd
 - **Manufacturer:** Medtronic CryoCath LP

None of above results showed the device name 'JUKA Cryosauna', or the advertiser, 'Polarbare Club Cryotherapy'.

¹³ <http://tga-search.clients.funnelback.com/s/search.html?query=Cryotherapy&collection=tga-artg>

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Dr Harvey contacted Trent Greentree, Assistant Director of the Device Support Team at the TGA by email who suggested the following list of search terms to identify the device.

Cardiac cryosurgical system
Analgesia unit, cryogenic
Cryolipolysis skin contouring system
Cryosurgical unit, general-purpose
Cryogenic spray, cutaneous
Cryotherapy set
Cryogenic spray, dental
Electronic general cryosurgical system
Cryosurgical unit, ophthalmic
Cryogenic temperature control unit
Cold air therapy unit
Ophthalmic cryosurgical system, electronic
Cardiac cryosurgical system catheter
Electronic ophthalmic cryosurgical system applicator, retinal
Cryogenic laboratory freezer, liquid nitrogen
Wart cryogenic kit
Cryosurgical system handpiece tip

This provided no additional help. We contacted a representative (Jessica) of Polarbare Club Cryotherapy via telephone (1300 337 222) on 30 November 2018. She confirmed that Polarbare Club Cryotherapy use the 'JUKA Cryosauna' but could not give us details about the device's ARTG ID. Although we were told the company would get back to us, we have not received a reply at time of writing.

We then contacted the Australian distributor of 'JUKA Cryosauna', Griffiths Cryotherapy Pty Ltd, ABN 85 626 039 049, P: 08 9468 7219 on 12 December 2018. They confirmed that this device was not included on the ARTG.

Searching the ARTG for medical devices is unhelpful. This has been noted before in a submission to the TGA Consultation: Therapeutic Goods Advertising Code.¹⁴ The brand name of the device advertised often does not appear on the ARTG entry, the advertiser may not mention the name of the device sponsor, the intended purpose of the device can lack important information that is crucial to the use for which the device is promoted, and the advertised use may bear no relation to the intended purpose.

These problems need to be fixed.

¹⁴ <http://www.medreach.com.au/wp-content/uploads/2017/10/Consultation-Submission-The-Therapeutic-Goods-Advertising-Code-Harvey-Ranaweera-Kay-FSM-Final.pdf>