



11 September 2018

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health, ACT

Dear John,

REVISITING THE FALSE CLAIMS FOR THERAPEUTIC BENEFITS BY ARTG LISTED BIO-RESONANCE MACHINES.

We believe the evidence below and elsewhere presents an overwhelming case for the de-listing of the [BICOM](#) and the equally fraudulent [CyberScan](#) from the ARTG and the banning of their use in Australia.

This letter includes the following:

- Part A - Scenario of a new bioresonance device listing request;
- Part B - The history of FSM and the TGA from 2013 to 2018 with the BICOM (including over 60 complaints sent to the TGA Advertising Compliance Unit);
- Part C - The informed opinions of five biofeedback and bioresonance experts who support our view that the BICOM and CyberScan devices have no place on the ARTG, &
- Part D - Example of claims by manufacturer, importer and practitioner.

We ask you to review this request with some urgency as we are talking about harmful fraud from which the TGA should protect consumers.

Regards

Professor John Dwyer AO. PhD, FRACP, FRCPI, Doc Uni (Hon) ACU.
Emeritus Professor of Medicine and President of FSM www.scienceinmedicine.org.au

PART A

We would ask you to examine the following scenario and consider what actions your department would take if all the points herein were proven to be accurate.

1. A manufacturer seeks ARTG listing for his product claiming it is an instrument that works by providing patients with 'Biofeedback' that provides therapeutic benefit. Experts in biofeedback examine the machine and state authoritatively that it is not a biofeedback machine.
2. In its advertising for this machine the manufacturer actually claims it works through Bioresonance not Biofeedback.
3. The manufacturer of the machine claims that based on quantum physics the machine can detect more than 400 anomalies that could be injurious to health. The BICOM machine, they say, can treat a huge array of human and animal diseases including allergies, inflammatory bowel disease, migraine headaches and many more serious conditions.
4. This manufacturer knows that in seeking ARTG listing he must have evidence to back up any therapeutic claims made but actually on his website under "Legal Affairs" notes:-
*"The BICOM BIORESONANCE is just like Homeopathy, Acupuncture, and other methods of complementary therapy directions in the form of regulatory medicine. Within the special therapy BICOM BIORESONANCE therapy is recognised as a proven therapy method. In conventional medicine, however, BICOM BIORESONANCE has **not been subject to scientific research** and is not yet recognized".*
5. The concepts involve are anti-scientific and totally distort established causes of disease which make a nonsense of the manufacturers claim that:-
"Each BICOM device features multiple treatment programs developed and tested in 30 years of practice for a broad range of energetic stresses acting on the body. In addition, the electromagnetic frequency spectra of more than 400 substances are stored digitally (frequency patterns of active substances). These can be used to complement treatment".

There is neither evidence nor plausibility for the concept of "electromagnetic frequency spectra" providing diagnostic information.

(Part C provides you (TGA) with expert reports demonstrating that BICOM is not a biofeedback device and is based on an antiscientific theory incompatible with our knowledge of physiology).

Consumer protection from this "scam" is being pursued in the UK as can be seen in the following statement:-

British electroacupuncture device marketer ordered to stop making extravagant claims

"The British Advertising Standards Authority has ordered BICOM UK, based in Leeds, West Yorkshire, to stop claiming that its "bio-resonance" machines are effective against allergy; food intolerance; bacterial and fungal infections; viruses; toxins; cancer; depression; smoking; weight gain; sports injuries; digestive and skin problems; neurological disorders; irritable bowel syndrome; Crohn's disease; neuro-dermatitis; ADHD; dental problems; and even Ebola".

<<https://www.ncahf.org/digest15/15-05.html>>

A BICOM Optima brochure claims that the device is premised on assumptions that organs, organ areas, and organ systems in a healthy body are imbued with and surrounded by characteristic electromagnetic frequency patterns.

- Interference with these patterns can lead to significant disruption in the body and ultimately to disease;
 - The device can “modulate” the patterns associated with specific health problems and apply "therapeutic patterns" to the patient, &
 - The device has *“over 1,000 preloaded treatment programs for a wide range of symptoms”* and *“preloaded frequency patterns from over 400 therapeutic agents.”*
6. We also provide evidence here that the claims for efficacy made by the manufacturer are repeated by the Australian importer of the device, the sales representative for the machine and numerous practitioner websites where the nonsense claims of the manufacturer are exaggerated further by practitioners making a lot of money from this fraud. A BICOM Machine costs about \$35,000 but purchasers are advised that its use could net them up to \$115,000 per year.

The clinical use of this device causes significant harm as consumers are paying a lot of money with no hope of benefit, having serious conditions treated by practitioners with no qualifications required for the diagnosis and treatment of these conditions. Too often an accurate diagnosis and effective management is delayed or withheld. It should be delisted, removed from sale in Australia while every effort is made to alert the public to the scam and practitioners using the device told to desist.

PART B

HISTORY

There is, as you know, a “History” of complaints about BICOM.

FSM has been alerting the TGA to this fraudulent promotion for the past 5 years – examples include:

2013:< <http://www.scienceinmedicine.org.au/wp-content/uploads/2018/09/TGArevsub02.pdf>>

2014:<<http://www.scienceinmedicine.org.au/wp-content/uploads/2018/09/PathologyLetrTGA02.pdf>>

2015:< <http://www.scienceinmedicine.org.au/wp-content/uploads/2018/09/PathologyTGAletr06.pdf>>

2017: < <http://www.medreach.com.au/wp-content/uploads/2017/05/Consultation-Submission-Options-for-the-future-regulation-of-%E2%80%9CLOW-risk%E2%80%9D-products-Harvey-Ranaweera-Final.pdf>>

In 2015 responding to our concerns then you noted:-

“The TGA has also been working closely with the BICOM device sponsor to make its website; www.bicomaustralia.com.au compliant with the therapeutic advertising legislation”

They have failed to do as their claims continue with no credible science available to support those claims.

The TGACRP upheld complaints about the [BICOM in 2008](#). The upheld decision of the [TGACRP did see retractions published](#) by two users. One of the claims retracted was [about](#) treating serious infections while another concerned smoking cessation. However the manufacturer and importer also made those same claims (and still do) but no action was taken to have them provide a retraction and withdrawal of the claims!

It appears that the TGA at the time was willingly to accept most of the claims made for BICOM despite numerous complainants providing evidence of the fraud.

In your letter to us of November 16, 2015 you told us:-

*“A number of the 54 BICOM practitioner websites identified by you have been reviewed by the TGA and we have noted that some of these websites are advertising claims for this medical device outside the manufacturers' intended purpose, mainly in relation to 'weight loss' and 'quit smoking'. The sponsor has written to Australian BICOM practitioners to whom they have supplied the medical device **about the claims that can be legally made in relation to this device. We worked with the sponsor on the content of their letter to their customers** and have also commenced follow up action to confirm that the known list of customers has indeed been contacted. The TGA will be following up with the other BICOM device 'practitioner' advertisers identified by you”*

PART C

During our meeting on 4 March 2016 you stated that you would not cancel the BICOM because it was a 'Biofeedback' device. FSM has now received five informed opinions relating to this device :

- **Biofeedback:**
 - Michelle G Aniftos BCN, MAPS, FCCLP, QEEGD, FANSA, BSSc; GradDipEd; PGDipEd; MEd; MPsy (Clinical); GradCertClinNeurophysiology, Fellow & Chair, Biofeedback Certification International Alliance. (letter attached) &
 - Dr Tania M. Slawecki, PhD. Energy and the Environment Laboratory (formerly Materials Research Lab), Penn State University, USA (Author of "How to Distinguish Legitimate Biofeedback/Neurofeedback Devices" (report attached);
- **Electronic devices:**
 - Dr Stephen J Roberts, BSc ARCS DIC PhD. Consultant on electronic devices;
- **Psychology:**
 - Emeritus Professor Joseph P Forgas, AM, DPhil, Dsc (Oxford), FASSA, Scientia Professor, Psychology, UNSW (letter attached), &
- **Alternative medicine:**
 - Emeritus Professor Edzard Ernst MD, PhD, FMed Sci, FSB, FRCP, FRCP(Edin) (letter attached).

Their comments include the following:

- **Ms Aniftos:** *"Having reviewed the specifications of the BICOM device, I find that its inclusion on the ARTG as a 'biofeedback device' is erroneous";*
- **Dr Slawecki:** *"the BICOM device does not fit the criteria of a legitimate biofeedback device";*
- **Dr Roberts:** *"The claims of how the BICOM and CyberScan work are preposterous. "Quantum physics" is not at work";*
- **Professor Forgas:** *"The BICOM is NOT a biofeedback device and should be cancelled"; "The description of this device makes it crystal clear that it cannot possibly have any effective diagnostic or therapeutic function, and certainly has nothing at all to do with biofeedback. "The claims made for the device amount to the worst kind of psychological manipulation, and their sole purpose is to mislead and exploit vulnerable people for financial gain. As a civilised society, we should not allow this kind of immoral exploitation to continue and the device should be banned forthwith";*
- **Professor Ernst:** *"Bioresonance is not biologically plausible, not of proven effectiveness, potentially harmful and associated with exorbitant costs. I cannot recommend it for anyone or any purpose".*

They all support the cancellation of all the ARTG-listed so called 'bioresonance' devices (in fact they are no such thing) on the basis that they are certainly *not* 'biofeedback' devices. These include the BICOM and the CyberScan.

As then, and now, there are no claims that can be made legally as the machine's listing is erroneous as it not a biofeedback instrument and, more importantly the machine has no capacity to deliver any of the benefits it claims. This remains a pervasive scam.

Again we are providing you with many websites currently claiming non-existent benefits which have already been submitted as complaints:

BICOM: <<http://www.scienceinmedicine.org.au/wp-content/uploads/2018/09/TGABiofeedbackBICOM.pdf>>

CyberScan: <<http://www.scienceinmedicine.org.au/wp-content/uploads/2018/09/TGABiofeedbackCyberScan.pdf>>

PART D

1. Manufacturers list of diseases it can treat:

<<https://bioresonance.com/>

DISORDERS
♥ Hay Fever & Allergies
♥ Parasites
♥ Cancer
♥ Smoking & Drug Addiction
♥ Weight Gain
♥ Depression
♥ Electronic Smog
♥ Auto Immune Disease
♥ Lyme
♥ Migraine
♥ Sports Injuries
♥ Pain
♥ Dental
♥ Neurological Disorders
♥ Infectious Diseases
♥ Skin Problems
♥ Digestive
♥ Asthma

2. CLAIMS BY THE AUSTRALIAN IMPORTER AND PROVIDER OF PRACTITIONER TRAINING

<https://bicomaustralia.com.au/about/>

BICOM Bioresonance Therapy in Australia

Over the past fifty years allergy-related conditions have increased. Training as a BICOM Bioresonance Therapist will give you a rewarding career successfully treating allergy sufferers. Established in Europe for over 30 years this therapy is now flourishing in Australia.

BICOM Therapy was introduced to South Australia in 1998 by Andrew and Anna Barrie. Within the first year they had a 6 month waiting list and went on to become the official agents and trainers for whole of Australia. There are now over 100 therapists in practice throughout the country.

With their recent retirement, Megan Hill is now the Australian representative for Regumed and the BICOM machine. Megan has established her own successful treatment clinic, and brings with her an extensive background in Medical Sales.

All Bicom Bioresonance devices, and their accessories, are manufactured by registered manufacturers in Germany to ISO 9001 quality standards. They comply with the European Union Directive 93/42/EEC on medical devices and are included in the Australian Register of Therapeutic Goods under the ARTG number 138918. These are medical devices for use by a trained practitioner and are not consumer products.

Official "Intended Purpose"

This electronic system provides visual and auditory signals corresponding to the patient's physiological status. It detects changes in physiological functions that are outside of normal awareness, amplifies these signals and provides this as feedback to the patient with the intention of promoting the healing process. Examples of use are pain reduction, muscle relaxation, stress reduction and reduction of allergic reactions.

3. CLAIMS FROM AN AUSTRALIAN THERAPIST AND SELLING AGENT FOR BICOM From Megan Hill's website

<https://www.chooseyourwellbeing.com.au/>

Bicom Bioresonance therapy is a holistic therapy which works to decrease the body's overall toxic load, identifying and treating the underlying causes of your illness – not just the symptoms.

If you suffer from food intolerances, allergies, heavy metal toxicity, viruses, chronic fatigue, muscle and joint pain, digestive issues and recurring infections, then this may just be the therapy for you.

This clinic uses the most up to date machine, the BICOM Optima.

Bioresonance therapy has proven to be successful with the following:

- Allergies
- Food Intolerances
- Headaches
- Hormonal Imbalances
- Chronic Fatigue
- Muscle and Joint Pain
- Fungal Infections
- Digestive Issues
- Skin Conditions
- Emotional Wellbeing

How to Distinguish Legitimate Biofeedback/Neurofeedback Devices January 2009 Report

The market of therapeutic biofeedback devices has become flooded with a number of machines purporting to be biofeedback machines when, in fact, they either operate on different principles or else provide an unconventional form of “feedback” to the individual. This document is meant to offer distinctions from a laboratory research perspective.

Traditionally, biofeedback machines make use of any of a number of sensors that can quantify specific physiological parameters in the body, such as heart rate, blood pressure, skin temperature, muscle tension, sweat gland activity..., etc. Neurofeedback is similar in that it employs electrodes attached with a conducting gel to certain areas of the scalp to monitor EEG (brainwave) patterns. These quantifiable parameters are all indicative of the unconscious state of the autonomic nervous system (for biofeedback) or of brain function (for neurofeedback). The devices typically utilize blinking lights, audible tones or computer software images that alert the individual to their state of being, bringing it into their conscious mind, and providing them with a means to gain control over these otherwise unconscious bodily or cognitive functions.

Sensors for biofeedback include: galvanic skin response (skin voltage is very sensitive to moisture levels from sweat glands), thermistors (to measure skin temperature), photoplethysmographs (or PPG's for measuring peripheral blood flow and heart rate), electromyographs (for measuring muscle tension) and others. Wikipedia and other online sources provide ample examples. Biofeedback has enjoyed great success in treating numerous conditions including those related to muscle tension (temporomandibular-joint disorder, back pain, tension headaches/migraines, tendonitis, incontinence), plus anxiety, hypertension, epilepsy, some chronic pain conditions, certain breathing disorders, some types of cardiac arrhythmias, and substance abuse. Neurofeedback can also address a number of these but is more commonly used to address learning and psychological disorders such as ADHD, obsessive-compulsive disorder, and depression, to name just a few. To emphasize: biofeedback and neurofeedback allow an individual to become aware of unconscious, unhealthy physiological patterns that they can then be guided to consciously change. Repetition of this change reprograms the subconscious mind so the etched pattern of the previous, unhealthy state is erased, hence the individual experiences a healed or improved state of function and being.

By contrast, there exist other devices on the market under the guise of biofeedback that either (a) do not make use of medically-understood physiological sensing technologies or (b) do not involve the individual in the “reprogramming” process, but, instead, impart energy/information to the individual as some form of signal. If the device purports to operate on quantum principles and/or purports to balance the energy of the individual by imparting certain frequencies of energy or information, it is not a biofeedback device as has been conventionally defined. An example is used to clarify.

To be fair and very clear from the start, this example does *not* purport to be a biofeedback technology, but it includes each of the elements that other device manufacturers claim to be biofeedback. The NES machine (Nutri-Energetics System) utilizes a proprietary technology to read information encoded in the electromagnetic field emanating from the hand of an individual. This high-tech sensor, which resembles a larger computer mouse, is *not* measuring galvanic skin response. The device is said to operate on quantum physical principles, and there is a great deal of information about the physiological and energetic health of the individual that is encoded in phase information from the electromagnetic field of the individual's index and middle fingers, which is the primary area scanned by the sensor. The NES computer software then analyzes the signal and provides information – “feedback”, if you will – on specific physiological problems as well as energetic imbalances. The physiological problems cited can be as specific as “the big toe on the right foot is swollen” or that a specific complex chemical toxin is in the body. The energetic balances are much more difficult to validate. In either case, the individual has the opportunity to “treat” their imbalances by drinking water that the NES machine can “imprint” with “information” that is beneficial and tailored specifically to that individual. Is this biofeedback? It stretches the definition considerably but generally does not fit. The NES more closely approximates the combination of an MRI machine with a homeopath.

The Ondamed is another machine that, like the NES, has some unconventional mechanism for sensing the state of an individual, and then feeds back “healing frequencies.” Here is the description directly from their website (http://www.ondamed.net/how_does_ondamed.php):

ONDAMED[®] works by using mild sound and accompanying magnetic pulses to stimulate the body at various frequencies. A medical practitioner monitors the response of the autonomic nervous system to these frequencies by noting changes in the pulse and informs the patient of findings, thus providing the information needed for biofeedback to occur. The identified stimulating sound and magnetic frequencies are then temporarily applied to identified areas while the patient relearns how to be in a healthier state. A key feature of ONDAMED is that relaxing frequencies are part of the re-education process. Many studies have shown that tension and stress reduce feelings of wellness and the addition of relaxing frequencies help re-establish the proper balance between the sympathetic nervous system and the parasympathetic nervous system.

In this description, the Ondamed sounds more like an echocardiogram than a biofeedback machine. The practitioner is observing the “changes in the pulse” and acts as an intermediary between the device and the individual under treatment. The individual is not in the driver's seat here: a practitioner is required to interpret the findings, verbally share this with the individual, and then administer therapeutic sound and electromagnetic frequencies. Further, additional “relaxing frequencies” are imparted that aim to relax the individual – rather than allowing the individual to relax using their own will and capabilities.

This document is not addressing the efficacy of devices like NES or Ondamed to diagnose or treat real health conditions. The point of this article is simply to clarify what constitutes a

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conventional biofeedback device versus some of these other devices on the market that claim to be biofeedback or biofeedback-like. The differentiating criteria are clear.

1. Biofeedback devices utilize well-understood technologies to sense quantifiable physiological parameters.
2. This information is directly manifested to the individual who, at all times, is “in the driver’s seat”.
3. The individual, under their own conscious will, changes their physiological state until the sensors indicate the parameters are in some improved or more acceptable range.

Non-biofeedback devices can utilize unconventional sensing technologies whose output is not medically recognized as a valid reflection of physiological state. They may require a practitioner or intermediary who translates the results to the individual and directs them accordingly: the individual is **not** in the driver’s seat! In most cases, the “feedback” treatment is **not** internally generated by the individual, but arises from an external source: electromagnetic frequencies imparted directly to the individual or into water or some other substance to be ingested by the individual.

Various combinations exist: some technologies use EEG patterns as the physiological input to their proprietary computer software, but the output is, again, some sort of electromagnetic or “information” signal that is externally imparted to the individual. If any one of the three criteria above are not met, the therapeutic device is not true biofeedback.



JOSEPH P FORGAS

PROFESSOR
School of Psychology

3rd September 2018

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health

Re: Cancellation of the BICOM Biofeedback device.

I received a request from Friends of Science in Medicine to review the specifications of the BICOM device (ARTG 138918) which was accepted onto the ARTG in 2007. I have investigated this appalling device and it has no place on your register.

According to the ARTG, the sponsor obtained a listing claiming it is a 'biofeedback device' with the intended purpose:

"This electronic system provides visual and auditory signals corresponding to the patient's physiological status. It detects changes in physiological functions that are outside of normal awareness, amplifies these signals and provides this as feedback to the patient with the intention of promoting the healing process. Examples of use are pain reduction, muscle relaxation, stress reduction and reduction of allergic reactions"

[https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=23B99B20F20420BBCA2577DD000279FA&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=23B99B20F20420BBCA2577DD000279FA&agid=(PrintDetailsPublic)&actionid=1)

The description of this device makes it crystal clear that **it cannot possibly have any effective diagnostic or therapeutic function**, and certainly has nothing at all to do with biofeedback. The claims made for the device amount to the worst kind of psychological manipulation, and their sole purpose is to mislead and exploit vulnerable people for financial gain. As a civilised society, we should not allow this kind of immoral exploitation to continue and the device should be banned forthwith.

Legitimate biofeedback devices are used by Clinical Psychologists for a wide range of conditions including back pain, hypertension and substance abuse. I have attached a review from Penn State University, Material Research Unit, "How to Distinguish Legitimate Biofeedback/Neurofeedback Devices", which describes and rejects several devices similar to the BICOM.

The BICOM is NOT a biofeedback device and should be cancelled.

Regards,

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Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
6 September 2018

Dear Prof Skerritt

EXPERT REPORT ON BICOM AND CYBERSCAN BIORESONANCE DEVICES

The BICOM and CyberScan devices are not 'biofeedback systems'. They are a category of devices referred to by alternative medicine practitioners, as 'bioresonance', and any therapeutic diagnostic or treatment claims, are not backed by credible evidence. These types of devices have no place in any countries therapeutic goods register.

Bioresonance is an alternative therapeutic and diagnostic method employing a device developed in Germany by the scientology member Franz Morell in 1977. His bioresonance machine was further developed and marketed by Morell's son in law Erich Rasche and is also known as 'MORA' therapy (MOrell + RASche). It is based on the notion that one can diagnose and treat illness with electromagnetic waves. The claim is that, via resonance, such waves can influence disease on a cellular level. The following seven points might be relevant:

1. Even though these devices are sometimes promoted as biofeedback devices, they clearly do not belong into this category. Biofeedback is the process of gaining awareness of real physiological phenomena such as (heart rate, pain, muscle tone) using instruments that provide information on the activity of those systems, with a goal of influencing them and thus improve health outcomes. Biofeedback is an accepted and evidence-based technique.
2. Bioresonance instruments are akin to the scientologists' 'E-meter' which essentially consists of an electronic circuit measuring skin resistance or conductivity. They are neither accepted nor evidence-based.
3. The literature on bioresonance is a prime example how pseudoscientific language is being used to mislead us all: *"Clarity of language is an essential element for effective communication. Using the example of bioresonance therapy, this article demonstrates how pseudo-scientific language can be used to cloud important issues. This can be seen as an attempt to present nonsense as science. Because this misleads patients and can thus endanger their health, we should find ways of minimizing this problem."*¹
4. Practitioners of bioresonance claim that they are able to detect and cure a range of diseases, including allergies, gastrointestinal conditions, addictions, etc. Such claims are, however, not plausible.
5. The diagnostic reliability of bioresonance has not been established.² In other words, the method is likely to generate false-positive and false-negative diagnoses.
6. The therapeutic effectiveness of bioresonance for any human condition remains unproven.³ In other words, there is no reason to believe that bioresonance can bring about a cure of a disease or alleviate symptoms.
7. Bioresonance is harmful in several ways. As the costs involved are considerable, it causes financial harm. As it has no diagnostic validity, it will false-negative diagnoses. This will delay or prevent effective treatments which, in extreme cases, can cost lives.

In summary, Bioresonance is not biologically plausible, not of proven effectiveness, potentially harmful and associated with exorbitant costs. I cannot recommend it for anyone or any purpose.

Emeritus Professor Edzard Ernst MD, PhD, FMed Sci, FSB, FRCP, FRCP(Edin)

6/9/2018 Cambridge UK

¹ <https://www.ncbi.nlm.nih.gov/pubmed/?term=ernst+e%2C+bioresonance>

² <https://www.ncbi.nlm.nih.gov/pubmed/20963379>

³ <https://www.ncbi.nlm.nih.gov/pubmed/9066509>