

This comprehensive buyer`s guide is designed to provide accurate and up-to-date answers on the most critical questions you may ask prior to obtaining a PEMF device for your personal and professional use!



Product safety of any PEMF device is the most basic and critical requirement. Proof of safety is defined by international regulations and the following norms have to be fulfilled by a PEMF manufacturer in order to legally market the device:

- **A)** Electrical safety: Provision of a **valid** "CE" Certificate (electrical safety and electromagnetic compatibility), in the USA it can be also labelled as "UL", in Canada as "CSA"!
- **B)** Every PEMF manufacturer/supplier, advertising health/medical claims, needs to label their device with the official "CE" mark, followed by four digits, i.e. CE 0123 (the four digits representing the notified body to certify the device for the manufacturer/supplier) The four digits also validate the listing and approval of the country where the device is being marketed! In other words, the labeling assures that the respective device is legally registered and certified as an audited medical device, considered to be safe to use!



### **Summary:**

If a manufacturer/supplier of a PEMF system for home use omits or is not able to provide proof of safety certificates, including pertinent regulations, their device is NOT conforming to legal safety standards. This by itself can result in immeasurable risks for the user!



### Is the intensity of the applied electromagnetic field crucial for its effectiveness?

PEMF systems appear on the market in all kinds of intensity levels. So-called **high-intensity devices** (mainly in the Tesla range) are usually used in a clinical environment and require highly trained staff as the electromagnetic field strength may harm if not applied properly! Nevertheless, a typical PEMF technology within the high Tesla range is known as "**rTMS**" (**r**epetitive **T**ranscranial **Magnetic S**timulation). It is, among other things, clinically approved for depression, however NOT suitable for home use. Such systems are specifically certified as medical devices, fulfilling all necessary norms and regulations. In addition, they are listed, cleared and approved by governing agencies (FDA, Health Canada, Health Agency of the European Union etc.). There are several high intensity devices on the market aggressively advertised for home use using misleading medical claims. None of them carry a recognized safety certificate, are registered, cleared or approved by the governing agencies! For this reason, this buyers guide will not include their technical data nor function. **Low-intensity PEMF systems** (usually within the range of approximately 1-300 microTesla) are very safe for home use without the necessity of a trained technician onsite. They offer a vast collection of clinical studies, confirming superior supportive efficiency. Low-pulsed PEMF systems range between 1 and 300 microTesla, mimicking the earth's natural magnetic field strength, nowadays

measured between 20 to 70 microTesla. Whole-body applications within these intensity levels have proven most effective in activating the body's own healing capacity.

### **Summary:**

High-intensity PEMF devices are only effective and medically approved for a very limited selection of indications (such as depression). Since the use of these devices necessitates a qualified medical technician, they are not meant to be in homes and are therefore not the right choice. Low-intensity PEMF devices are safe and approved for home use.

Most clinical trials and success rates refer to intensity levels between 1 and 300 microTesla!



### Is the frequency of the applied electromagnetic field crucial for its effectiveness?

In general frequency (measured in Hertz = Hz) is defined as the "information content" of the applied pulsed electromagnetic field. Similar to intensity, you can find PEMF devices emitting very high frequencies (up to the high kilohertz = KHz range) as well as very low frequencies (0-30 Hz). Evaluating existing clinical studies, the phrase "less is more" perfectly describes the best approach. Low carrier frequencies in the range between 0.1 and 30 Hz are also abundantly present in nature (Schumann waves, 7.83 Hz, carrier frequency of the earth magnetic field, roughly 11.7 – 11.9 Hz) as well as in our brainwaves (Beta, Alpha, Delta and Theta, between roughly 0.2 and 38 Hz). Low-frequency PEMF devices utilize the principal of resonance: It describes the phenomenon of increased amplitude that occurs when the frequency of a periodically applied force is equal or close to a body`s natural frequency!



### **Summary:**

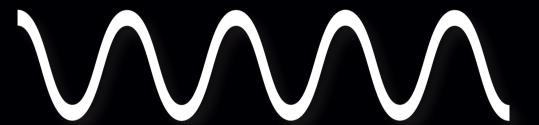
Low-pulsed PEMF systems utilize carrier frequencies within the natural range (0.1-30 Hz). This ensures a high potential of resonance and with it a much more effective reaction of the targeted area. At the same time, low-frequencies do not create a noticeable thermal effect, the exposed tissue will not get warm or even hot. The most efficient PEMF systems for home use are within this described "natural frequency range".

### Is the waveform of the applied electromagnetic field crucial for its effectiveness?

Another important parameter of a PEMF system is the so-called waveform. It describes the concept of transmitting frequency of a pulsed magnetic field as it would appear on a graph. The simplest waveform is hereby the sine wave. In order to transmit 5Hz from the sender to the receiver via a simple sine wave, the wave needs to repeat it`s cycle 5 times per second in sequence. This waveform is technically easy to gain but very limited in efficiency and extremely time-consuming in transferring information from the sender to the receiver. Surprisingly, most available low-pulsed PEMF systems on the market are still using simple sinewaves. Engineering, development and also manufacturing of such frequency generators are very cheap but also less effective. A more complex waveform is the so-called square wave. A square wave is a non-sinusoidal periodic waveform in which the amplitude alternates at a steady frequency between fixed minimum and maximum values, with the same duration at minimum and maximum. Square waves are also producing odd harmonics, which are very important to increase resonance effects. Due to its sharp rise and fall times, the immediate response rate of the targeted tissue is much higher. The most complex wave form used in modern PEMF systems is known as the saw tooth. Saw tooth waves are characterized by a constant rise and rapid fall time and are producing all odd and even harmonics of its

basic frequency. Since the main objective of an effective PEMF system for home use is to target ALL cells of your body, the wave form is a very crucial parameter to be aware of. Some manufacturers advertise "patented" wave forms, which are not documented in common physics. Such waveforms are artificially altered sine wave combinations, offering little independent clinical evidence as to their effectiveness. Their published clinical trials are mostly conducted by the company itself (industry-friendly) and therefore not considered as publicly acknowledged scientific study designs.

Sine Wave





Square Wave

Saw tooth Wave



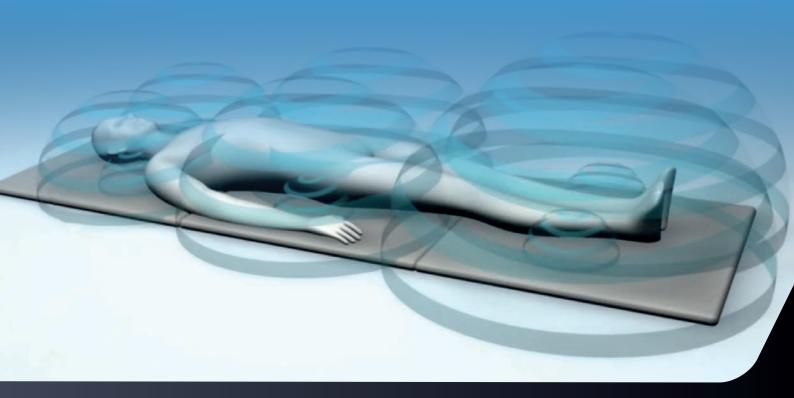
### **Summary:**

PEMF devices with sine wave frequency generators are not only outdated and cheap to manufacture, but also ineffective in creating the desired resonance effect. Applying only one frequency at a time with slow rise and fall times, inhibits and/or delays resonance with most cells in the body. Square waves are scientifically proven to be very effective for local, targeted applications. Modern PEMF devices offer square wave signals to treat isolated body parts. As of today, the most valuable saw tooth patterns are only used by very few manufacturers. The saw tooth wave is regarded as the gold standard for whole-body applications. Its signal is ideal to make use of upper harmonics within the even and uneven range, resulting in the highest resonance effect on the body. Recently only two systems in the world are capable of producing the extremely complex triple sawtooth pattern, which progressively increases the desired resonance effect!



# How do PEMF systems transfer the electromagnetic field from the applicator to the user?

Electric fields are created by differences in voltage: the higher the voltage, the stronger the resultant field. Magnetic fields are created whenever an electric current flows through a conductor. Manufacturers of modern PEMF systems are using different concepts of conductive designs. The most simple and cheapest approach is the use of flexible, insulated mesh wire coils of all kinds of shapes and sizes (round, oval, square). Companies using this concept usually advertise the advantage of better transport handling since the applicators can be rolled. However, the major disadvantage of this concept is the inevitable spacing between consecutive, insulated windings which distorts the magnetic field lines leading to an impure signal, consequently diminishing the inductive force. Highend PEMF devices solely utilize pure, uninsulated and solid copper coils, assuring an uninterrupted signal structure which then creates the highest inductive force. Meaningful clinical study designs usually use prototypes which offer copper coils, known to be the most effective (Reference: NASA study for stem cell growth).



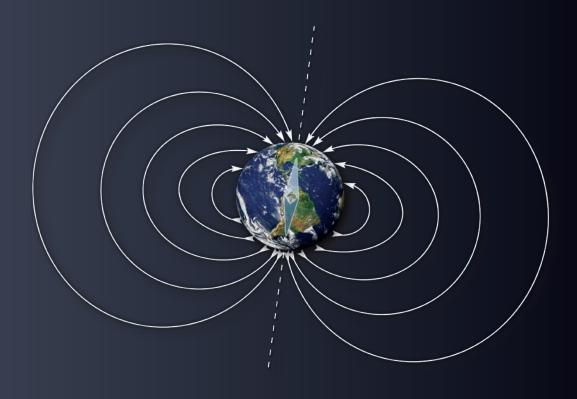
### **Summary:**

Transmitting an electromagnetic field to a living organism via applicators is without doubt THE most deciding efficiency-factor. Cheap, insulated mesh-wire solutions lack purity and inductive force. Applicators with built-in solid, uninsulated copper coils deliver a pure magnetic field and the highest induction rate.



## Whatdoes it mean, if a PEMF system switches the polarity of the applied electromagnetic field?

Switching the signal polarity consecutively from South to North and vice versa, is a very important feature of any state-of-the-art PEMF system. Our organism tends to acclimate or habituate to external, simplistic information and gets literally "used to it" or "tiresome" (i.e. static magnets or simple PEMF sine wave forms). As a result, over time, PEMF benefits may diminish and the application becomes less sustainable. Polarity changes in a PEMF device differ slightly from the South and North polarity of a static magnet. You will NOT find magnets in PEMF applicators, rather and ideally pure copper current loops, generating pulsed electromagnetic fields with a high variation in frequency. Therefore, switching polarity occurs once the current in the loop is changing direction. This added signal variety prevents the body's fatigue to the same wave form.



### **Summary:**

The higher the complexity and variation of a PEMF signal, the lower the risk of undesired habituation. Only PEMF systems offering sophisticated waveforms and polarity change can achieve this important effect.

### What is the benefit of PEMF systems integrating a biorhythm clock?

The existence and function of an internal "organ clock" in living organisms is meanwhile scientifically proven as well as awarded (Nobel Prize in Medicine 2017, Hall, Rosbash and Young: Discoveries of Molecular Mechanisms Controlling the Circadian Rhythm). Our bodies and brains as well as planetary systems are changing frequencies at different times of the day. This has a profound impact on our wake/sleep cycles and our energetic/tiredness phases throughout 24 hours. While working and being active during the day, we "operate" on higher frequencies (brainwaves mainly in high beta ranges), whereas on lower frequencies during evening and night (alpha = awake but relaxed, delta and theta = sleep/dream). Sophisticated PEMF systems take this important fact into account and automatically deliver the appropriate frequency ranges according to the time the application is performed. This feature is only available in a very few PEMF devices, even though it represents an essential requirement in achieving the highest "biological" effect.



### **Summary:**

Changing frequencies according to the time of day a PEMF application is performed, represents a very important and rewarding feature. In order to benefit from the organ-clock function, look for a device offering this valuable property.

### Why is the coil layout of a PEMF whole-body mat very important?

Exposing an entire human organism (ideally all 75 trillion body cells) to an electromagnetic field through a whole-body mat application guarantees the best holistic effect. For this reason, a whole-body mat offering pairs of conducting coils, capable of gradually increasing the magnetic field intensity from head towards feet, is the best choice. This means that the device needs to have 3 pairs of coils mimicking the flow of the earth's magnetic field, ideally covering head/neck, hips/torso, legs/feet and each side of the body. To be even more detailed, the coils covering the upper body need to expose a lower intensity (achieved by fewer windings in the coils), while the coils toward the feet should have greater intensity (more windings in the coils). This is of utmost importance because in comparison to our head and neck, our most sensitive body parts towards electromagnetic fields, our legs and feet can tolerate much higher intensity levels. Lower intensity levels in the upper portion of a whole-body applicator are crucial for people who are chemically or magnetic field sensitive. In addition, higher intensity levels could overstimulate or irritate the thyroid. BE AWARE: Manufacturers with mesh wire mats claim to offer a more uniform field (and they do) but at the expense of exposing both feet and head to the same intensity. This in turn may lead to unpleasant reactions, especially with people, who are hypersensitive to electromagnetic exposure!



### Summary:

Whole body applicators are key components of modern PEMF systems as they provide the desired electromagnetic exposure to the entire body (= holistic effect). Premium PEMF systems are equipped with 6 uninsulated, solid copper coils, divided in three pairs, whereas each pair has a different number of windings. The applied intensity levels are therefore lower around the head/neck area and slightly increase towards legs and feet. This natural approach allows gentle and safe applications for electrically- and chemically-sensitive people.

### What are the most important properties of local applicators?

Local PEMF applicators are designed to treat specific body parts. Applicator designs come in different shapes and sizes. In general, the intensity levels (magnetic flux) of local applicators are higher than whole body applicators. Area applicators (pillows or pads) are designed to treat larger surfaces and come in two different variants: A) one-coil design (usually insulated mesh wire), delivering uniform field exposure. B) two-coil design (usually uninsulated, solid copper coils), delivering field exposure with two separate magnetic field hot spots. This design increases the probability to pinpoint the cause of a prevailing condition without knowing the exact location of the trigger. Spot applicators (spots or intensive applicators) are designed to treat very specific body areas. They usually emit the highest intensity levels and come in two different variants: A) one-coil design (mesh wire or solid copper coils), delivering a uniform field exposure or B) two-coil design (solid copper coils), utilizing a very specific physical effect, called the "Helmholtz Coil" effect. This particular spot applicator consists of two conductive coils, connected with an elastic band. The applicator can be wrapped around the treatment area and as both coils are now facing each other in the same axis, the magnetic field becomes uniform, cancelling out possible disturbing magnetic fields within that particular region. Two-coil spot applicators are very effective and widely used in a clinical environment for faster bone- and wound-healing, pain relief and to increase local blood circulation.



### Summary:

Local applicators are additional accessories that enhance the application spectrum of modern PEMF systems. A basic PEMF system for home use should at least come with one area applicator (ideally two built-in solid copper coils). Leading brands also offer two-coil spot applicators, which greatly extends the application spectrum and increases treatment success.

### Do I have to be an expert to properly operate a PEMF system?

During the development process, reliable and well-known manufacturers of modern PEMF systems for home use invest a lot of time, thoughts and knowledge into usability and user-friendly operation. Although several, crucial parameters have to be pre-adjusted prior to an application, the most modern devices are meanwhile equipped with so-called "Fast Start Programs". Desired effects such as sleep improvement, regeneration, activation, relaxation, balance, performance etc. can be selected by pressing one single button and the system delivers all preprogrammed parameters for all applicators accordingly. In addition, these devices include a database of PEMF applications collected from clinical trials and comprehensive user feedback. It provides a customized protocol for specific effects. This not only enhances efficiency but also ensures a high level of application safety.













### **Summary:**

users, they also improve results while utilizing preselected, proven protocols. In case of individual support, leading PEMF brands offer first-class customer service and an assigned



# Are there PEMF systems on the market, capable of providing updates, upgrades and further developments?

### Basically, the market for PEMF home systems can be divided in two groups:

- **A)** Systems with a final product design and fixed operation structure. These systems are designed and programmed for a particular use. They cannot be updated or upgraded nor can they offer additional accessory development and expandability.
- **B)** Systems with an integrated, processor-based hardware structure, a development operating system, offering tools for future additions (hard and software). These systems are designed to provide the user with periodic improvement-based updates and upgrades, even additional application possibilities.

Consequently, investing in newer updated systems is no longer needed. Statistically, the operational life span of a certified PEMF home device can easily exceed 10 years. Based on the design, good care should eliminate any additional maintenance. It is therefore crucial to carefully investigate, which systems provide the greatest benefit for the user, not only in efficiency and usability, but also in their capability to sustain the newest, most advanced version.





### **Summary:**

Digital, operating system-based PEMF devices, capable of updates, upgrades and additional accessories represent the new industry standard. Considering the long operational lifespan of a PEMF system, it seems much more cost-effective and future-oriented to favor a system, which can be updated and upgraded; furthermore, extended in functionality and application advancements.

# Do PEMF systems also provide combining treatment modalities?

With the rapid development of digital technology, leading PEMF companies have already started to implement complementary and meaningful applications in their systems to provide a multimodality, therapeutic approach. State-of-the-art, processor-controlled PEMF systems with a comprehensive operating system are meanwhile capable of controlling and applying additional therapy methods within and outside of the electromagnetic spectrum, such as light-, sound- and color-therapy as well as far infrared technology. A regular PEMF treatment is usually performed while lying comfortably on a whole-body mat. Innovative inventions make it now possible to include far infrared therapy as well as brainwave entrainment in one single application. This approach not only saves valuable time for the user but enhances and optimizes the desired recovery processes. The described modalities are usually available as options and can be easily plugged into the system, controlled by the operating surface of the control unit. Ultimately, it saves a lot of money in comparison to obtaining similar therapeutic devices separately.



**Summary:** 

Always consider investigating the newest generation of digital PEMF systems, offering the benefit of adding other affordable applications in combination with electromagnetic field therapy. This approach will enhance the therapeutic effect in the most reasonable financial outcome.

# What kind of service/support can I expect from a trustworthy PEMF company?

### There are basically two existing distribution channels for home use PEMF systems on the global market:

**A)** online-shopping platforms (either exclusive supplier websites or through existing online shopping platforms, such as Amazon, eBay etc.)

B) direct selling through independent and certified company distributors of the respective manufacturer. Buying a PEMF system online might be a simple and modern choice. Doing so, please be aware that a fancy website, attracting with all kinds of claims and promises does not necessarily guarantee a competitive, legalized product, nor a reliable customer-oriented professional service and support. The decision to buy a comprehensive PEMF system for home use comes with a considerable investment, requiring expert advice. However, in no case should price be the most important criteria in acquiring a device, rather the assurance of an established, well-known manufacturer. Another important criterion is the availability of personal assistance, a service which is offered only by companies that are aware of the responsibility which associates their product. You should be able to receive answers through first-class customer service and/or a contact person to assist. Obtaining a PEMF system through an independent certified manufacturer representative in your region can give you this confidence. Your assigned representative is also

your "first responder" in case of product issues or service requirements which pertains to the manufacturer. Trusted companies also provide you with real contact people, faces and phone numbers, not just email addresses and/or contact forms!



### **Summary:**

Purchasing a PEMF system for home use is a considerable investment, which requires personal consultation as well as proper support - before, during and after the sales process. Don`t get impressed by tricky, promising websites without seeking professional advice from a competent specialist who represents a well-known legal manufacturer, operating in many countries. Every buyer deserves personal contact with a company, willing to provide real names, faces, and phone numbers of the responsible operating executive as well as its customer service staff.

### Is it possible to monitor and evaluate the immediate effect of a PEMF application?

Only very few modern PEMF systems for home use are equipped with sophisticated monitoring and analyzing technology, capable of measuring physiological functions during an external stimulus. Specific sensors detect and mirror the body's own biofeedback, providing pertinent information. One of the easiest, most effective and medically acknowledged forms of biofeedback is Heart Rate Variability (HRV), which can be easily and accurately measured through a pulse rate (finger or ear sensors). HRV analysis provides a "picture" of the autonomic nervous system which is constantly changing depending on activity, thoughts or external stimulus (PEMF). Depending on the HRV response during an application, the PEMF device is capable of adjusting the field intensity accordingly, thus providing a custom tailored therapy session. In addition, the recorded HRV data can be downloaded for further analysis, a software feature only provided by digital PEMF systems.



### **Summary:**

Heart Rate Variability analysis serves as a perfect monitoring concept to evaluate the physiological reaction during a PEMF application, adjusting magnetic field intensities appropriately.

# How can I find out, if a PEMF system is certified and legally approved for distribution?

A company and product background check needs to become an inevitable task prior to any purchase decision, especially in the health care industry. PEMF devices for home use are classified as medical devices, without exception! PEMF manufacturers/supplier, advertising any kind of health claims, need to be in compliance with the respective norms and regulations of the country the system is being offered to the public. Whether a medical device manufacturer/supplier or any electronic health product is considered legal, can easily be researched by demanding the following proof of concepts:

- 1. Product Certificate "Electrical Safety and Electromagnetic Compatibility" (depending on country: CE/CB/UL/CSA...).
- 2. Notified Body Certificate "Quality Management System for Medical Devices":
  - · if the manufacturer is a US company: FDA 21 CFR Part 820!
  - · if the manufacturer is a European company: ISO 13485:2018!
  - · if the manufacturer is a Canadian company: ISO 13485:2016 or higher!
- 3. Every medical device manufacturer/supplier must provide proof of medical device clearance, regulation or approval within the respective country the product will be marketed. The approval usually depends on the "intent of use" of the respective device. You can find this information inside the product`s instructions for use (IFU), an important question to ask before you buy. The intent of use includes also product claims the company is legally allowed to publish and advertise. Demand the following proof of product clearance:
  - if the PEMF device is marketed in the US: FDA listing information (establishment listing AND product listing, eventually 510K exempt confirmation or 510K approval or premarket approval, always depending on the classification of the product)!
  - · if the PEMF device is marketed in Europe: Product certificate MDR 2017/745!
  - if the PEMF device is marketed in Canada: Health Canada MDEL = Medical Device
     Establishment License AND MDL = Medical Device License!

### Summary:

Proof of compliance and legality of PEMF systems for home use should not be considered factoids. Once you demand the necessary documentation, you will indeed find the facts. Don`t get deceived by false, misleading promises or alluring advertising. PEMF systems are considered medical devices and therefore governed and regulated by respective laws and norms. You are entitled to claim this evidence!

### Comparison of Swissbionic Solutions PEMF Systems

(You may compare yourself with competitive PEMF systems by filling in the respective data from your personal research)

Features	<b>IMRS</b>	OMNIUM)	?	?
Intensity range whole body mat	0.27-45 microTesla	0.27-45 microTesla		
Intensity range area applicator (pad)	0.35-120 microTesla	0.35-120 microTesla		
Intensity range area applicator (spot)	0.43-300 microTesla	0.43-300 microTesla		
Frequency spectrum	0.5-25 Hz + odd and even harmonics	0.5-25 Hz + odd and even harmonics		
Waveform whole body mat	Triple Sawtooth	Triple Sawtooth		
Waveform pad applicator	Square Wave	Square Wave		
Waveform spot applicator	Square Wave	Square Wave		
Coil Concept (all available applicators)	Solid, uninsula- ted copper coils	Solid, uninsula- ted copper coils		
Polarity switch	yes, every two minutes	yes, every two minutes		
Built-In Organ Clock	yes	yes		
Helmholtz-Coil effect (spot)	yes	yes		
Fast Start Programs	Yes, 7 incl. Brain- wave	Yes, 5 incl. Brain- wave		
Brainwave Entrainment (sound, light, color)	yes, Exagon Brain	yes, OmniBrain		
Far Infrared/ PEMF combined application	yes, Exagon FIR	Not available		
Biofeedback Technology	yes, Exagon Sense	Not available		

### Comparison of Swissbionic Solutions PEMF Systems

(You may compare yourself with competitive PEMF systems by filling in the respective data from your personal research)

Features	<b>IMRS</b>	OMNIUM)	?	?
Frequency generator (for clinical studies and clinical oper- ation, optional with "Trial" Upgrade	Yes, sinewave, square wave, triple-sawtooth, triangle, trapezoid	Not available		
Programmable users	yes, up to 100	yes, up to 100		
Split Mode (using two applicators with one control unit independently)	yes	Not available		
Data recording	yes	Not available		
Music upload	yes	yes		
Rechargeable battery operation	Not available	yes		
Power plug	100-240V	100-240V		
Firmware and Software Up- dates/Upgrades	yes	yes		
Operating System	Windows IOT	Android		
Sales and Service	Personal, through certified representatives	Personal, through certified representatives		
Medical Certifications (products)	MDR 2017/745, FDA-regulated	MDR 2017/745, FDA-regulated		
QM-System Swissbionic Solutions (manufacturing medical devices)	ISO 13485:2018, MDSAP	ISO 13485:2018, MDSAP		
Product Safety	Certified CE/CB	Certified CE/CB		
Engineering/ Manufacturing	Switzerland/ Germany	Switzerland/ Germany		

#### **■** Swiss Bionic Solutions Schweiz GmbH

Schulhausstrasse 17, 8834 Schindellegi, Switzerland Phone: +41 (62) 295 5951 | Fax: +41 (62) 295 5952 | E-Mail: ch@swissbionic.com



#### Swiss Bionic Solutions Deutschland GmbH

Biberacher Str. 87 | 88339 Bad Waldsee, Germany Phone: +49 (7524) 996 950 | Fax: +49 (7524) 996 9518 | E-Mail: de@swissbionic.com

#### Swiss Bionic Solutions USA Inc.

12330 SW 53rd Street | Suite 703 & 704 | Cooper City | Florida 33330, USA Phone: +1 (954) 766 4153 | Fax: +1 (954) 766 4156 | E-Mail: us@swissbionic.com

#### Swiss Bionic Solutions Canada Inc.

195 North Service Rd W. Unit B8, Oakville, Ont. L6M 2W2, Canada Phone: +1 (905) 465 0753 | Fax: +1 (1866) 792 8182 | E-Mail: ca@swissbionic.com

#### Swiss Bionic Solutions Asia Ltd.

Unit B, 7/F. Office Plus @Mongkok, 998 Canton Road, Mongkok, Kowloon, Hong Kong Phone: +852 2337-8774 | Mail: asia@swissbionic.com | E-Mail: asia@swissbionic.com



### iMRS prime PEMF and Omnium1 medical systems are listed, regulated and approved as following:

### Europe:

Regulation: MDR 2017/745, clinically approved for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

#### USA:

Regulation: FDA, iMRS prime, Omnium1, product code "ISA", 890.5660, approved for: Pain treatment

Regulation: FDA, Exagon Brain, OmniBrain, product code "HCC", 882.5050, approved for: Sensitivity training, Muscle

reeducation

Regulation: FDA, Exagon FIR, product code "IRT", 890.5740, approved for: Dry heat therapy for body surfaces

#### Canada:

Recently pending approval process under regulation: Health Canada, MDSAP, ISO 13485:2018, MDL application, approval request for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

#### 🌇 Austra<u>lia:</u>

Recently pending approval process under regulation: TGA, MDSAP, ISO 13485:2018, MDL application, approval request for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

#### Brazil:

Recently pending approval process under regulation: ANVISA, MDSAP, ISO 13485:2018, MDL application, approval request for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

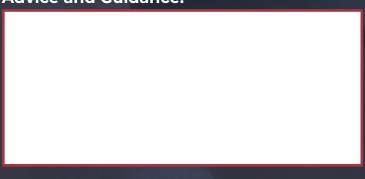
#### Japan:

Recently pending approval process under regulation: PMDA, MDSAP, ISO 13485:2018, MDL application, approval request for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

#### Taiwan:

Recently pending approval process under regulation: TFDA, MDSAP, ISO 13485:2018, MDL application, approval request for: Faster wound healing, Faster bone healing, Pain treatment, Improving blood circulation

### **Advice and Guidance:**





Disclaimer: iMRS prime and Omnium1 systems are listed, certified and approved medical devices within the scope of MDR 2017/745! The particular intent of use may differ from country to country due to non-harmonized standards, norms and regulations. Swissbionic Solutions Schweiz GmbH is a listed and certified manufacturer of medical devices within the scope of ISO 13485:2018 incl. MDSAP. All information provided in this brochure is for educational purposes only, and does not substitute for professional medical advice. Always consult a medical professional or healthcare provider if you're seeking medical advice, diagnoses, or treatment. iMRS prime including accessories are exclusively distributed by independent and certified LifeStyle Consultants trained by Swissbionic Solutions in accordance with the respective regulations. Swissbionic Solutions® and iMRS® are registered trademarks of Swissbionic Solutions Holding GmbH.