



**International Scientific Committee of
Ozone Therapy**

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CIRCULAR LETTER
Code of Conduct of ISCO3 Members

Date: 14 January 2018

From: ISCO3 Governing Body

President: Gregorio Martínez (signed)

Vice president: Fadi Sabbah (signed)

Secretary: Adriana Schwartz (signed)

To: All ISCO3 members

Subject: Code of Conduct of ISCO3 Members: Members have to apply in their daily practice the Madrid Declaration on Ozone Therapy and other documents of ISCO3

Deadline: 1st. September 2018

Dear Members of ISCO3,

Regulation of the ozone therapy and ISCO3

The committee from its inception in 2010 decided to support activities leading to the legal recognition of the practice of the therapy worldwide. For that reason in 2012 approved two key papers to contribute in this endeavor, one on the scientific basis of the therapy,¹ and the other one on the legal basis for its recognition.²

Before the creation of ISCO3 a few countries had obtained the regulation. But most of them have got it thanks to efforts made later on by the committee, and IMEOF (International Medical Ozone Federation). The result: 12 countries have already regulations on ozone therapy.

Nevertheless the progress towards achieving this objective has met with challenges that are not easy to overcome. Health authorities and/or legislative powers in some countries are totally against the acceptance of the ozone therapy, among them, the FDA in the United States,³ the Mexican Government,⁴ and the Brazilian House of Representatives.⁵

¹ Ozone Therapy and Its Scientific Foundations

<http://isco3.org/wp-content/uploads/2015/09/ISCO3-QAU0019-1.pdf>

² Ozone therapy and legislation - analysis for its regularization

<http://isco3.org/wp-content/uploads/2015/09/Update-May-2015-for-ISCO3.pdf>

³ Ozone therapy and legislation - analysis for its regularization. P. 41

<http://isco3.org/wp-content/uploads/2015/09/Update-May-2015-for-ISCO3.pdf>

⁴ The Mexican House of Representatives Health Commission had approved in 2014 a project to include ozone therapy in the article 79 of the 1984 General Health Law of 1984, as a "technical and auxiliary health activity". However the Mexican Government in a written paper expressed its opinion against it saying that "ozone is a toxic gas without standardized use in medicine (...) the use of ozone as a therapy can generate undesirable effects (...) its inhalation can generate and cause pulmonary edema (...) there is no solid evidence of effectiveness and safety in the therapeutic use of ozone, which can even constitute a health risk."

⁵ The Brazilian Senate had approved the federal law project 227/2017 authorizing ozone therapy as a medical treatment of complementary character throughout the country (Article 1). It was sent on November 1, 2017 to House of Representatives which rejected it.



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Powerful pharmaceutical companies are not interested in the progress and development of the therapy, and unfortunately within the professional health sector are groups or individuals that in the way they teach and use ozone-therapy are objectively working against its legal recognition and putting its practice even in danger. Examples: use of ozone-therapy in non-facultative contexts, lack of or inadequate training, use of non-certified ozone generators, obtaining ozone from industrial oxygen sources, "selling" the use of medical ozone as a therapy that heals everything. Advocating and using empirical methods, such as DIV (direct intra venous application), hyperbaric (HBO3) multi passes method, and intraperitoneal (i.p.) ozone. Methods that are putting at risk ozone therapy and human lives, as unfortunately has already occurred.⁶

We must take into account the differences between science and pseudoscience.

Pseudoscience. It is based on beliefs, feelings, convictions, ideas, etc., where the subconscious plays a fundamental role, something that science is not capable of explaining. It is not based on a valid scientific method, lacks plausibility or support by scientific evidence or cannot be verified reliably. Pseudoscience is subjective.

Science. It is the knowledge obtained through the observation of regular patterns, reasoning and experimentation in specific areas, from which questions are generated, hypotheses are constructed, principles are deduced, general laws and systems are organized and elaborated. Science is objective.

The main difference between both is the research method. Science poses hypotheses so they can be refuted. A succession of alternative hypotheses is confronted by experiment and observation. This body of knowledge is called the scientific method. Pseudoscience is the process in which, from some data, half-truths, partial claims and a partial use of certain scientific data, try to present certain theories as scientific without using any scientific method.

Ozone therapy is a science based on scientific studies and scientific data that can be proven and our duty as a scientific body is to make those principles prevail.

Official documents of ISCO3

As you well know the committee since its foundation has discussed, approved and issued 31 papers (ten of them have been translated into Spanish), all of them of free access, except the Madrid Declaration, divided in the following subjects:

1. Global reference document: Madrid Declaration on Ozone Therapy.
2. Papers of Good Clinical Practice.
3. Clinical Applications.
4. Analytical Laboratories.
5. Reference Documents for Recognition and/or Regularization of the Ozone Therapy

⁶ Two naturopaths were imprisoned in Las Vegas (USA) accused on a count of second-degree murder of a victim 60 years of age or older for administration of direct intravenous ozone in 2014.

<http://www.fox5vegas.com/story/28995673/2-accused-of-death-during-alternative-med-procedure>



by the Health Authorities.

6. Continuing Education on Ozone Therapy.

7. Medical and technical requests for the use of ozone therapy generators.

8. Pioneers of the Modern Ozone Therapy.

9. Forms & Templates: (a) Records. (b) Quality Assurance

In addition ISCO3 has created and keep updating the “ISCO3 Online Ozone Therapy International Library” which intends to have all published and presented papers on ozone therapy. It contains more than 2788 records so far. The library is also of free access.

Other documents will follow and each member has the duty to write at least one paper assigned previously by the president.

Ozone therapy daily practice and ISCO3 documents

ISCO3 is implementing little by little the objective that its recommendations may become source of guiding and reference to all those who practice ozone therapy. It is clear that it is up to each ozone therapist to follow or not the recommendations issued by the committee.

Nevertheless it is not the case for the members of our committee because according to article 6 of the by-laws of the committee: “Participate actively in the process of analyzing, discussing and approving the new edition of the Madrid Declaration on Ozone Therapy is an obligation of all members of the committee, who must know it in detail, promote it, disseminate it, defend it, implement it in their daily practice and propose scientifically based modifications to the Governing Body they consider this appropriate.”

Having as reference for our work the Madrid Declaration on Ozone Therapy all the papers issued by ISCO3 have been discussed and approved by the members of the committee. So each member has to be consistent with what the committee has approbated, and he is obliged to apply in his daily practice the contents of the ISCO3 papers. This way will be one of the best examples to influence others to follow the same path.

If a member of ISCO3 during a presentation in a congress favors a position against a paper of the committee, or in a hands-on practice teaches a procedure that does not comply with the criteria that have been previously adopted by ISCO3, he is undermining both the credibility of the work of this committee and sending erroneous messages to the health authorities that the therapy must not be approved.

ISCO3 is a scientific committee where its decisions are taken based on scientific evidence in a transparent and democratic way. So as members of the Governing Body we are making a call on each member of the committee to translate into his daily practice the contents of the documents democratically approved by the committee.



The following are examples of practices that each member must follow:

Low doses

Ozone therapeutic indications are based on the knowledge that low physiological dose of ozone may play important roles within the cell and that the response dependent of the activation of nuclear transduction mechanisms signals (Nrf2: Nuclear factor (erythroid-derived 2)-like 2) and keeping in balance the index of Nrf2 / NF-Kb ending finally with the synthesis of thousand antioxidant proteins such as SOD (superoxide dismutase), CAT (catalase), HO1 (heme oxygenase 1), etc.). This occurs only by using low doses of ozone.⁷

Since in the majority countries the laboratory clinic diagnostic of oxidative stress of the patient it is not available yet, the ozone treatment should always be applied in a gradual and progressive manner, starting with low doses and increasing gradually to avoid unnecessary risks. *“It is therefore preferable to start with low doses and to increase according to patient response. This is the general practice rule.”*⁸

Routes of application

They have been detailed by ISCO3 in at least two documents.^{9 10} On the performance of the major autohemotherapy, the committee has unanimously approved a document on how this procedure should be performed and it details the materials which should be used. Anything that goes beyond the approved standards will be against the guidance duly approved by ISCO3.¹¹

Materials

“All materials used must be disposable and ozone resistant: glass, silicone probes, catheters and silicone tubes, connections of Kynar or stainless steel 316, and siliconized syringes (...) all the disposable material used for training must comply with the rules listed in this Declaration.”¹²

⁷ Viviana, C. & Gabriele, T. Exposure to low ozone concentrations induces cytoskeletal reorganization, mitochondrial activity and nuclear transcription in epithelial human cells. in *Europeana Cooperation of Medical Ozone Societies Congress* (Zurich, 2014).

Viebahn-Hänsler, R., Fernández, O.S.L. & Fahmy, Z. Ozone in Medicine: The Low- Dose Ozone Concept. Guidelines and Treatment Strategies. *Ozone Science & Engineering* 34, 408-424 (2012).

Bocci, V. Is it true that ozone is always toxic? The end of a dogma. *Toxicol Appl Pharmacol* 216, 493-504 (2006).

Gregorio Martínez-Sánchez “Ozone as U-Shaped Dose Responses Molecules Hormentines” Dose Response (Prepress) Formerly Nonlinearly in Biology, Toxicology, and Medicine. Copyright © 2010 University of Massachusetts. ISBN: 1559-3258 DOI: 10.2203/dose response 10-001.

⁸ Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 11,12,15,25,32

⁹ Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 18-28

¹⁰ Non-recommended routes of application in ozone therapy

<http://isco3.org/wp-content/uploads/2015/09/Non-recommended-routes.pdf>

¹¹ <http://isco3.org/wp-content/uploads/2017/03/ISCO3-MET-00-01-MAHT-V1-03102016.pdf>

¹² Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 12,33



Training

“The practical training must necessarily be done in a controlled clinical environment that meets the current health legislation of each country.”¹³ “Practical training should take place in certificate medical facilities (...) the practical training must be done within clinical controlled environment, preserving all the sanitary requirements of the country where the course is performing. All the material use during the instruction must be ozone resistant and follow the Madrid Declaration on Ozone Therapy (ISCO3/QAU/01/03) guidelines.”¹⁴

Scientific gatherings in hotels, cultural centers, and similar are well accepted for teaching and disseminating ozone therapy theories and for demonstrations but not for hands-on practices because, as any medical procedures, they must be performed in a controlled clinical environment, i.e. “certified medical facilities”. This is for the safety of the patient, the therapy and the physician.

It is of the utmost importance that members of the committee give presentations and/or give hands-on practices in different types of scientific gatherings. But at the same time members have the obligation to inform previously the organizers of the meetings that the hands-on practices must be organized in “certified medical facilities”. Should the organizers do not accept this condition ISCO3 members should not participate in the hands-on practices.

Equipment

“To use the appropriate equipment to generate and apply the ozone therapy. These should also have the required authorizations from the appropriate sanitary authorities. In the case of the European Community equipment should be marked with the CE. The equipment to generate ozone must be calibrated or revised periodically, according to the recommendation of the manufacturer, to avoid incorrect applications or concentrations.”¹⁵ The “absolutely necessary” resources and technical details that a medical ozone generator must have are enumerated by ISCO3.¹⁶

Conditions of the medical centers

The medical centers where the ozone therapy is practiced should have mandatory sanitary authorization for its functioning and should abide by the” 10 requirements listed in the Declaration.¹⁷

¹³ Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 33

¹⁴ ISCO3 Methodology Recommendations for Professional Training in Ozone Therapy. P. 5.

<http://isco3.org/wp-content/uploads/2015/09/ISCO3-HUM-00-01.pdf>

¹⁵ Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 32

¹⁶ Guidelines and Recommendations for Medical Professionals Planning to Acquire a Medical Ozone Generator. P. 4

<http://isco3.org/wp-content/uploads/2015/09/ISCO3-DEV-00-01-Guidelines-and-Recommendations-for-Medical-Professionals-Planning.pdf>

¹⁷ Madrid Declaration on Ozone Therapy, ISCO3, 2ª. ed., 2015, p. 33



BASED ON THE ABOVE THE GOVERNING BODY

1. Has decided, based on article 6¹⁸ and 28¹⁹ of the by-laws of ISCO3, to call on each member of the committee to apply in his daily practice the contents of all the documents of the committee. Each member has to be consistent with the documents he has contributed to adopt, writing them, and/or participating in their discussions and/or casting a vote.
2. Has determined to give certain time to the members to provide them the opportunity to conform their daily practice as per the documents of the committee, taking into consideration that the implementation in their integrity in the daily practice the Madrid Declaration on Ozone Therapy (2nd. ed., 2015) and the other official documents of ISCO3 may take some months. **So as of 1st. September 2018** all members of the committee must apply them in their integrity. Failure to do so will imply that the Governing Body may start procedures against non-compliant members leading to apply article 25, b²⁰ of the by-laws.
3. Has no interest at all in applying art. 25, b to any member of ISCO3. On the contrary it encourages everybody to apply the decisions adopted and at the same time to participate actively during the discussion and voting period of each draft document.

¹⁸ **Article 6. PURPOSES**

h) "Participate actively in the process of analyzing, discussing and approving the new edition of the Madrid Declaration on Ozone Therapy is an obligation of all the members of the committee, who must know it in detail, promote it, disseminate it, defend it, implement it in their daily practice and propose scientifically based modifications to the Governing Body they consider this appropriate."

¹⁹ **Article 28. OBLIGATIONS.** Members shall have the following obligations:

- a) Share the aims of the Committee and collaborate for the achievement of the same.
- b) Comply with these By-Laws and the resolutions of the Governing Board.
- c) Perform the obligations inherent to the post they occupy on the Committee.
- d) Contribute with their conduct to the good name and prestige of the Committee.
- e) Inform the Secretary promptly of any change of address, telephone, email or similar information.

²⁰ **Article 25. LOSS OF MEMBERSHIP**

Members shall lose their status as such on any of the following grounds:

- b) Presentation of work assigned. If a member does not present work which has been assigned to him within the time previously determined, without justification, the President shall send him a written warning. If this conduct continues the Board shall act in accordance with letter a) of this article.