# SIOOT

SCIENTIFIC SOCIETY OF OXYGEN-OZONE THERAPY

24020 GORLE • BG • VIA ROMA 69

Tel. 035 300 903 - www.ossigenoozono.it info@ossigenoozono.it

FISM ASSOCIATED - FEDERATION OF MEDICAL AND SCIENTIFIC ITALIAN SOCIETIES


# AUTOHEMO INFUSION
# SYSTEMIC OXYGENATION

## ORGANIZATIONAL REQUIREMENTS AND PROTOCOLS

SIOOT, Scientific Society of Oxygen Ozone Therapy, is a scientific association that promotes research and studies for the development and Oxygen Ozone application in the medical field. It was founded in 1983, and since then the members are over 2500 doctors, many are also the Hospitals and Universities who practice this therapy. It is associated with the FISM, Federation of Medical and Scientific Medical Societies. SIOOT organized six National Congress, two International Conferences and four World Congresses. It has its own international scientific committee that oversees research, collaborates with various University Institutes for the promotion and upgrading of doctors, with exclusive clinical protocols, for continuous technological improvement. In SIOOT there are doctors, the methodical scholars from many Nations of the world. In thirty years of business it has dealt with great efforts to study and develop the best practices for the preservation and protection of patient and the doctor. It won major therapeutic successes, legal and authorization including certification by Institutions. In the report about the auto intravenous ozonated are attached extracts of Institutional documents that make the procedure unequivocally authorized procedure on condition of compliance with the SIOOT and use protocols of equipment and bags specially certified.

*Extract and English translation of the original letter*

*Istituto Superiore di Sanità - Conferenza di Consenso ISSN 1123-3117 Rapporti ISTISAN 08/9*

*CIRCOLARE DGFDM/III/P/1752/14 CC. del 20 gennaio 2005*

# ESSENTIAL REQUIREMENTS FOR TO PACTICE OXYGEN OZONE THERAPY

The Istituto Superiore di Sanità (Italian notified body) confirms that the doctor, on his own responsibility, and his knowledge and belief, can perform the medical oxygen therapy practice ozone in complying with the following requirements:

1. must operate in a clinic/doctor's office properly equipped (life-saving drugs, ventilation support principals or ambu balloon, hygiene and safety conditions suitable, waste disposal);

2. must complies with the Therapeutic Protocols and Guidelines issued by the SIOOT and presented to the Orders of Physicians and the Ministry of Health, it is also recommended the use of informed consent;

3. must attended at least one of the learning and annual updating of methodical theoretical and practical course (master's degrees, master classes and refresher courses of SIOOT);

4. **must use equipment and supplies (bags, etc.) certified to the DL. vo 46/97, Directive 93/42 EEC Class 2A**;

5. Please note that in addition to medical equipment oxygen ozone therapy certified in class 2A of Directive 93/42, **it is essential to use pouches specifically certified for blood and ozone**;

6. The equipment, as described in the enclosed service manual, should be reviewed after 4 years / 200 hours of use.

# AUTO EMO INFUSION

**SIOOT Protocols presented at the Istituto Superiore di Sanità for the practice of autoemoinfusion strictly require the use of bags (SANO3) made of CE certified plastic specifically for this practice.**

It is necessary to clarify a fundamental principle of the procedure.

The first part of the autoemo infusion is called "taking the blood", and as such must follow the directives issued by the Ministry of Health said that the following procedure:

1. The taking shall be drop (physiological).
2. The blood during the taking should be mixed continuously: tilting scale.
3. The quantity in ml must be set before you begin the same: scale with settings in ml.
4. At the end, the scale should be locked automatically: scale equipped with automatic locking ability.

**It is evident, from what has been said above, that the bottle is exhaustively "excluded" from this procedure for obvious contraindications that had arisen in the 70s and that had led to completely abandon the glass and adopt the plastic.**

The most obvious reasons were and now are the following:

A. Forced taking the blood with suction (internal air to the vacuum bottle) which speeds up the picking procuring very often the squeezing of the donor's vein or patient resulting in blocking the process.

B. Il sangue entra nel flacone con veemenza e i globuli rossi sbattono violentemente contro le pareti rigide del flacone procurando danni irreversibili agli stessi (forte emolisi) e formazione di schiuma iniziale esteticamente negativa oltre che dannosa. The blood enters the bottle vehemently and red blood cells slam violently against the rigid walls of the bottle procuring irreversible damage to them (strong hemolysis) and creating foam aesthetically negative as well as harmful.

**For these evident and verified damages, the plastic (blood bags) has been used for many years in Europe.**

Italian doctors now can take advantage of this new device that guarantees:

1. The blood is taken when physiologically falls down — an advantage for the patient;
2. The amount of red blood cells available is very high (no foam, no hemolysis);
3. The oxygenation with $O_2O_3$ is much more effective for the patient.

In conclusion, we can make some fundamental observations:

- No to the bottle because the forced taking of the blood is contrary to the ministerial regulations.
- No to the bottle because it damages the red blood cells.
- No to the bottle because it does not guarantee the exact and unique concentration of $O_2$ e $O_3$.
- No to the bottle because it is prohibited to waste the glass in special waste (Alipac).
- No to add other products (drugs or homeopathic remedies) in the bag because the ozone interaction with such products is unknow and can be dangerous.
- **Yes to plastic, phthalate-free, because it specifically authorized by the Ministry of Health for the autoemoinfusione with blood-ozone.**

*Extract and English translation of the original letter*

*Ministero della Salute*

**Ministero della Salute**

**Dip. Prof. San. e Ass. San.**

**DPS.VI/16SORV 38/3498**

Roma, 17.11.1999

**Subject: Use of plastic bags for collecting blood and blood components in the course of practice of autohemotherapy ozonated.**

The bags for storage of blood, with the entry into force of the Directive 93/42 / EEC, are considered medical devices, class IIB, and need to be CE marked by a Notified Body. Destinations and methods of use of the devices are clearly marked by the manufacturer on the basis of the elements contained in the technical documentation. Therefore, if a bag is provided only for a use intended for the storage the blood or its fractions it can not be used for other purposes such as those provided in the course of autohemotherapy ozonized. In fact, a different use of defined in by the manufacturer automatically involves the termination of the responsibilities of the latter.

*Extract and English translation of the original letter*

*Ministero della Salute*

**Ministry of Health**
**Directorate General of Drugs and Medical Devices**
**DGFDM 0003682 del 30.01.2000**

addressed to

**Haemopharm Healthcare S.r.l.**

**Subject: Ozone therapy, Major Autohemo infusion.**

Il prodotto chiamato Kit SANO3 è stato da Voi marcato CE espressamente per l'uso nella autoemoterapia ozonizzata. L'Organismo notificato ISS che ha rilasciato la prevista certificazione ha fatto presente, su nostra richiesta, di aver valutato anche il problema del rilascio di ftalati dalla sacca, verificando l'utilizzo di un PVC che non rilascia tali sostanze.

Ciò premesso si ribadisce il richiamo agli utilizzatori a non usare sacche in PVC non espressamente marcate CE per l'uso in corso di autoemoterapia ozonizzata.

The product called SANO3 Kit is CE marked by you specifically for use in ozonated autohemotherapy. The Notified Body that issued the certificate, upon our request, had also evaluated the problem the release of phthalates from the bag, verifying that the PVC used in the Kit does not release such substances.

Therefore users must not to use PVC pockets not specifically CE marked for use in the course of ozonated autohemotherapy.

*Extract and English translation of the original letter*

*Extract from the letter:*

*Ministero della Salute*

**Centro Nazionale del Sangue**
**Ministero della Salute**
**Istituto Superiore di Sanità**
**I.S.S. - C.N.S.**
**CNS 28/11/2014 - 0002232**

**Parere tecnico sulla nota 0029700-07/11/2014 - DGPRE-CO-UO-P, Prot. n. 2083.CNS.2014 del 10 novembre 2014 avente per oggetto "Autoemoterapia ozonizzata endovenosa"**

The Ministry of Health, Department of Public Health and Innovation, Directorate General of Prevention, National Center called for the writer to carry out its duties, opinion on the question raised by the Lombardy Region, Directorate General Health Council, concerning Autohemotherapy ozonated intravenous.

OPINION

**In reference to the subject in question is stated that the current legislation does not provide for the transfusion of the specific activities the practice dell'autoemoterapia ozonated, consisting of blood infusion, previously collected from the patient, supplemented with a mixture of oxygen and ozone therapeutic purposes.**

Based on the data available in the literature, ozone therapy appears to be generally well tolerated by patients, the most common side effects, mainly related to the mode of administration, are represented by a temporary feeling of heaviness, by a transient burning pain, by appearance hematoma in the venous access site or by vagal reactions, usually transient.

For these technical considerations it is believed that:

- the procedure intravenous autohemotherapy ozonated does not fall in any way in transfusion activities;

- the therapeutic product resulting from the mixing of the patient's blood with oxygen / ozone for the method of preparation is not free from risks of microbiological contamination if prepared in an unsuitable environment; it follows that where the

structures is prepared should ensure, through environments and appropriate operational mode, the maintenance of product sterility.