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Approved by

User guide of the

sedation machine

Manufactured in collaboration with

Accademia Archimede

Reviewed and approved by

AISOD

Table of contents.

In this guide reference is made to the conscious sedation with nitrous oxide (hereinafter cos.sed.).
Is part of the basic conscious sedation techniques according to A.D.A. (American Dental Association) 2020.

How to use this guide:

Additional on-line contents with 365 SmartLink

Several parts of this guide have links to additional contents and to supplementary material available on-line and in some cases downloadable. When you find the symbol indicated on the side click to have access to additional contents.

Click to access!

Conscious sedation. A quick guide.

The purpose of this guide is to provide professionals with a modus operandi concerning the operational flow of the conscious sedation with nitrous oxide.

Why a quick guide?

To analyse all operational steps and make the professionals aware of which are the benefits for the treated persons and for the surgeons.
This guide was drawn up with the collaboration of experienced dental sedation professionals for the benefit of the professional community. The contents were reviewed and approved by the AISOD-Italian Association of Dental Sedation professionals.

The conscious sedation is a technique already widespread around the world for years. The controlled administration of oxygen and nitrous oxide by inhalation induces a relaxing feeling, reducing the emotional load, the perception of pain and anxiety situations, increasing the patient's treatment possibilities and making easier the collaboration with the doctor, however keeping unchanged the conscious reflexes. It is always useful to remind that the conscious sedation is a safe practice. However, reversible adverse events may occur (for ex. vomit, paradox effect, etc...) and relative and absolute contraindications are present in the literature.

Conscious sedation. Why?

The conscious sedation with nitrous oxide has evident and widely documented positive pharmacological effects, but what is frequently forgotten is how this translates into great advantages for the doctor. The patients treated with this technique usually make the work of the dental team more simple, straightforward and relaxed, for the benefit of a consistent increase in productivity.

Patient advantages

- Relaxation
- Maximum collaboration
- Less pain perception
- Positive experience
- Immediate recovery

Medical advantages

- Less operational stress
- Maximum patient collaboration
- Extra quick learning curve
- Easy access to the oral cavity thanks to Intelliflux circuits

Conscious sedation. How?

This is the era of the digitally interconnected conscious sedation.

There are conventional solutions in the market where the sedation machine is simply “another equipment” of the clinic, but the technology available today allows an unprecedented integration and control (both functional and managerial).

The important is to be able to choose

Thanks to the new generation devices it is possible to decide about using or not the advantages deriving from the technological innovation or renounce them in favour of a stand-alone utilisation.

Thanks to interconnection the professional can sedate the patient and keep track of all operations carried out:

- Baseline
- Gas increment/decrement
- Residual litres per minute
- Litres per minute in use
- Name of the patient
- Name of the professional
- Use statistics per professional or per patient
- Generation of a .pdf file for the traceability of the treatment to be associated to the clinical folder

Information that are presently indispensable to analyse the flows, to be aware of the exact cost of the conscious sedation per treated persons and to record data regarding any sedation in the respective forms.Interconnected conscious sedation means approaching the management of the 4.0 clinic.

1.0

Work flow: a new approach.

Traditional devices

Pneumatic or electronic devices capable of dispensing oxygen and nitrous oxide through dedicated handles. Such devices are equipped with protections that ensure their safe use.

Connected digital devices

Electronic devices capable of dispensing the sedation gas properly adjusted and signalled on the command display.
Feature pneumatic and electronic safety for their correct utilisation.
Equipped with interconnection to a server for the registration of the professionals, the treated persons and the utilisation data of the device, for the traceability of all sedation operations.

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Presentation video of the MasterFlux Smart, the first interconnected electronic conscious sedation device

The work flow changes radically with use of interconnection for devices dedicated to conscious sedation. From now on it is indeed possible to analyse and prepare reports on all utilisation data of the device for each treated patient. This analysis can be integrated to the healing plan shared with the patient that therefore is always involved.

Welcoming and informed consent

Patient access to the treatment area.

Preparation and parameter assessment

Evaluation of vital patient parameters (measuring of heart beats, saturation...). Preparation of the patient for the sedative administration.

Administration

Administration of the oxygen and nitrous oxide mixture and the following optimisation of the dosing based on the patient tolerance.

Treatment

Development of the performance required by the patient's therapeutic plan.

Dismissal

Administration of pure oxygen during the time necessary for the total recovery of the patient and the following removal of the mask. The patient is then taken to the waiting room for a short time.

Saving

Saving of the sedation data for future utilisation or for eventual consultation requirements.

2.0

Welcoming and informed consent.

2.1

Purpose.

Welcoming is the phase in which the patient fills in the informed consents for the medical records, he/she is informed about the advantages and effects of the sedative analgesia treatment and then, if apt for conscious sedation, has access to the treatment area and then remains in the common area or in the surgical treatment unit. The two fundamental aspects of this moment concerns the preservation of the biological safety of the environment and all the necessary measures to create a positive experience of the treatment. The non-clinical personnel is in charge of carrying out a trial and a preparation suitable to ensure the necessary hygienic-sanitary safety standards, but it is the medical team responsibility to check their correct application. At the same time it is necessary to establish a first relationship with the patient, whether is this a habit or it is new in the structure, intended to achieve maximum collaboration. The machine is now ready with the sterile mask mounted and open cylinders (in the rear part) in order to reach the necessary pressure for the device operation.

Presentation of the conscious sedation treatment.

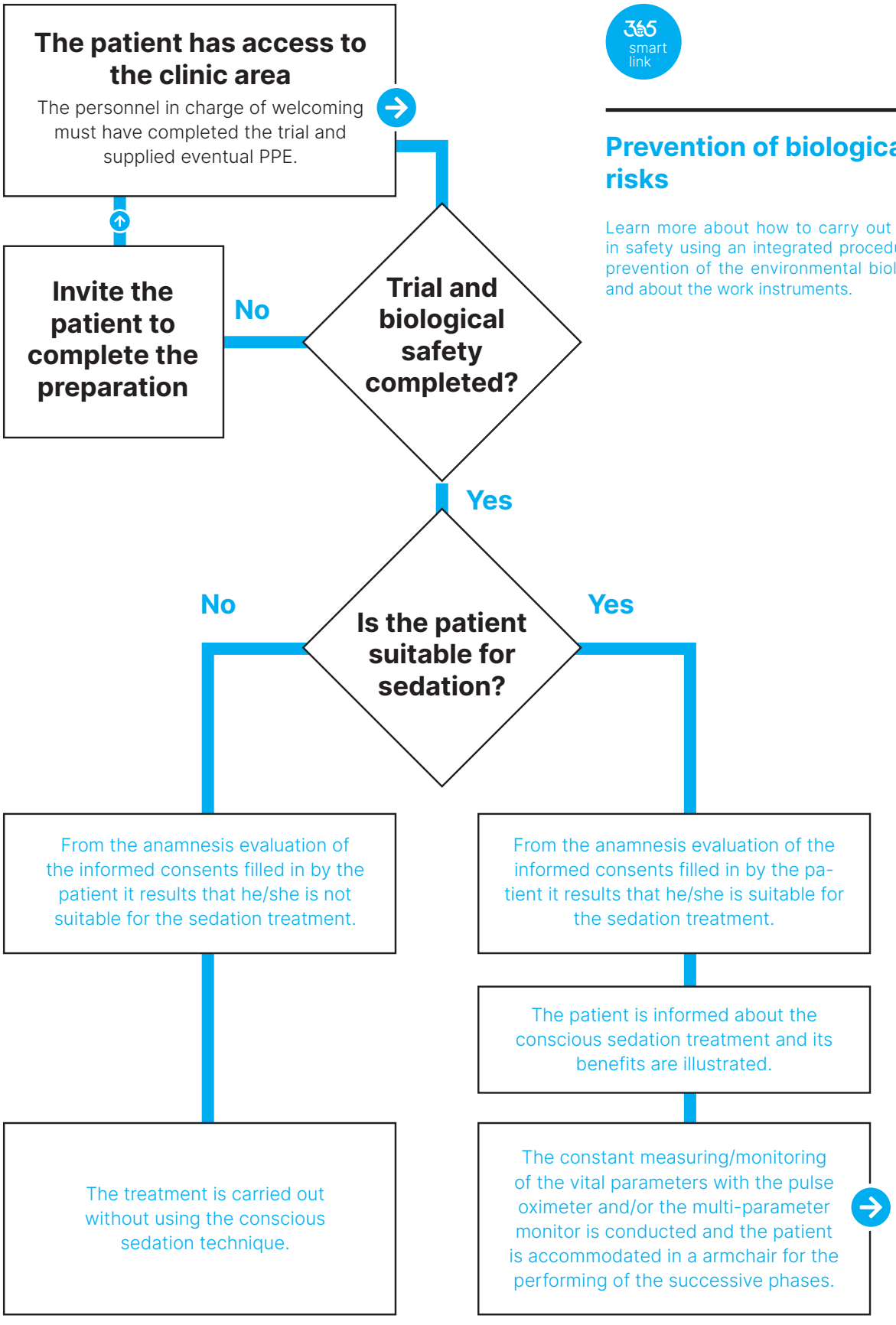
A structure that is equipped with conscious sedation devices can and must inform the patients that they can be treated with this technique. Even better would be to post illustrative material already in the waiting room or in an eventual mail for the appointment confirmation. Thanks to the conscious sedation the patient is more calm and less prone to avoid the treatment inconveniences. To operate in this way allows the reduction of sedation times, particularly those with long duration, thus increasing the number of patients treated per day.

User guide of the sedation machine

Safety and information

Check that the patient has filled in the informed consent and, if a person apt for the conscious sedation with nitrous oxide, was correctly prepared.

Modes.



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Prevention of biological risks

Learn more about how to carry out your work in safety using an integrated procedure for the prevention of the environmental biological risk and about the work instruments.

2.3 Operational sequence.

2.3.1

Access of the patient to the waiting room

The patient with whom the intervention was already agreed will complete the trial and will be accepted in compliance with the standards in force in safety matters.

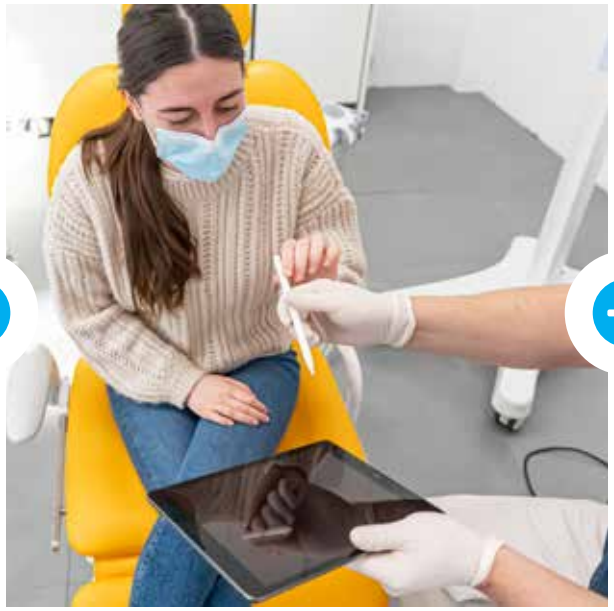
Shoe protection

We remind the importance of providing the supply of shoe protection to the patient (already when entering the clinic) to keep the operation environment clean.

2.3.2

Informed consents

The Patient fills in the informed consents and the medical team assesses the possibility of subjecting him/her to the conscious sedation.



Informed consent modules

Prepare the modules normally used, whether in paper or electronic, being careful to include one section concerning the conscious sedation.

The preliminary phases of the treatment are a delicate moment for the patient and the psychological aspect cannot be underestimated. The term welcoming is particularly suitable to explain how this phase should not be understood only as “access to the treatment”, but rather as an occasion to make the patient feel comfortable.
For adult patients the moment of reading the informed consent, with any clarification by the team, may constitute a useful distraction for any stress condition. Information is the key to obtain collaboration. Patients that have never received a sedation treatment with N2O can hardly understand the advantages for them and how much better will be their experience with the treatment with respect to the initial expectations. For children the approach can be modified considering the several cases, it is necessary to involve the parents and start as soon as possible the administration of the sedation so they will experience the advantages directly.

2.3.3

Information for the patient

The patient must be informed by means of a language that he/she can understand, about the benefits of the conscious sedation.

2.3.4

Access to the treatment unit

The patient is escorted to the operation room and prepared for the vital parameters monitoring phase directly on the armchair.

Illustrative material

With purpose of making the communication even more simple it is possible to use either paper or multimedia material that the patient can watch before being submitted to treatments with conscious sedation.

Pulse oximeter and/or multi-parameter monitor

The use of instruments that allow the monitoring of the vital parameter is necessary, such as the blood oxygenation and the heartbeats.

3.0

Preparation of the patient.

3.1

Purpose.

The preparation has the purpose of making the patient comfortable and well adjusted to the operation armchair.
In this phase the mask that suits better the patient is identified (they have different sizes and the one that adapts better to the treatment must be chosen).
Some professionals, attempting to achieve a better response of the patient for the following administration, resort to aromatherapy and relaxing music.

Monitoring of parameters and connection of the device.

This step foresees the application on the patient's finger of a pulse oximeter and/or a multi-parameter monitor which allows the monitoring of the vital parameters such as the blood oxygenation and heartbeats.
The conscious sedation device must be connected to an active (to the common area or to an aspiration system) or a passive discharge (tube equipped with a discharge to a different environment than the operation one) to prevent the gas not breathed by the patient from spreading into the environment.

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Recommendations for a comfortable environment

We recommend the absence of telephones and wall clocks to avoid stressful noises and the patient's perception of a sense of time (the effect of the conscious sedation can be impaired if it is possible to consult a clock).

Modes.

Environment preparation

The environment is prepared in the correct way avoiding acoustic stimulation for the patient and creating comfortable conditions.

Monitoring of the vital parameters

The patient seats on the armchair and is prepared for the treatment by means of the monitoring.

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Monitor MD 80 Plus

Ten inch multi-parameter monitor with ecg, pressure measurement, pulse oximeter, temperature probe, printer and rechargeable battery.

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Vital Test

Professional multi-parameter oximeter: oxygenation, heartbeat control, plethysmographic wave.

3.3 Operational sequence.

3.3.1

Patient preparation

The masks are tried to know which size is the most suitable for the patient's sight.

3.3.2

Help relaxation

There is an attempt to render the environment the most relaxing and comfortable as possible.

Masks

There are many mask sizes, the best one must be chosen based on the age and the size of the face of the patient to be treated.

Aromatherapy and music

Some professionals use relaxing music or aromatherapy to achieve a better response of the patient for the administration.

3.3.3

Positioning of the pulse oximeter

A pulse oximeter and/or a multi-parameter monitor is applied to the patient's finger.

3.3.4

Connection of the sedation device

The conscious sedation device must be connected to an active (to the common area or to an aspiration system) or a passive discharge (tube equipped with a discharge to a different environment than the operation one).

Pulse oximeter and/or multi-parameter monitor

The use of instruments that allow the monitoring of the vital parameter is necessary, such as the blood oxygenation and the heartbeats.

Disposal of the gas

It is necessary to prevent the gas not breathed by the patient from spreading into the environment.

4.0

Administration and treatment.

4.1

Purpose.

The administration is the phase in which the patient starts to inhale first the oxygen and then the mix of oxygen and nitrous oxide. In this phase, as in the rest of the entire the conscious sedation treatment process, the constant monitoring of the patient is provided by means of the instruments already mentioned.
In this phase it is necessary to start with the administration of oxygen and use a bag balloon to optimise the administration with the indication of the litres per minute breathed by the patient.

The patient.

The patient is instructed (welcoming phase) to breath only through the nose in a normal manner (as it were breathing without mask). During the first intervention in conscious sedation made on the patient, it is necessary to "title it", or the litres per minute values of oxygen and nitrous oxide (baseline) must be identified.

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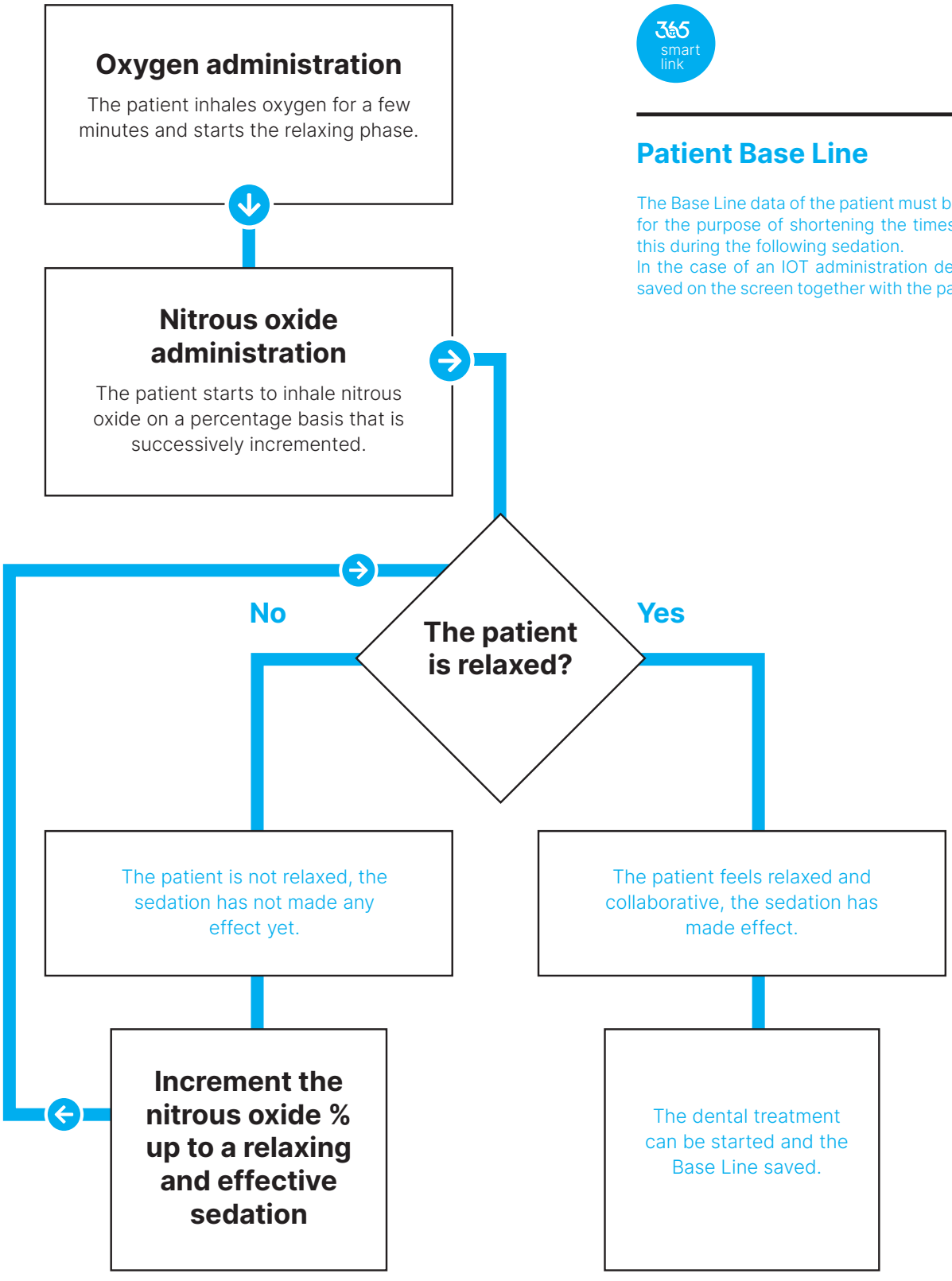
Flow adjustments

The sedation treatment is performed on several kinds of patients, among which also phobic.
Some times hyperventilation may arise, which can be managed comfortably by adjusting the administration flow.

Modes.



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Patient Base Line

The Base Line data of the patient must be registered for the purpose of shortening the times to achieve this during the following sedation.
In the case of an IOT administration device, this is saved on the screen together with the patient's data.

4.3 Operation sequence.

4.3.1

Opening of the oxygen

The maximum of oxygen is opened to allow the patient to breath in a correct manner and inhale the amount it needs.

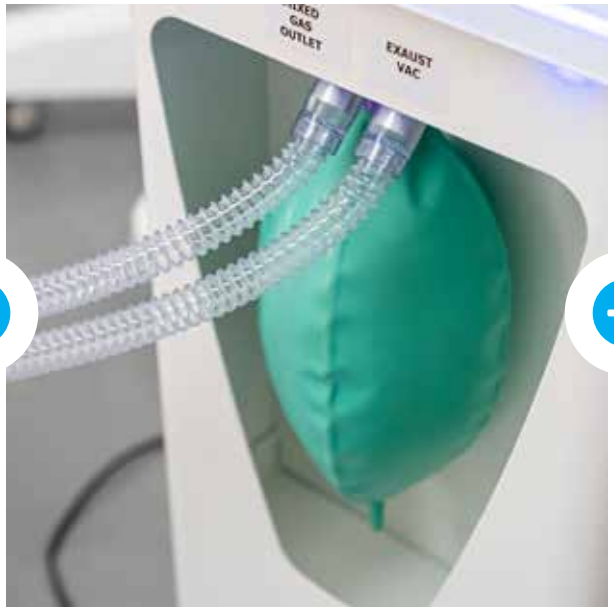
Balloon inflation

The balloon present on the device must be left to inflate abundantly.
The balloon works as an additional lung for the patient and monitors its breathing flow.

4.3.2

Lowering of the oxygen flow

The oxygen administration is lowered through the oxygen command on the device until a constant size of the balloon is achieved.



Balloon monitoring

The same balloon will follow the patient's breathing by slightly inflating and deflating during the expiration and inspiration phases.

The first thing to do is opening the oxygen to a maximum, allowing the patient to breath in a correct manner for the amount it needs, at the same time making the balloon present on the device inflate abundantly. The balloon works as an additional lung for the patient and monitors its breathing flow in litres per minute. Once the balloon is abundantly inflated, it is necessary to lower the oxygen administration through the oxygen command on the device until a constant size of the balloon is achieved. The same balloon will follow the patient's breathing by slightly inflating and deflating during the expiration and inspiration phases. The oxygen is administered for 3 minutes, during which the patient already perceives a relaxation and, in the case of hyperventilation, the breathing level is normalised. Just after this the administration for 2 minutes with 10% of nitrous oxide is started. Then there is a 5% increase on every minute until the patient relaxation is reached (an effect similar of drinking 2/3 glasses of wine with the stomach empty). From this moment on the patient will be relaxed and collaborative.

4.3.3

Nitrous oxide administration

The administration starts with approx. 10% of nitrous oxide, to be administered for 2 minutes.

4.3.4

Achievement of the patient relaxation

The nitrous oxide administration is increased by 5% on every minute until the patient relaxation is reached. From this moment on the patient will be relaxed and collaborative.

Oxygen level balance

Find the correct administration to allow the breathing normalisation, avoiding hyperventilation.

Duration of the administration

The gas mix is administered during the entire dental treatment, whichever it is.

5.0

Data and dismissal.

5.1

Purpose.

The saving of the sedation data (patient baseline) provides the possibility of consulting very quickly the patient's baseline values in terms of the oxygen flow in litres per minute of and of nitrous oxide flow in litres per minute.
The IOT devices allow the saving of all the patient's data automatically on the device, and if connected through a wifi network, also to a dedicated portal.

Dismissal of the patient

Once the data saving is performed the preparation for the patient dismissal is conducted.
This procedure has the purpose of restoring the psycho-physical condition of the person submitted to the conscious sedation treatment to the same state present before the sedation on the armchair.
To do this it is necessary to administrate pure oxygen to the patient for a period of at least 5 minutes.
When the oxygen administration time has ended it is necessary to keep the patient (standing up calmly from the operation armchair without haste) for 10' in the waiting room and proceed to the dismissal.
For long treatments the dismissal with a companion person is recommended.

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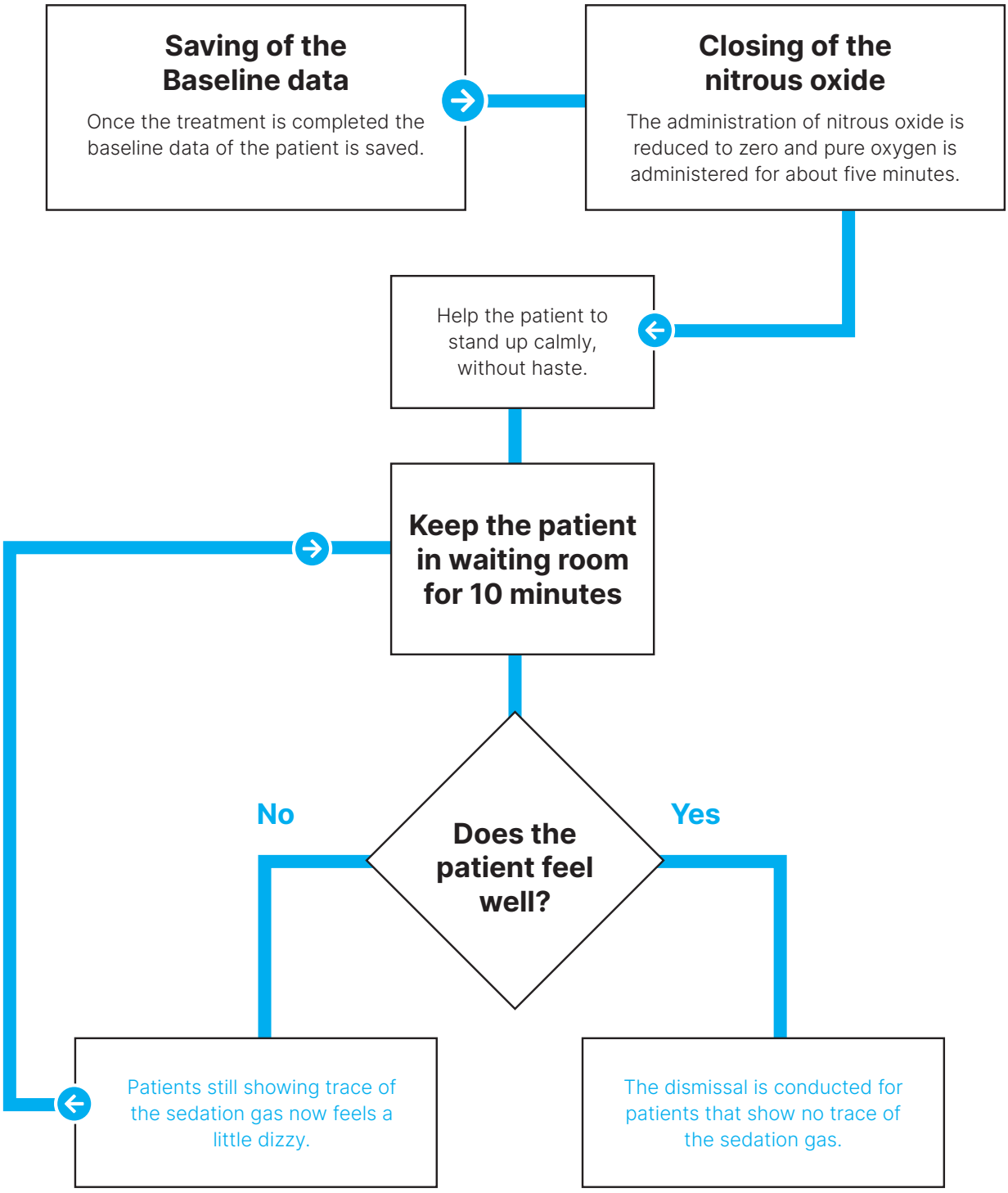
The importance of the post-treatment waiting

Once the oxygen administration has ended it is necessary make the patient stand up calmly from the operation armchair without haste.
After this, keep the patient for 10' in the waiting room.

Modes.


Saving of the Baseline data
Once the treatment is completed the baseline data of the patient is saved.
Closing of the nitrous oxide
The administration of nitrous oxide is reduced to zero and pure oxygen is administered for about five minutes.
Help the patient to stand up calmly, without haste.
Keep the patient in waiting room for 10 minutes
Does the patient feel well?
No
Yes
Patients still showing trace of the sedation gas now feels a little dizzy.
The dismissal is conducted for patients that show no trace of the sedation gas.

5.3 Operational sequence.

5.3.1

Baseline Data

The registry data of the patient and the sedation data are saved to make possible a quicker consultation in further administrations.

5.3.2

Closing the nitrous oxide emission

The nitrous oxide handle is lowered down to the zero value.

IOT Devices

The IOT devices allow the saving of the patient data, which can be used in future treatments.

Aromatherapy and music

Some professionals use relaxing music or aromatherapy to achieve a better response of the patient for the administration.

5.3.3

Oxygen administration

Oxygen is administered to the patient for about 5 minutes, then it should stand up slowly from the operation armchair.

Oxygen

To restore the psycho-physical situation of the patient to the same state as before the sedation on the armchair, it is necessary to administrate pure oxygen to the patient.

5.3.4

Patient dismissal

The patient is took to the waiting room to wait for 10 minutes, then it can leave the clinic.

Time in the waiting room

It is fundamental to make sure that the patient presents no trace of the sedation gas and that it has returned to the same state as before the sedation.

6.0

Appendix.

6.1

Clinical aspects.

The conscious sedation used in the dentistry sector induces the relaxing of the patient without loss of consciousness. The drugs used in the dentistry sector act on the Central Nervous System and according to the doses used they determine principally anxiolysis and slight changes in the motor coordination, not harming the consciousness and the reflexes that protect the airways.
The maintenance of the consciousness and of the patient's protective reflexes is fundamental for the success and the safety of the conscious sedation in the dentistry environment.
This technique ensures the stability of the vital functions and the anxiolysis helps to reduce the response of the organism to the stress.

The Italian Association of Dental Sedation Professionals (AISOD) is totally in agreement with the vision of the General Dental Council (GDC) **"The dentists have the obligation to guarantee and the patients the right to receive adequate measures for the control of pain and anxiety".**

The conscious sedation is therefore a treatment that presents many advantages for both the professional dentist and the patient.

Patient advantages

- Relaxation
- Maximum collaboration
- Less pain perception
- Positive experience
- Immediate recovery

Medical advantages

- Less operational stress
- Maximum patient collaboration
- Extra quick learning curve
- Easy access to the oral cavity thanks to Intelliflux circuits

6.2

What is the Sedation Machine.

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Presentation video of the MasterFlux Smart, first conscious sedation device electronically connected.

The conscious sedation with N2O-O2 inhaling is performed with specific equipment defined as **Sedation Machines**: this is equipment capable of dispensing gaseous mixtures of nitrous oxide and oxygen, with the possibility of determining the flow (the quantity of mixture dispensed, expressed in litres/minute) and the percentage of nitrous oxide, which can range between 0 and 70%.

- **These devices allow the administration of nitrous oxide only in the presence of at least 30% of oxygen in the mixture. In case of lack of oxygen the device activates the safety block and interrupts the administration.** Even at the maximum of its utilisation potential, 70% of nitrous oxide and 30% of oxygen, an oxygenation level higher than the one we breath in the atmosphere (21%) is always available.
- **The Sedation Machines must also interrupt immediately the flow of nitrous oxide in case the oxygen flow is interrupted;** the machine closes the N_2O flow in case of exhaustion of the oxygen cylinder, the patient breaths the ambient air, the sedation effect is lost but there is no risk of hypoxia.

The excess of the mixture can be eliminated with surgical aspiration.

The IOT digital sedation devices, in addition to what was previously mentioned, are capable of providing the user with many other advantages:

- traceability of the administrations performed
- registration of patients and surgeons
- recall of use statistics sorted by name or date
- viewing of the residual gas present in the cylinders in use.

All data are available for consultation in a portal that also allows the generation of .pdf files to be annexed to the patient documentation concerning the conscious sedation treatment.

Maximum transparency and total documentation of the intervention.

6.3

Productivity.

6.3.1

Myths and false myths.

Can I administrate local anaesthesia during the conscious sedation?

Yes it is better accepted by a relaxed patient.

Can the sedation be made by the dentist alone?

Yes The Italian Leg. Decree of February 28, 2011 (AIFA) stipulates that the dentist can use the nitrous oxide in concentrations above 50% and up to 70% in out of hospital environments.

Which are the monitoring systems required for patients that are submitted to dental treatment in conscious sedation?

No but in the case of the treatment of persons that have a baseline above 50% it is recommended to avoid nausea (that occurs only in some cases).

Does the patient need to wait too long after the conscious sedation until the effect ceases?

No after the treatment, 5 minutes of oxygen at 100% is administered to the patient and then he/she must wait for 10 minutes in the waiting room.

Which are the monitoring systems required for patients that are submitted to dental treatment in conscious sedation?

The clinical monitoring comprises:

- consciousness state and sedation level (response to verbal stimulation);
- maintenance of the reflexes that protect the airways (cough and swallowing);
- respiration (frequency and intensity);
- colouring of the skin and of the mucosa (rosy);
- capillary refilling time (< 3 seconds);
- the frequency (FC), the rhythm and the quality of the arterial pulse.

Are there informed consents for conscious sedation?

Yes Tecno-Gaz can provide them to our own clients for free.

Can I treat patients with heart disease?

Yes the sedation is particularly indicated because it has a muscle relaxation effect.

How much does the gas cost?

0.25 Euro per minute, or about 12 € for an average sedation work (the calculation is absolutely excessive and is made based on the data supplied by a medical gas dealer, includes the annual rent of the cylinders and is based on a replacement of 5 cylinders per year per each gas).

Is a pulse oximeter used during the sedation?

Yes The constant monitoring of the patient is recommended as well as the anticipated warning of the sedation signs by evaluating the heartbeats.

6.3.2

More productivity thanks to the conscious sedation.

The use of conscious sedation in dentistry encourages the collaboration of the patient, with the consequent increase in the treatment effectiveness and the reduction of the treatment times.

Is it possible to make more visits with the use of sedation?

When the professional dentist treats a collaborative patient, he/she spends less work time on the same.. **Roughly 5 minutes less for each sedation** (hypothetical calculation for an average treatment of 45 minutes) meaning that for 10 treatments made with conscious sedation, 50 minutes are saved, or one additional treatment can be made in the same day.

To recover about 5 minutes of sedation means increasing one sedation every 8 hours **Total 9**

Without practising the sedation **Total 8**

Without sedation With sedation

MasterFlux Smart

The first 4.0 electronic conscious sedation system

Worldwide news!

100% Made in Italy

Tecno Gaz s.p.a. a leader in sedation for more than 30 years, has developed MasterFlux Smart, the first electronic conscious sedation system with advanced IOT connectivity 100% Made in Tecno-Gaz.

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