

**MIXER SOURCE FOR CENTRAL SUPPLY OF
MEDICAL AIR PIPELINE SYSTEM COMPLIANT WITH
93/42 CEE & 2014/68/UE**

MIXTEL

OVERVIEW

MIXTEL is a primary source of synthetic medical air available in different models, in function of the corresponding peak flow-rate: **MIXTEL 30 – MIXTEL 60 – MIXTEL 120 – MIXTEL 200 – MIXTEL 500**.

MIXTEL consists of a mixer unit (cabinet) and a buffer tank: both the elements are essential in order to implement the intended purpose and, mainly, to comply with the safety requirements of the medical device directive 93/42/CEE.

MIXTEL is the result of the collaboration between two leading and specialized companies of the worldwide: **TGE s.r.l.** - Techno Gas Equipment, for years involved in design and production of components and mixing systems, and **AMBRA Sistemi s.r.l.**, with decades of experience in designing and manufacturing of systems for local and remote control of cryogenic gas storages.

The intended purpose of **MIXTEL** is the production of Synthetic Medical Air obtained through mixing of Oxygen F.U. and Nitrogen F.U., which from several years is finding increasing use in hospitals applications, for example:

- *In intensive care for ventilatory assistance;*
- *In conditions of chronic respiratory deficit to provide respiratory assistance;*
- *In anesthesia as a carrier gas of volatile anesthetics;*
- *In nebulising therapy as a carrier of pharmaceutical substances;*
- *In the management of immunocompromised patients, such as in cases of organ transplantation, cell transplantation or extensive burns;*
- *In incubators to provide controlled quality air flows;*
- *For cavity insufflation.*

The Synthetic Medical Air, obtained by the primary gases Nitrogen and Oxygen mixing, has some chemical and physical characteristic undoubtedly better compared to the traditional Medicinal Air obtained directly from the ambient air for compression and subsequent filtration.

In detail, Synthetic Air offers:

- High degrees of purity, for the absence of harmful gases and chemical pollutants products, such as lubricant oils.
- Total absence of bacteria, determined by an environment not easily accessible, and unsuitable for their breeding.

The production process of the Synthetic Medical Air occurs directly from end users through mixing system installed in hospitals, taking primary gases from their cryogenic storage facilities and mixing them with the correct proportions.

Therefore, Synthetic Medical Air supply includes not only the supply of primary gases, but also the provision of the mixing system and its maintenance.

As a result of the particular application and the high safety margins required, the service is normally performed with the following procedures:

- Initial system monitoring, until a perfect set-up
- Regular preventive maintenance and set-up
- Constant monitoring of accidental events
- Emergency service during anomalies

The system was developed with the main purpose to provide a complete and efficient solution for the production of the Synthetic Medicinal Air, which includes not only a mixing technologically advanced mixing unit, but also a powerful set of tools to support operators involved in the operation and perform maintenance of the plant, all with a low energy consumption.

Periodic maintenance provided by TGE s.r.l. is easy and intuitive and does not involve any particular difficulty.

Another feature of the mixer is the possibility to customize the front panel by entering the customer's logo.

All materials used for the construction are exclusively of European origin.

For the full protection of the system, **MIXTEL** and tank are equipped by safety valve.

In brief, these characteristic make **MIXTEL** different to the other traditional mixers.



BALANCED PRESSURE REGULATORS WITH PNEUMATIC CONTROL

IN COMPLIANCE WITH 93/42/CEE AND MARKED CE 0425

Superior mixture stability and extreme ease of use

The center of the mixing system is a double, pneumatically - controlled, high - precision and balance pressure regulator, of high precision, designed and built by **TGE s.r.l.**, thanks to this regulator, the synthesis mixture composition is repetitive and with long - term stability.

In addition, this technology simplifies the set-up operations. In fact, the operators have to use only two valves:

- The first one to determinate the flow rate, modulating the pressure downstream of the regulator
- The second one to correct the percentage of Oxygen in the mixture



ZIRCONIA ANALYZERS, KNUDSEN DIFFUSION EFFECT

Long life and reduction of periodically calibration

Designed for the specific applications by Ambra Sistemi s.r.l., the Oxygen analyzers use a miniaturized zirconia cell based on a new design concept operating on the current limitation principle known as "*Knudsen diffusion effect*".

MICROPROCESSOR CONTROL MODE

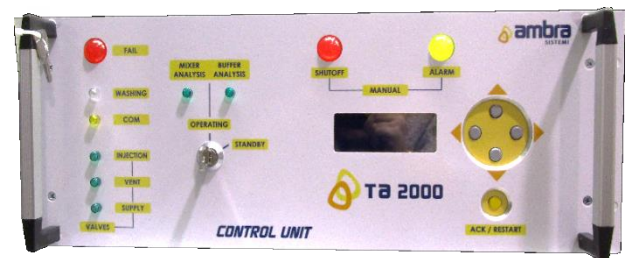
High safety margins and new tools for technical staff

The microprocessor Control Module TA2000, designed for the specific application by Ambra Sistemi s.r.l., regulates the mixing process and supports a series of complete new functions.

The module is designed to improve safety margins and facilitates the operators for management and maintenance of the device.

Therefore, the Control Module offers the following functions:

- Digital indicator for the operating parameters
- System parameters and alarms threshold programming through keyboard and / or remotely, via modem
- Local (optical and acoustic) and remote signals for alarm and shut-off statuses, in accordance with standard alarm signal for medical devices
- Notification for periodic maintenance empire time
- Actual situation consulting and historical data from remote in real time
- Re - start from remote
- Direct connection, via local network RS485, or via other telemetric equipment
- Auto system check-up



NOTICE OF TIME EXPIRED TO MAINTENANCE

Automatic schedule of the programmed operations

The Control Module TA2000 uses four programmable timers with range from 0 to 999 days, associated to various programmed operations. Upon expirations of each timer, they generate a different alarm status with transmission via modem.

Through a specific option of the device menu, the operator can decide if the timer alarms should also activate optical and acoustic local signals.

REMOTE CONTROL

Complete system monitoring from office and / or at home

The remote control monitoring is available by the central unit with the web application CrioSystem Supervisor though data communication by GPRS, TCP-IP, GSM and PSTN phone line.

This web application allows technical operators to establish real-time connection with MIXTEL whenever require, from office or at home.

REMOTE ALARM TRASMISSION

Alarm messages sending to maintenance operators on mobile phones

The central unit with CrioSystem Supervisor web application is required to support the remote alarm transmission functions.

MIXTEL through a modem unit MOD-COM (GPRS, TCP-IP, GSM and PSTN) will inform the central station in real-time about alarms, shut-off events and expired maintenance timers.

After receiving alarm information, the central unit will contact immediately the maintenance operators on their mobile phones transferring the alarms in progress (type and plant location) by synthesized voice messages, SMS and e-mail.

MIXEL TECHNICAL SPECIFICATIONS

Power supply	220 Vac 50/60 Hz., P max 60 VA, fuse 0,5 A
Visual indication	Display 4 lines x 20 characters backlight Medium priority alarm: LED Ø 20 mm, yellow High priority alarm: LED Ø 20 mm at high efficiency, red
Alarm sound	Magnetic speaker, volume adjustable up to 95 dB at 1 meter
Self-checking	O ₂ analyze, input and output pressure, flow production, valves anomalies, leaks, wrong analyzes
Input pressure range O₂ and N₂	12 ... 20 bar
Minimum pressure drop IN/OUT	4 bar
Working pressure range	7 ... 9 bar
Combined error O₂	< ± 1 % O ₂ full range (25 %)
Long term drift O₂	< ± 0,2 % O ₂ / year
O₂ Analyzers warm-up	2 minutes
Auxiliary output switch	V _{max} =250 Vdc/Vac; I _{max} =100 mA; N.C. or N.O. operations
Local network interface	Proprietary protocol CRIONET on insulated bidirectional RS485
Integrated optional communication card	FSK modem for PSTN phone network
Operating temperature	0 ... 45° C

Models	MIXEL 30	MIXEL 60	MIXEL 120	MIXEL 200	MIXEL 500
MIXING RANGE	30 Nmc/h	60 Nmc/h	120 Nmc/h	200 Nmc/h	500 Nmc/h
HOUSING	Metal cabinet 800 x1200 (P)800 mm, RAL 7035, IP55	Metal cabinet 600 x 1800 (P) 800 mm, RAL 7035, IP55	Metal cabinet 600 x 1800 (P) 800 mm, RAL 7035, IP55	Metal cabinet 600 x 1800 (P) 800 mm, RAL 7035, IP55	Metal cabinet 800 x 2000 (P) 800 mm, RAL 7035, IP55
CONNECTIONS	Nitrogen inlet ½" Oxygen inlet ½" Users ½" GAS F	Nitrogen inlet 1" Oxygen inlet ½" Users 1" GAS F	Nitrogen inlet 1" Oxygen inlet ½" Users 1" GAS F	Nitrogen inlet 1" Oxygen inlet ½" Users 1" GAS F	Nitrogen inlet 2" Oxygen inlet 1" Users 2" GAS F
WEIGHT	150 Kg.	200 Kg.	200 Kg.	200 Kg.	300 Kg.
TANK	50 Lt.	500 Lt.	500 Lt.	500 Lt.	3000 Lt.

Tank

Available in two variants:

- Stainless steel AISI304 – Complies with Directive 2014/68/UE and marked CE0497 (Produced by TGE s.r.l.)
- Carbon steel – Complies with Directive 2014/68/UE

Reference standards and directives

- **Directive 93/42/CEE** as medical device II°B class, notified body n°0425.
- **Directive 2014/68/UE** as under pressure device group I Category 4, notified body N°0497
- **UNI EN 7396-1/2016** Medical gas distribution systems - Part I: Medical and vacuum gas distribution systems.
- **EN 61000-6-2: 2005** Electromagnetic compatibility (EMC) Part 6-2: Generic standards. Immunity for industrial environments
- **EN 61000-6-3:2007+A1:2011** Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments
- Standard **UNI EN 10524-2-2006**



DEVICES AND TECHNOLOGY FOR INDUSTRIAL AND MEDICAL GASES

Strada Privata delle Valli, 10
24040 Suisio (Bergamo) – Italy
Tel +39 035 4933372 Fax +39 035 4933990
www.tgesrl.com – info@tgesrl.com

In collaboration with:

AMBRA SISTEMI SRL
TECHNOLOGY APPLIED TO HOSPITAL AND INDUSTRIAL CONTROL

Strada del Portone, 125
10095 Grugliasco (Torino) – Italy
Tel +39 011 9677775 Fax +39 011 9677725
www.ambrasistemi.it – info@ambrasistemi.it