



## C 400 TC and C 500 TC chamber machines

For medical and pharmaceutical packaging solutions



**MULTIVAC**  
BETTER PACKAGING



## C 400 TC and C 500 TC chamber machines

For medical and pharmaceutical packaging solutions

The MULTIVAC C 400 TC and C 500 TC chamber machines were developed for the special demands of the medical sector and pharmaceutical industry. They ensure that your products are packed in accordance with GMP guidelines, particularly in regard to packaging quality, process reliability and cleanroom suitability.

The main areas of application are products which are to be packed in small batch sizes. At the same time both machines are also suitable for the packing of products in a modified atmosphere with controlled oxygen content.

The chamber machines in the TC range are ideal for the packaging of implants, sterile medical products, combi-packs, diagnostic devices, etc. with efficiency and reliability.

The C 400 TC and C 500 TC offer in particular

- Process reliability
- Seamlessly programmable process parameters
- Measurability and reproducibility
- Cleanroom suitability
- Flexibility in the use of very diverse packaging materials
- Consistently high and measurable packaging quality
- Multiple possibilities for data collection, recording and documentation
- Operating security through comprehensive control systems such as RFID user log on, etc.
- User-friendliness

## Application

### Packaging in bags

MULTIVAC chamber machines are semi-automatic packaging systems in which the packaging procedure takes place in a chamber. As their means of packaging these systems use pre-made bags, manufactured from film, aluminium laminate material or Tyvek\*, into which the product to be packed is inserted. The chamber machine produces the required atmosphere in the pack for the product by means of evacuation and gas flushing.

Packaging procedure:

- The filled bags are manually loaded into the opened chamber and positioned with the open, unsealed side on a sealing bar
- After the chamber lid has been closed the packaging procedure starts automatically
- After the evacuation, gas flushing and sealing of the packs the chamber is opened automatically
- The finished packs can be removed.
- The chamber machine is ready for the next packing cycle

With two chambers, the C 500 TC double chamber machine allows the simultaneous loading of one chamber while the packaging procedure is being carried out in the other.

\* Tyvek is a registered trademark of DuPont





## Consistently high packaging quality

Our priority is to ensure that MULTIVAC packaging solutions always meet your quality requirements. In order to guarantee consistent packaging quality, the TC range of chamber machines is equipped with sealing systems which allow a particularly precise control of the sealing temperature, thereby delivering the highest possible seal quality and pack integrity.

The C 400 TC and C 500 TC offer the following features for the packing of medical and pharmaceutical products

- Reproducible sealing and packaging quality
- Uniform distribution of sealing pressure
- Flexibility in the use of very diverse packaging materials
- Reproducible gas flushing values for MAP applications
- Programmable vacuum and gas flushing processes (sequential evacuation and gas flushing)
- Equipment for locating the packs securely (optional)
- Residual oxygen measurement in the chamber (optional)

## Advantages

### Process reliability

With the C 400 TC and C 500 TC chamber machines we have combined innovative machine concepts with pioneering control technology to ensure maximum process reliability.

#### Precise IPC control

- Reproducible, verifiable and visualized processes
- Adaptable options for connections to external units, e.g. scanners or printers
- Ethernet interfaces

#### Comprehensive measuring units

- Sensitive monitoring and independent control of all the critical individual parameters
- Fixed installation of easily accessible calibration connections at the front of the machine
- Calibration instrument for harmonizing the sealing bar surface temperature to the temperature displayed at the terminal (optional)

#### Secure user identification

- Process and access control through user identification with RFID chip card and entry to pre-defined user levels
- Traceability through recording of parameter changes by individual users

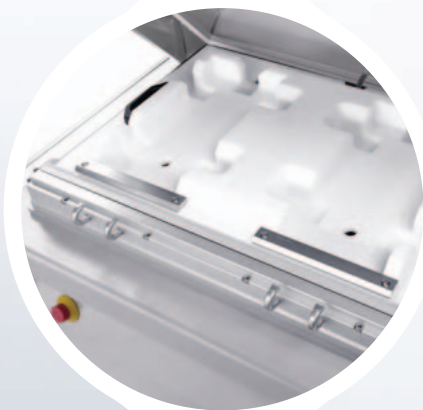
### Cleanroom suitability

The compatibility of any packaging method with cleanroom conditions and clean operation is influenced largely by the nature of the product to be packed and by the technology of the packaging procedure itself. MULTIVAC is continuously developing practical concepts and solutions for the packaging of many different types of pharmaceutical and sterile products.

With the C 400 TC and C 500 TC chamber machines we offer two versatile packaging systems, which are suitable for installation in a cleanroom environment thanks to their GMP compliant construction and materials. The formation and accumulation of particles in the production environment is reduced to an absolute minimum.

The chamber machines in the TC range are characterized by

- Compact and enclosed stainless steel construction
- Ease of cleaning of the smooth and level surfaces
- Low particle emission
- Air discharge collection for pneumatic components (optional)
- Internal or external vacuum pumps or connection to central vacuum supply



## Advantages

### Maximum user-friendliness

#### Maximum user-friendliness

The user interface of the machine control, together with all the machine components to be operated by the user, are designed for optimum user-friendliness and safety.

#### Ergonomic design

- Control terminal with touchscreen which can be rotated and pivoted
- Shielding of the sealing bars against contact when the chamber lid is open (optional)
- Motorized closing and opening of the chamber lid by foot switch (optional) or manual operation with piezo button (C 400 TC)
- Chamber lid brake controlled by sensor handles (C 500 TC optional)

#### Convenient IPC machine control with HMI 2.0

- Intuitive operation on a touchscreen with graphics for user guidance
- Simple setting and storing of parameters
- Process visualization on the touchscreen
- > 200 memory spaces for user recipes
- > 36 operating languages
- Troubleshooting support with graphics



## Technical data

C 400 TC chamber machine	
<b>Technical specifications</b>	
Usable seal length: (with cutting)	
Sealing bar(s) front:	1 x 660 mm or 2 x 270 mm
Sealing bars in U shape:	1 x 545 mm front + 2 x 355 mm at sides
Usable chamber depth: (without / with cutting)	
Sealing bar(s) front:	450 mm / 440 mm
Sealing bars in U shape:	440 mm Distance between sealing bars at sides 575 mm
Max. chamber height (with / without guard plate)	120 mm / 190 mm
Max. sealing temperature:	200 °C
Temperature variance along a short sealing bar:	+/- 3 °C
Temperature variance along a long sealing bar:	+/- 5 °C
Services connections:	
- Electrical:	400V / 50Hz, 3 x 220V / 60Hz
- Compressed air:	4.5 - 6 bar
- Cooling water:	1.5 - 6 bar
- Inert gas:	max. 3 bar
- Vacuum:	connection for external vacuum pump
- suitable vacuum pumps:	100, 150 m <sup>3</sup> /hr (internal/external), 250 m <sup>3</sup> /hr (external)
Machine dimensions (L x W x H):	1.120 mm x 950 mm x 2.100 mm (incl. terminal arm)
Machine weight:	approx. 300 kgs
<b>Equipment options</b>	
<b>Packaging process:</b>	
Evacuation	
Evacuation and gas flushing	
Multiple evacuation and gas flushing	
Residual oxygen measurement in the chamber (optional)	
Cutting (optional)	
<b>Additional equipment:</b>	
Foot switch (optional)	
Housing with height adjustable feet (standard)	
Housing with swivel castors (standard)	
Centralised air discharge collection (optional)	
Water recycling and chilling unit (optional)	
Quick connection couplings for gas, water, air (optional)	
CFR 21 Part 11-version (optional)	
External calibration connections (standard)	
Calibration package (optional)	

C 500 TC double chamber machine	
<b>Technical specifications</b>	
Usable seal length: (with cutting)	2 x 640 mm or 4 x 270 mm
Usable chamber depth: (without / with cutting)	755 mm / 725 mm
Position of the sealing bar:	front and rear
Max. chamber height (with / without guard plate)	110 mm / 180 mm
Max. sealing temperature:	200 °C
Temperature variance along a short sealing bar:	+/- 3 °C
Temperature variance along a long sealing bar:	+/- 5 °C
Services connections:	
- Electrical:	400V / 50Hz, 3 x 220V / 60Hz
- Compressed air:	4.5 - 6 bar
- Cooling water:	1.5 - 6 bar
- Inert gas:	max. 3 bar
- Vacuum:	connection for external vacuum pump
- suitable vacuum pumps:	160, 180, 250 m <sup>3</sup> /hr (internal/external), 300 m <sup>3</sup> /hr (external)
Machine dimensions (L x W x H):	2.050 mm x 1.300 mm x 2.050 mm (incl. terminal arm)
Machine weight:	approx. 700 kgs
<b>Equipment options</b>	
<b>Packaging process:</b>	
Evacuation	
Evacuation and gas flushing	
Sequential evacuation and gas flushing	
Residual oxygen measurement in the chamber (optional)	
Cutting (optional)	
<b>Additional equipment:</b>	
Sensor handles (optional)	
Housing with height adjustable feet (standard)	
Housing with swivel castors (standard)	
Centralised air discharge collection (optional)	
Water recycling and chilling unit (optional)	
Quick connection couplings for gas, water, air (optional)	
CFR 21 Part 11-version (optional)	
External calibration connections (standard)	
Calibration package (optional)	

# Our service

Our aim is to fulfil your requirements reliably and efficiently with our packaging solutions. To this end our team of experts offers you a wide range of support services and technical assistance.

## Validation

Our comprehensive validation package complies with the relevant GMP and ISO guidelines. This includes among other things

- Risk analysis
- Functional specification
- Software design specification
- Hardware design specification
- Installation Qualification
- Operation Qualification

We also support you in the implementation of qualification and validation processes on site and will assist you in the creation of procedures for special validation and retrospective validation in the case of packaging machines which have already been installed.

## Calibration

In order to ensure the integrity of reproducible processes and package quality the relevant process parameters in our packaging procedures are calibrated. We record the results in a calibration protocol and make the corresponding documentation available to you for correction of measurement deviations.

## FDA CFR 21 Part 11

In order to comply with the requirements of the FDA CFR 21 part 11 guideline, our IPC machine control can be equipped with the following function capabilities for the monitoring and recording of the packaging procedure:

- Personalized user administration
- Password administration
- Audit trail
- Recipe change log
- Data back-up

## Project management

From the initial idea to the first test run - a competent and experienced project team will be at your side during the implementation of your packaging solution, a team which will accompany you from the first consultation to the completion of the packaging project.

## Training

We offer you comprehensive training courses so that you can become familiar with the operation, maintenance and care of your machine. This allows you to fully exploit the potential of your MULTIVAC packaging solution.

## Service

Worldwide there are over 800 MULTIVAC experts in the field: around 300 sales advisors to develop the most efficient packaging solutions with our customers, as well as more than 500 service technicians to assist with service support, retrofit equipment and training.

[www.multivac.com](http://www.multivac.com)