



MEDICAL H 460-610-710-810 ATDP R25

ISO 11607.2 FULLY VALIDATABLE IMPULSE SEALERS

FOR MEDICAL POUCHES AND REELS

TOTAL SEALING PARAMETERS CONTROL

PC INTERFACE

NEW ROPEX RESISTRON[®] RES 5450 CONTROLLER

IMPULSE SEALERS WITH TOTAL CONTROL OF SEALING PARAMETERS.

FULLY VALIDATABLE TO THE ISO 11607.2, ISO TS 16775, EN 868-2, DIN 58953-7 STANDARDS.

AISI 304 STAINLESS STEEL COVER.

IMPULSE FLAT SEAL, SEALING WIDTH MM 8, SEALING LENGTH MM 460/610/710/810.

MATERIALS: PRE-MADE STERILE BARRIER SYSTEMS, UNCOATED TYVEK[®], NEWEST GENERATION PACKAGING MATERIALS.

MANUAL OPERATION OR BY OPTIONAL ELECTRIC FOOT PEDAL BUTTON.

STANDARD WITH NEW ROPEX RES 5450 CONTROLLER, EVEN MORE HIGH-PERFORMING.

ADVANTAGES AND BENEFITS

PACKAGING PROCESS VALIDATION

TOP-NOTCH TECHNOLOGY FOR MOST ACCURATE SEALING PARAMETERS CONTROL TO GUARANTEE CONFORMITY TO ISO 11607.2, EN, ISO TS 16775, EU GMP ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS STANDARDS.

SEALING PARAMETERS - TEMPERATURE, FORCE, TIME - ARE ACCURATELY CONTROLLED 50 TIMES A SEC. DURING CYCLE BY NEW ROPEX RESISTRON[®] RES 5450 CONTROLLER, THUS GUARANTEEING REPEATABILITY OF TOP QUALITY SEAL. IF ANY DEVIATION FROM SET PARAMETERS, MACHINE AUTOMATICALLY STOPS AND AN ALARM APPEARS ON THE DISPLAY.

SAFETY

FLAT MM 8 WIDE SEAL FOR PERFECT SEAL STRENGTH WITH EASY, SAFE AND EFFECTIVE PEELABILITY.

COMMUNICATION INTERFACES

USB-C PORT INTERFACE FOR UTMOST ADVANCED COMMUNICATION WITH DEDICATED TRACEABILITY SOFTWARE.

TRACEABILITY AND PC INTERFACE

DEDICATED TRACEABILITY REMOTE MANAGEMENT SOFTWARE, WITH PC INTERFACE, TO REMOTELY SET THE SEALER, RECORD AND MANAGE SEALING PARAMETERS FULL TRACEABILITY FUNCTIONING DATA, THAT CAN BE STORED AND MANAGED AS DOCUMENTS OF PROCESS VALIDATION.

OPERATOR'S INTERFACES

LCD AND EASY TO USE SOFTWARE FOR USER FRIENDLY AND ERGONOMIC APPROACH TO THE SEALER.

CLEANING AND DISINFECTION

AISI 304 STAINLESS STEEL COVER FOR EASY AND EFFECTIVE CLEANING AND DISINFECTION.

VERSIONS

SEALING LENGTHS MM 460, MM 610, MM 710, MM 810.

GT WITH BUILT-IN ROLL HOLDER AND CUTTER. CUTTING LENGTH MM 370, MM 500, MM 610, MM 610.

TESTING AND VALIDATION SERVICES

GANDUS SALDATRICI OFFERS A RANGE OF TESTING AND VALIDATION SERVICES TO ENSURE SAFE AND RELIABLE DAILY MONITORING OF MEDICAL SEALING MACHINES FOR STERILIZATION POUCHES IN ACCORDANCE WITH ISO 11607.1.2 AND ASTM F1929 STANDARDS.

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NEW CONTROLLER ROPEX RESISTRON[®] RES 5450

- GRAPHIC DISPLAY OF THE MEASURED VALUES
- RECIPE MANAGEMENT, MAX 9 RECIPES
- TRC CALCULATOR: ADJUSTMENT OF THE HEAT SEALING BAND TC BY MEANS OF REFERENCE VALUE INPUT
- CSA CERTIFICATION
- PASSWORD MANAGEMENT
- HIGH RESOLUTION COLOR DISPLAY (TFT)
- INTUITIVE CONFIGURATION MENU
- BATCH COUNTER
- GALVANICALLY ISOLATED ANALOG OUTPUT
- USB-C FOR ROPEX VISUAL SOFTWARE
- DYNAMIC QR CODE WITH INSTRUCTIONS FOR
- TROUBLESHOOTING (ROPEX WEBSITE)
- PARTS COUNTER
- PC INTERFACE FOR DIAGNOSTICS AND MAINTENANCE



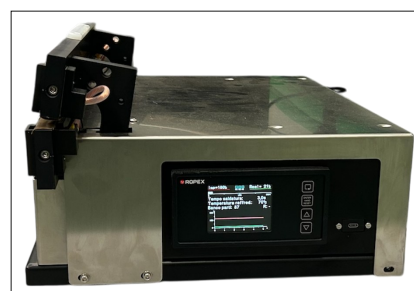
- FORCE AND TEMPERATURE MEASUREMENT WITH DIAGNOSTICS
- AMBIENCE TEMPERATURE DETECTION FOR AUTOCAL
- OUTPUTS STATUS DISPLAY
- HIGHER POWER DUE TO PRIMARY SIDE CONTROL
- WIDE VOLTAGE RANGE
- SEALING CYCLES COUNTER
- ON-SITE FIRMWARE UPDATE (ROPEXUPDATE)
- SEVERAL CONFIGURABLE GALVANICALLY ISOLATED OUTPUTS AND INPUTS SIGNALS
- ALARM OUTPUT
- PUSH-IN CONNECTORS

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TOTAL SEALING PARAMETERS CONTROL, PC INTERFACE
NEW ROPEX RESISTRON[®] RES 5450 CONTROLLER

TECHNICAL FEATURES	MEDICAL H 460-610-710-810 ATDP R25
COVER	AISI 304 STAINLESS STEEL
SEALING	IMPULSE, FLAT
SEALING HEIGHT	MM 8
MAX SEALING LENGTH	MM 460 (MEDICAL H 460 ATDP) MM 610 (MEDICAL H 610 ATDP) MM 710 (MEDICAL H 710 ATDP) MM 810 (MEDICAL H 810 ATDP)
MATERIALS	SEALABLE PAPER POUCHES ACCORDING TO EN ISO 11607-1/EN 868-4 SEALABLE POUCHES AND REELS ACCORDING TO EN ISO 11607-1/EN 868-5 MADE OF FILM AND PAPER ACCORDING TO EN 868-3 SEALABLE POUCHES AND REELS ACCORDING TO ISO EN 11607-1/EN 868-5 MADE OF FILM AND UNCOATED MATERIALS MADE OF POLYOLEFINS ACCORDING TO EN 868-9 (E.G. TYVEK [®]) SEALABLE POUCHES AND REELS ACCORDING TO ISO 11607-1/EN 868-5 MADE OF PP FLEECE OR PP NONWOVEN PEELABLE POUCHES PA/PE BAGS MADE OF THERMOPLASTIC MATERIALS, HEADER BAGS (PP, PE, PVC), PEELABLE FILMS IN PA/PE, LAMINATES INCLUDING ALUMINUM LAMINATES
SEALING BAR	DOUBLE SEALING BAR OPTIONAL -> CHOOSE SEALING MODE, EITHER SINGLE OR DOUBLE SEALING BAR
ROLL HOLDER AND CUTTING DEVICE	INCLUDED IN GT VERSIONS
SEALING CYCLE ACTIONING	MANUAL OR VIA ELECTRIC PEDAL SEALING BARS CLOSING VIA ELECTROMAGNET
FREE EDGE	ADJUSTABLE
TEMPERATURE SETTING AND CONTROL ISO 11607-2	VIA DIGITAL ELECTRONIC TEMPERATURE CONTROLLER <i>ROPEX RES 5450</i> CRITICAL SEALING PARAMETERS AUTOMATIC CONTROL, VISUALIZATION AND RECORDING SEALER FUNCTIONING DIAGNOSTIC AND CHECK ALARM AND STOP TEMPERATURE TOLERANCE $\pm 5^{\circ}\text{C}$ (DIN 58953-7) ALARM AND STOP ADJUSTABLE TOLERANCE FORCE / TIME ALARM AND STOP
INTERFACES	LCD PC CONNECTION REMOTE CONTROL RS 232 PORT USB-C PORT
MENU	MULTILANGUAGE
TEMPERATURE CONTROL	ELECTRONIC 0-250°C, TOLERANCE $\pm 1\%$

ERRORS AND/OR OMISSIONS EXCLUDED



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TRACEABILITY AND SOFTWARE	TRACEABILITY VIA USB-C PORT REMOTE CONNECTION VIA SOFTWARE ROPEX VISUALIZATION
FUNCTIONS	TEMPERATURE CONTROLLER <i>ROPEX RESISTRON[®] RES 5450</i> DATA RETENTION WITH MACHINE OFF PERIPHERIES CONDITION AND DIAGNOSTIC CHECK UP AT START-UP DISPLAY SHUTDOWN SETTABLE COUNTER CLOCK AND CALENDAR FUNCTION DISPLAY OF SET AND ACTUAL SEALING TIME AND TEMPERATURE SEALING COUNTER AND ACTUAL SEALING FORCE GRAPHICAL REPRESENTATION OF SEALING CYCLE SETTING SEALING TIME AND TEMPERATURE SETTING COOLING TEMPERATURE RESETTABLE CYCLE COUNTER SEALING CYCLE START DELAY SETTING DISPLAY OF ACTUAL SEALING TEMPERATURE IN 'HOLD' MODE AUTOMATIC SELF-CALIBRATION SETTING (AUTOCAL) COOLING MODE SETTING (ABSOLUTE, RELATIVE/PERCENTAGE, TIME) 9 SEALING RECIPES SETTING SETTABLE RECIPES NUMBER WORKING MODE SELECTION ONLY VIA RECIPES PASSWORD FOR CONFIGURATION LOCK SEALING SETTING 1 OR 2 SEALING BARS (OPTIONAL)
COMPLIANCES	UNI EN ISO 11607-2 UNI EN 868-5 DIN 58953-7 2006/42/EC-2014/30/UE-2014/35/UE UNI/TR 11408:2011 EU GMP ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS MANUFACTURED IN A UNI EN ISO 9001:2015 QUALITY SYSTEM CERTIFIED COMPANY
POWER SUPPLY	V 230 - Hz 50/60 - SINGLE PHASE 2350W - 2600W (A SECONDA DEL MODELLO) ONLY DURING SEALING CYCLE AT SEALING TEMPERATURE
DIMENSIONS (L. X H. X D.) WEIGHT	MM 560 x 230 x 390 / KG 33 (MEDICAL H 460 ATDP R25) MM 710 x 230 x 360 / KG 38 (MEDICAL H 610 ATDP R25) MM 810 x 230 x 360 / KG 42 (MEDICAL H 710 ATDP R25) MM 910 x 230 x 360 / KG 42 (MEDICAL H 810 ATDP R25)
ACCESSORIES UPON REQUEST	FRONT SUPPORT TRAY ROLL HOLDER AND CUTTING DEVICE PEDAL CALIBRATION PROBE KIT TERMOMETER AND PROBE FOR TEMPERATURE CALIBRATION