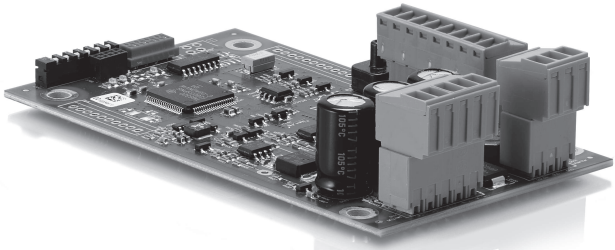
DMCX

ENG INSTRUCTIONS FOR USE.

Other languages available on https://dental.bienair.com/IFU



CE 0123 Rx Only

REF 2100253-0005/2023.12

Set supplied - Set DMCX REF 1600811-001

REF 1302410-001(1) / 1302411-001 (2)

REF 1501566-001

Compatible items

BOARD RELAY
REF 1503075-001

BOARD MODULE 24V-32V
REF 1500580-001

CABLE RS232 L = 30 cm
REF 1500579-001

COUPLING (Exhaust air)
REF 249.39.11-001

HOSE MCX GREY
REF 1600756-001

HOSE B-MCX GREY
REF 1600824-001

HOSE MCX 400 GREY
REF 1601081-001

HOSE MCX GREY 400° Ø20.2x40
REF 1601096-001

MOT MCX LED
REF 1600751-001

MOT MCX
REF 1600780-001

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1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Catalogue number.
	CE Marking with number of the notified body.		Consult instructions for use or consult electronic instructions for use.
	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.		Medical device.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		Authorized EC Representative in the European Community.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Batch code.
	Data Matrix code for product information including UDI (Unique Device Identification).		Temperature limit.
	Humidity limitation.		Atmospheric pressure limitation.
	Keep away from rain.		Recyclable electrical and electronic material.
	Electrostatic sensitive devices.		

2 Identification & Intended Use

2.1 Identification

Medical device manufactured by Bien-Air Dental SA.

Type:

Bien-Air Dental DMCX drive motor.

Description:

The DMCX electronic board* is dedicated to drive up to two Bien-Air Dental MCX micromotors.

(*) Hereafter referred to as "electronic board"

2.2 Intended use

Product intended to be used with MCX micromotors, which is intended for use in general dentistry as defined in the micromotor IFU.

2.3 Intended patient population

The intended patient population of the device includes any person visiting a dental practitioners' office to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.4 Intended user

Product intended for professional use only. Used by dentists and dental professionals.

2.5 Use environment

Professional healthcare facility environment.

2.6 Intended medical conditions

General dentistry which includes restorative dentistry, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health.

2.7 Patient contra -indications and side effects

No specific patient contra- indication, side effects nor warning exist for the device when it is used as intended.

2.8 In case of accident

If an accident occurs, the device must not be used until repairs have been completed by a qualified, authorized and trained technician in a repair center.

If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

⚠ **WARNING**

Any use other than that for which this device is intended is unauthorised and may be dangerous.

3 User and Patient Safety: Warnings & Precautions for use

This medical device must be used by professionals in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and these instructions for use.

In accordance with these provisions, the user is responsible for ensuring he or she only uses devices which are in perfect working order.

Electrical safety & EMC compliance:

⚠ **WARNING**

Electrical safety can only be claimed when the device is used with Bien-Air Dental compatible motors and hoses. During integration, only use a medical power supply that conforms to standards IEC 60601-1 respecting the required withstand voltage.

To prevent any risk of explosion, the warning below must be observed:

⚠ **WARNING**

According to IEC 60601-1:2005 +A1 2012 / AnnexG, electrified devices (motors, control units, couplers and attachments), can be safely used in a medical environment in which potentially explosive or flammable mixtures of anaesthetic substances are delivered to the patient only if:

- The distance between the motor and the anaesthetic breathing circuit exceeds 25 cm.
- The motor is not used simultaneously to the administration of the anaesthetic substances to the patient.

To prevent any risk of injury and/or material damage the warnings below must be observed:

⚠ **WARNING**

- Ensure to follow the installation procedure to avoid any assembly error or wrong input value.
- Limit the use max 2000m altitude when the accessory 1503075-001 is used.

4 Electromagnetic Compatibility (EMC)

4.1 EMC Caution

⚠ **CAUTION**

- Since compliance with the international standard IEC 60601-1-2 does not guarantee immunity against 5G worldwide (due to the different frequency bands used locally), avoid the presence of devices equipped with 5G broadband cellular networks in the clinical environment or ensure that the network functionality of these devices is disabled during the clinical procedure.
- Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. Special precautions should be taken when using strong emission sources such as high-frequency surgical equipment and other similar devices, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Bien-Air.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Since this device is intended to be used adjacent to or stacked with other equipment, the responsibility of verifying normal operation in the configuration in which it will be used falls onto the dental unit manufacturer.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air as spare parts for internal components, may result in increased emissions or decreased immunity.

4.2 Electromagnetic compatibility – emissions & immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Guidance and manufacturer's declaration – Electromagnetic emissions:

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device uses RF energy for its internal operation only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Emissions due to voltage fluctuations IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – Electromagnetic immunity:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for other lnes	±2 kV for power supply lines N/A	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	Mains power quality should be that of a commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles at 0°	0 % U_T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles at 0°	Mains power quality should be that of a commercial or hospital environment. If the user of the device requires continued operation during mains power interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted disturbances induced by RF fields
IEC 61000-4-6</td><td>3 VRMS
0,15 MHz – 80 MHz

6 VRMS in ISM bands
0,15 MHz – 80 MHz

80 % AM at 1 kHz</td><td>3 VRMS
0,15 MHz – 80 MHz

6 VRMS in ISM bands
0,15 MHz – 80 MHz

80% AM at 1 kHz</td><td rowspan="2">Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [1] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>Radiated RF EM fields
IEC 61000-4-3</td><td>3 V/m
80 MHz - 2,7 GHz
80 % AM at 1 kHz</td><td>3 V/m
80 MHz - 2,7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td>Proximity fields from RF wireless communications equipment
IEC 61000-4-3</td><td><table><tr><th>Test freq. [MHz]</th></tr><tr><td>385</td></tr><tr><td>450</td></tr><tr><td>710, 745, 780</td></tr><tr><td>810, 870, 930</td></tr><tr><td>1720, 1845, 1970</td></tr><tr><td>2450</td></tr><tr><td>5240, 5500, 5785</td></tr></table></td><td><table><tr><th>Max. power [W]</th><th>Immunity test level [V/m]</th></tr><tr><td>1.8</td><td>27</td></tr><tr><td>2</td><td>28</td></tr><tr><td>0.2</td><td>9</td></tr><tr><td>2</td><td>28</td></tr><tr><td>2</td><td>28</td></tr><tr><td>2</td><td>28</td></tr><tr><td>0.2</td><td>9</td></tr></table></td><td>Distance: 0.3 m</td></tr>
<tr><td colspan="4">Note : U_T is the AC mains voltage prior to application of the test level.

Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED and the motor speed. The maximum speed deviation is ±5%.</td></tr>
</table>

(1) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the RF compliance level mentioned above, the device should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the device.

5 Electrostatic precautions

The device contains ESD sensitive elements, appropriate handling precautions must be observed.

⚠ CAUTION

The device uses semiconductors that can be damaged by electrostatic discharge (ESD). When handling, care must be taken so that the device is not damaged. Damage due to inappropriate handling is not covered by the warranty. The following precautions must be taken:

- Do not open the protective conductive packaging until you have read the following and are at an approved anti-static workstation.
- Use a conductive wrist strap attached to a good earth ground when handling the device.
- Always discharge yourself by touching a grounded bare metal surface or approved anti-static mat before touching the device.
- Use an approved anti-static mat to cover your work surface.

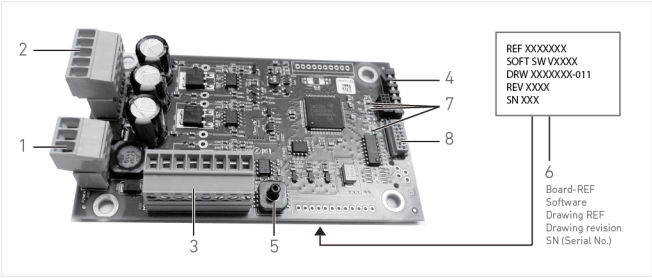


FIG. 1

6 Description

6.1 Overview

FIG. 1

The electronic board is designed to be used with a MCX motor and a MCX hose.

(1) Power supply
(2) Motor and light
(3) Analog inputs
(4) DIP switches
(5) Air pressure sensors
(6) Labelling
(7) Diagnostic LEDs
(8) RS 232

Note : *The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim.*

The original language of those instructions for use is English.

For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

6.2 Options of installation

Converter 24/32 Vdc and 24 Vdc:

REF 1500580-001

The electronic board is fed by 32 Vdc. If your system only has a 24 Vac feed, we recommend that you use this converter. This accessory enables you to obtain optimum performance from the electronic board and its connected devices, by providing two stabilised voltages: 32 Vdc (60W continuous, 130W peak) for the MCX motor feed.

Dual Motor Switch:

REF 1503075-001

We recommend this board to drive an additional micromotor. It allows switching of the 3 motor phases, the 2 light connections. The relays are switched simultaneously and controlled by the MUX Control input (24 Vdc).
To connect the dual motor switch, please consult the wiring diagram.

Exhaust air:

REF 249.39.11-001

This system is only necessary if the device is pneumatically controlled, with the air pedal in the raised position, and if the valve controlled by the pedal is not fitted with a vent. Contact your dealer for fitting.

6.3 Technical data

Technical data	
Dimensions	102 x 58 x 27 mm
Weight	approx. 53 g
Voltage	32 Vdc ±10% (min. 28.8 Vdc, max. 35.2 Vdc)
Nominal power	60 W

6.4 Classification

Class IIa in accordance with European Medical Regulation (EU) 2017/745.

6.5 Performances

No performances related to the electronic board alone. Refer to the IFU of the compatible MCX micromotors.

6.6 Operating conditions

Operating conditions		
	Temperature range:	+10°C — +35°C (+50°F — +95°F)
	Relative humidity range:	30% — 80%
	Air pressure range:	700 hPa — 1060 hPa

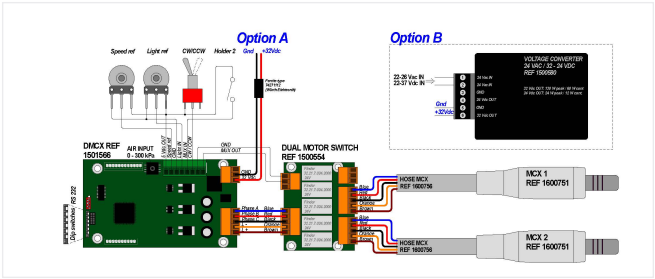


FIG. 2

7 Installation

FIG. 2

The device must be installed by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions.

In accordance with these requirements, the operators:

- Must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- Must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

7.1 Precautions to be taken during integration

⚠ **CAUTION**

- Only use a medical power supply that conforms to standard IEC 60601-1 respecting the required withstand voltage, creepage distances and distances in air.
- The DC power supply line overall length must be shorter than 3 m. The use of ferrite beads is strongly recommended. A ferrite Würth Elektronik 742 711 12 must be inserted on the supply cable of the board. In case the Bien-Air 24VAC to 32VDC converter REF 1500580 is used to power the board, a filter Schurter KFA4301.5206 must be inserted on the primary side of the transformer (230VAC).
- The secondary 32 Vdc circuit which is provided in the final application shall have a maximum transient impulse voltage of 1 kV (details see IEC 80601-2-60 cl.201.8.9.1.12 a).
- Connect the ground (GND) of all the electronic controls connected to the electronic board. This also applies to digital interfaces.
- The motor light must be powered from the electronic board.
- Do not use another power supply for the light.
- The input voltage levels can be configured via the RS-232 serial interface (document available on request).
- The overall RS-232 cable length must be shorter than 3 meters. The use of a shielded RS-232 cable is strongly recommended.
- For more information or if you have any questions about the integration, wiring configuration or programming of the MCX system, please contact your Bien-Air Dental representative.
- Only use accessories, transducers and cables specified by Bien-Air Dental SA.

FIG. 3

7.2 Operating mode selection by DIP-switches

The 6 DIP switches **FIG. 3** are used to configure the system, and in particular to select the operating mode (see table below). The system installation depends on the chosen operating mode. For more information and technical support, please contact your Bien-Air Dental dealer.

Mode	Dip Switches				Description
	1	2	3	4	
0	0	0	X	X	Electrical mode from 100 rpm to 40'000 rpm
1	0	1	X	X	Pneumatic mode with electric limitation
2	1	0	X	X	Pneumatic mode with electric limitation
3	1	1	X	X	Serial mode (RS232)
All	X	X	1	X	Status frame auto-send (1 = enabled, 0 = disabled)
All modes except 3	X	X	X	1	Light delay (1 = enabled, 0 = disabled)
Mode 3 only	1	1	X	1	Frame check (0 = checksum, 1 = CRC)

Note : *Dip switches states: 0 = OFF, 1 = ON, X = no influence.*

Main functions and controls:

- Pneumatic control
- Electric control by analog inputs or digital interface (RS-232)

Control with up to two MCX motors (using Dual Motor Switch REF 1503075-001)

- The system variable parameters are as follows:
    - Speed range 1000 – 40'000 rpm (maximum torque of over 2.0 Ncm available across the full speed range)
    - Progressive or ON/OFF mode speed adjustment
    - Brightness control (16 settings) or light ON/OFF
    - Reversal of rotation direction (clockwise/anti-clockwise)

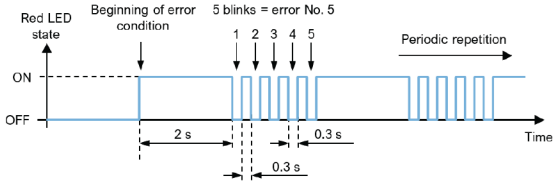
7.3 General wiring diagram

The general wiring diagram shows all the main connections of the complete MCX system. The connections required depend on the integration of the MCX system in the unit and the desired functions. The following table describes the main characteristics of each connection described in the wiring diagram.

Description ref.	Diagram	Specification	Notes
DMCX REF 1501566-001			
Voltage	Input	32 Vdc +/- 10%	
Speed reference	Input	0 to 5 Vdc (linear)	Pull-down Input
MUX IN Motor	Input	0 or 5 Vdc (TTL)	Pull-down Input
Rotation (CW/CCW)	Input	0 or 5 Vdc (TTL)	Pull-down Input
Brightness	Input	0 or 5 Vdc (16 output levels)	Pull-up Input
Pneumatic pressure reference	Input	0 to 3 bar (0 to 300 kPa, 0 to 43.5 psi)	
Motor Power	Output	Phases A, B, and C	
Motor Light	Output	L+/L-	
MUX OUT Motor	Output	24 Vdc, Max. current = 100mA	
RS-232		Digital interface	
Voltage converter REF 1500580-001			
Voltage	Input	22 to 27 Vac or 22 to 37 Vdc	
Voltage	Output	24 Vdc (24W peak/ 12W cont)	
Voltage	Output	32 Vdc (130W peak/ 60W cont)	
Dual Motor Switch REF 1503075-001			
IN motor	Input	3 motor phases: A, B, C (Max. current = 6A) 2 light connections L+, L- (Max. current = 3A)	Max. relay current
MUX Control	Input	24 Vdc, 200mW	Max. relay current
EV In	Input	Solenoid valve input (24 Vdc)	
OUT motor 1	Output	3 motor phases: A, B, C (Max. current = 6A) 2 light connections	Max. relay current
OUT motor 2	Output	3 motor phases: A, B, C (Max. current = 6A) 2 light connections	Max. relay current

ENG

7.4 Fault list and installed protection



The electronic board includes 3 diagnostic LEDs (see FIG. 1 point 7=Diagnostic LEDs).

Power ON:

The green LED lights up when the board is powered on

Diagnostic:

The red LED flashes (1-7 times) when a fault occurs (see fault list)

RS232 Communication:

The amber LED flashes during RS232 communication

As long as the error is present, the red LED repeats the error code according to the following diagram.

Fault list:

Fault 1: Short circuit in motor or cord

Fault 2: Motor phase disconnected in motor or cord

Fault 3: RS232 communication cut

Fault 4: EEPROM memory fault

Fault 5: Motor control overheating

Fault 6: Motor control voltage too low

Fault 7: Motor control voltage too high

Embedded Protection:

Temperature:

The electronic board temperature is continuously controlled by the software.

Power supply:

The electronic control system is protected against over-and undervoltage.

Motor and light:

The motor output (phases) is protected against short circuits.
The light output is protected against short circuits.
Interruption of one, two or three phases is detected by the system, and the motor either does not start or stops.

⚠ **CAUTION**

The electronic board does not feature any polarity inversion protection on the +32 V input. Reversing +32 V and GND may cause permanent damages to the hardware.

8 Maintenance and servicing

8.1 Maintenance

No maintenance can be performed on the device.

8.2 Servicing

Never dismantle the device.
For all servicing and repairs, it is recommended that you contact your usual supplier or Bien-Air Dental directly.

9 Transport - Storage & Disposal

9.1 Transport and storage

Transport conditions		
	Temperature range:	-20°C — +50°C (-4°F — +122°F)
	Relative humidity range:	5% — 80%
	Air pressure range:	650 hPa - 1060 hPa
	Keep away from rain	

Storage conditions		
	Temperature range:	0°C — +40°C (32°F — 104°F)
	Relative humidity range:	10% — 80%
	Air pressure range:	650 hPa — 1060 hPa
	Keep away from rain	

9.2 Disposal

This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2012/19/EU).

10 General information

10.1 Terms of guarantee

Bien-Air Dental SA grants the operator a guarantee covering all functional defects, material or production faults.

The warranty period is:
- 12 months from the date of invoicing.

In the event of justified claim, Bien-Air Dental or its authorised representative will fulfil the company's obligations under this guarantee by repairing or replacing the product free of charge.

Any other claims of any kind whatsoever, particularly claims for damage or injury and the consequences thereof resulting from:

- Excessive wear and tear
- Infrequent or improper use
- Failure to observe the servicing, assembly or maintenance instructions
- Damage caused by unusual chemical, electrical or electrolytic influences
- Faulty air, water or electrical connections

⚠ **CAUTION**

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized by Bien-Air Dental SA. Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

11 References

11.1 Set supplied (see cover page)

REF	Designation
1600811-001	Set DMCX

REF	Legend
1302410-001	Upper cover
1302411-001	Lower cover
1500579-001	Cable RS-232. L=30 cm
1500580-001	Converter 24/32 Vdc and 24 Vdc
1501566-001	Electronic DMCX
1503075-001	Dual Motor Switch
1600751-001	Micromotor MCX LED, with internal spray and LED
1600756-001	MCX hose, grey silicone (L=1.7m)
1600780-001	Micromotor MCX, with internal spray without light
1600824-001	B-MCX hose, grey silicone, bayonet connection to unit (L=1.7m)
1601081-001	MCX hose, grey silicon, 400° (L=1.7m)
1601096-001	MCX hose, grey silicon, 400°, ⌀20.2x40 (L=1.7m)
249.39.11-001	Exhaust air

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REF 2100253-0005/2023.12