



Braemar, Inc.

DXP1000 7Day

Operator Manual



Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Braemar Limited Warranty

Braemar products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Braemar to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, leadwires, patient cables and batteries. This warranty does not apply to any product that Braemar determines has been modified or damaged by the customer.

Except for the express warranties stated above, Braemar disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of Braemar for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of Braemar products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

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Table of Contents

Overview	2
Description	2
Indications for Use	2
Monitor Components	3
Precautions	4
Electrode Application	4
Electrode Placement	5
3 Channel (7 lead) Electrode Placement	5
3 Channel (5 lead) Electrode Placement (1 st option)	6
3 Channel (5 lead) Electrode Placement (2 nd option)	7
2 Channel (5 lead) Electrode Placement	8
Operation	9
How to Record	9
Recording Display	10
Patient Event Marker	10
Early Out	10
How to Download ECG recording	10
Service & Maintenance	11
Maintenance	11
Service	11
Service Items & Accessories	11
Equipment Symbols	12
Troubleshooting	13
Specifications	14
Electromagnetic Emissions	15
Electromagnetic Immunity	15
Recommended Separation Distances	18

Overview

Description

The DXP 7 Day Holter monitor is a battery operated solid state recorder designed for 1, 2, or 7 day continuous recording of ambulatory ECG data and the ability to detect and record pacemaker pulses in accordance with appropriate AAMI pacemaker detection criteria.

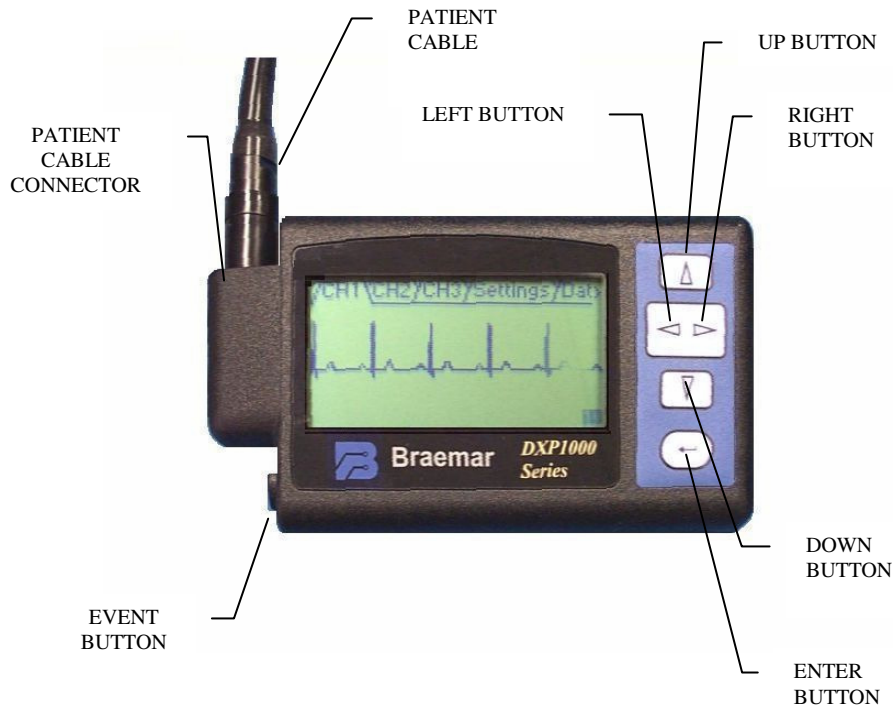
The DXP 7 Day is an AAMI Type I device, which is part of a conventional AECG monitoring system where the ECG is recorded on Flash memory resident in the DXP 7 Day. After the recording is complete, the DXP 7 Day is connected, via the USB cable, to the USB port on the Computer Analysis System. By following the instructions provided with your Computer Analysis System, the recorded ECG data is then down loaded and analyzed. The DXP 7 Day is compatible with Windows 98SE or higher and only computers complying with EN60950-1 should be used.

Indications for Use

The DXP 7 Day Holter recorder is intended for patients requiring ambulatory (Holter) monitoring from 1 to 7 days. Such monitoring is most frequently used for the indications below:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.
6. Evaluation of patients with pacemakers.
7. Reporting of time and frequency domain heart rate variability.
8. Reporting of QT Interval.

Monitor Components



Precautions

- Patient leads must be removed from electrodes before defibrillation.
- When using Pacer Detect, the physician should be aware that false positive and false negative pacer detects may occur.
False positives - may result from poor electrode hook-up or high noise conditions.
False negatives - may occur with bipolar pacers due to a weak pacer pulse signal at the patient's skin surface.
- When reviewing ECG data the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- Observe local laws for disposal of alkaline batteries.
- Do not leave the batteries in the recorder when it is not in use. Damage from corrosion could result.
- For the best recording results, the patient should be instructed to avoid close proximity to heavy electrical equipment or other sources of electromagnetic interference such as electric blankets, heating pads etc.
- No automatic analysis algorithm can replace data review by a qualified physician. Review and confirmation of analysis results is required.

Electrode Application

- It is recommended that trained medical personnel handle the application of electrodes.
- Use only electrodes designed for longer term Holter monitoring.
- Proper preparation of the patient's skin is absolutely essential for obtaining a quality ECG recording. Refer to your electrode provider for instructions on skin preparation techniques.
- Apply electrodes per Electrode Placement diagrams in this manual or as instructed by the physician.

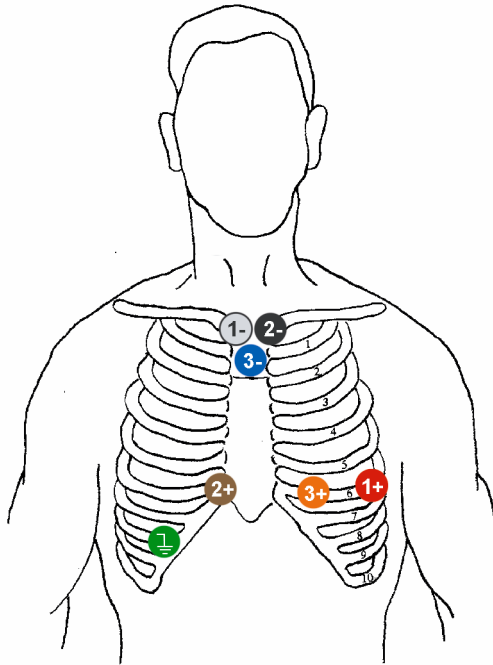
Additional equipment classification information as required in EN 60601-1

- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of WITH OXYGEN OR NITROUS OXIDE
- IPX0 Ordinary Equipment (enclosed equipment without protection against ingress of water)
- Internally Powered Equipment
- Mode of Operation - Continuous Operation

Electrode Placement

3 Channel (7 lead) Electrode Placement

Seven color-coded leadwires are utilized to create a 3-channel ECG recording. This is a typical electrode placement, refer to Analysis System software and the physician for recommended positioning.

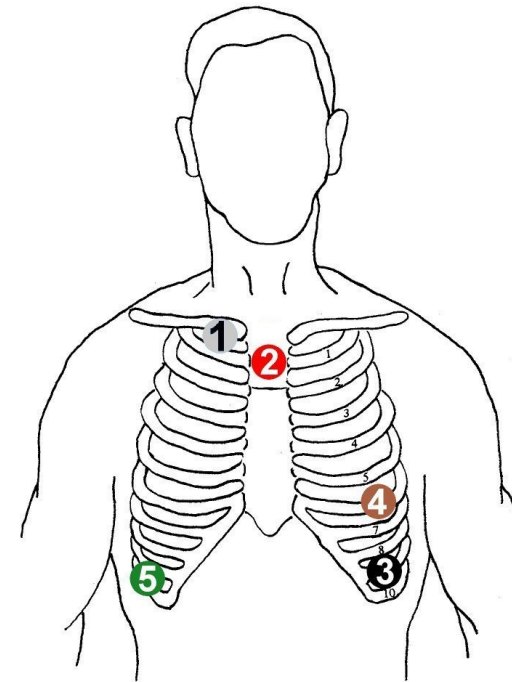


7 Lead Electrode Placement

Channel	Color	Placement
1-	White	Right Manubrial border of the Sternum.
1+	Red	Left Anterior Axillary line 6 th rib.
2-	Black	Left Manubrial border of the Sternum.
2+	Brown	Approximately 1 inch right of Xiphoid Process on the rib.
3-	Blue	Center of the Manubrium.
3+	Orange	Left Mid-Clavicular line 6 th rib.
⏚	Green	Lower right rib margin over bone.

3 Channel (5 lead) Electrode Placement (1st option)

Five color-coded leadwires are utilized to create a 3-channel ECG recording. This is a typical electrode placement, refer to Analysis System software and the physician for recommended positioning.

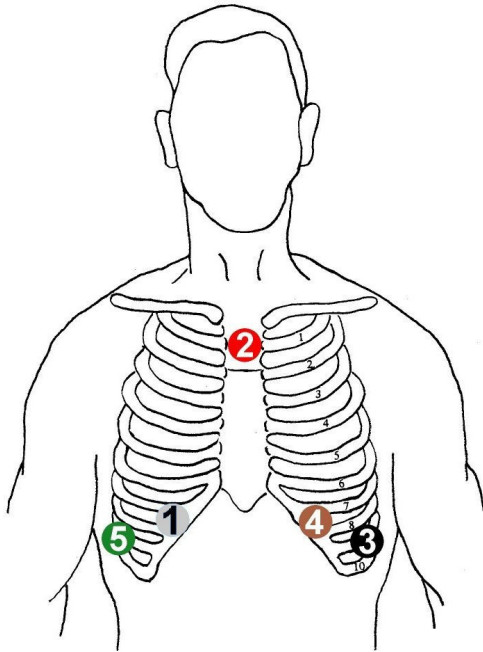


5 Lead Electrode Placement

#	Channel	Color	Placement
1	3-	White	Next to the right Manubrium border on the Clavicle
2	1-, 2-	Red	Centered on the Manubrium
3	2+, 3+	Black	Lower left rib margin over bone.
4	1+	Brown	Left Anterior Axillary line on the 6 th rib
5	⏚	Green	Lower right rib margin over bone.

3 Channel (5 lead) Electrode Placement (2nd option)

Five color-coded leadwires are utilized to create a 3-channel ECG recording. This is a typical electrode placement, refer to Analysis System software and the physician for recommended positioning.

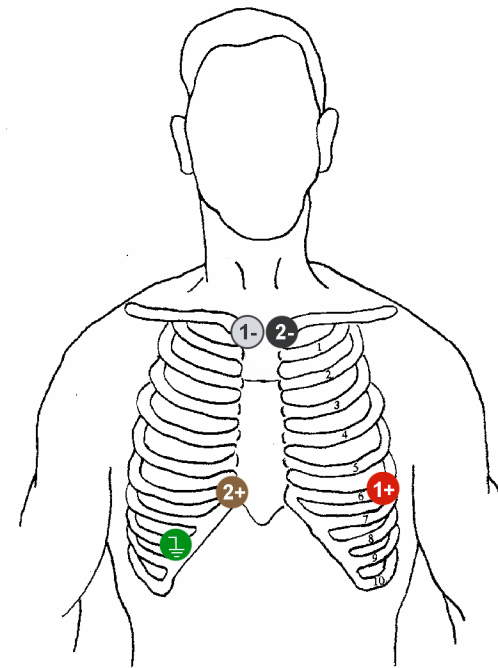


5 Lead Electrode Placement

#	Channel	Color	Placement
1	3-	White	Right side below the V1 position, at the bottom of the rib cage
2	1-, 2-	Red	Center on the Manubrium, the top of the sternum
3	2+, 3+	Black	Left side at the V5 position, on a rib
4	1+	Brown	Left side at the V3 position, on a rib
5	⊥	Green	Right side opposite V5 position.

2 Channel (5 lead) Electrode Placement

Five color-coded leadwires are utilized to create a 2-channel ECG recording. This is a typical electrode placement, refer to Analysis System software and the physician for recommended positioning.



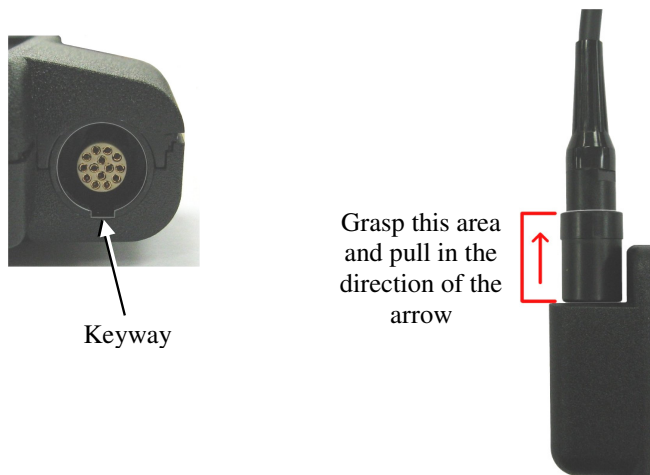
5 Lead Electrode Placement

Channel	Color	Placement
1-	White	Right Manubrial border of the Sternum.
1+	Red	Left Anterior Axillary line 6 th rib.
2-	Black	Left Manubrial border of the Sternum.
2+	Brown	Approximately 1 inch right of Xiphoid Process on the rib.
⊥	Green	Lower right rib margin over bone.

Operation

How to Record

1. Install two fresh **lithium** batteries in the DXP 7 Day if you want a 7 day recording. Otherwise Alkaline batteries listed in the back of this manual will provide 1 or 2 day recording.
 - Be sure to observe the correct battery polarity.
2. Hook up the patient to the device via the patient cable and leadset. While observing the keyway of the plug, insert the patient cable directly into the receptacle of the DXP 7 Day until it snaps into place. *When removing the cable, grasp the outer shell of the plug and pull straight away from the receptacle – this will release the locking mechanism of the plug.*



3. To turn on the recorder push any one of the keypad buttons. A splash screen will be displayed for a couple seconds, then the trace screen will be displayed.
 - The device will not turn on unless a cable is plugged in.
4. Push the ◀ or ▶ keypad buttons to change the active screen.

Screen	Description
Trace	Displays the signal trace in real time, and pacemaker pulse marks if selected. There is one screen for each ECG channel. <ul style="list-style-type: none"> • <i>Pacemaker pulse marks are displayed below the trace to indicate each pacemaker pulse detection.</i>

Settings	For setting the record time, user language, LCD contrast and selecting pacemaker detect. To change settings Press “enter” button for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◀ and ▶ buttons. Push “enter” again to save and exit. <ul style="list-style-type: none"> • <i>The default for pacemaker detect is OFF. It must be turned ON for each procedure in which it will be used.</i>
Date/Time	For setting the date and clock. To set the clock – Press “enter” for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◀ and ▶ buttons. Push “enter” again to save and exit.
About	Unit information and Copyright notice
Start	After configuring or reviewing all the settings select the start screen and push the “enter” button. This will start the recording.

Recording Display

During recording the DXP 7 Day displays the current time and time remaining to record.

Patient Event Marker

To register an event, push the event button.

Early Out

The DXP 7 Day supports an Early-Out feature that allows a trained individual to stop a recording before the selected recording time has elapsed. To initiate an Early-Out hold the ◀ button and event button simultaneously.

How to Download ECG recording

1. Connect the DXP 7 Day to the computer system, with the Holter Analysis Application, via the USB cable.
2. Refer to the instructions provided with your Holter analysis system.



Service & Maintenance

Maintenance

Cleaning

Dampen a soft cloth with mild detergent and water to clean the recorder, lead wires, and belt clip. Remove the batteries before cleaning the recorder.

Replacing Belt Clip and Battery Cover

To replace the belt clip:

1. Insert a coin (e.g., a dime) into the elongated slot and press down on the molded latch.
2. Pull the belt clip down until it is free.
3. Install a belt clip by aligning the two slots of the clip along the frame.
4. Slide the clip upward until it locks (with a clicking sound).

Replacing a Battery Cover

To replace a broken battery cover:

1. Align the new cover perpendicular to the recorder battery compartment ledge.
2. Place one hinge pin into the enclosure pivot hole and slide the opposite pin forward until it snaps into the other pivot hole.

Service






If there is a problem with the monitor, review the problem descriptions and solutions listed on the next page. If additional assistance is required contact customer support via phone, Fax or E-mail listed below. Call customer support before returning a recorder to make shipping arrangements.

Service Items & Accessories

Description	Part Number
Battery cover	100-1554-001
Belt clip	100-1555-001
Patient lead set 7 wire, 18"	200-1963-001
Patient lead set 5 wire, 18"	200-1963-002
Patient cable 3CH-7LD	350-0181-00
Patient cable 2CH-5LD	350-0181-02
Patient cable 3CH-7LD, 12"	350-0181-05
Patient cable 3CH-5LD	350-0181-06
USB cable	350-0185-00
Operator manual	600-0622-01



Equipment Symbols

Symbol	Description
	Type Applied Part
	Consult manual.
	Complies with the Medical Device Directive of the European Union.
	This product may only be disposed of through a government approved collection scheme or treatment facility.
	Year of Manufacture
SN	Serial Number
REF	Not shown - catalogue number is DXP 7 Day

Manufacturer: Braemar, Inc.

1285 Corporate Center Drive, Suite 150
Eagan, MN 55121 USA

Phone: 800.328.2719

651.286.8620


Fax: 651.286.8630

E-mail: service@braemarinc.com

Web: <http://www.braemarinc.com>

Authorized European Rep:

QNET BV

 Hommerterweg 286
6436 AM Amstenrade
The Netherlands



Troubleshooting

Symptom	Recommended Solution
No display	Ensure patient cable is connected.
	Ensure batteries are inserted with correct polarity.
	Install two new batteries
Low battery	Inspect battery compartment, clean contacts if necessary.
	Install two new batteries.
Unit does not last 7 days	Ensure two new lithium batteries are being used.
	Ensure 512MB CF Card is used
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to the patient.
	Replace the lead set.
No splash screen when connected to USB	Ensure USB data cable is connected to the DXP and PC.
	Ensure PC is powered on.
	Replace USB data cable.
Initializing Card message	The monitor memory is being setup to make a new recording.



Specifications

Functional

Channels	3
Resolution	8 bits
Recording	Full disclosure
Download interface	USB
Sample rate	128 or 133 / sec
Frequency response	0.05Hz to 60Hz, -3dB
Signal verification	LCD display
Pacemaker Detection	YES

Memory

Recording time	1, 2, or 7 days (24, 48, or 168 hrs)
Type	Flash
Capacity	512MB

Physical

Dimensions	2.75" x 4.37" x .80" (69.9mm x 111mm x 20.3mm)
Weight with batteries	6 oz. (170 grams)
Enclosure	Molded plastic (UL 94V-0)
Operating position	Any orientation

Electrical

Gain settings	1X
Connector	14 pin round
Patient cable	7 or 5 pin yoke

Environmental

Operating temperature	0°C to +45°C
Non-operating temperature	-20°C to +65°C
Operating humidity	10% to 95% (non-condensing)
Non-Operating humidity	5% to 95%

Battery

Type	(2) Energizer AA Lithium - L91
Life	7 Days (or)
Type	AA Alkaline IEC-LR6
Life	1, 2 Days

Warranty


12 months from shipment

Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DXP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DXP is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = 1.2 \sqrt{P}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800MHz, the higher frequency range applies.
 NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Refer to the following table for recommended separation distances between the DXP and portable and mobile RF communications equipment.

The DXP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the DXP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DXP as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



Braemar Inc.

*1285 Corporate Center Drive, Suite 150
Eagan, MN 55121 USA*

Phone: 800.328.2719

Fax: 651.286.8630

E-Mail: Service@BraemarInc.com

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