Braemar, Inc.

DL800

Operator Manual

Caution: US 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, which 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.

For service or technical support contact
your local supplier or Braemar.

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Overview

Description

The DL800 Holter Monitor is a battery operated solid state recorder designed for 24, 48, or 72 hour continuous recording of ambulatory ECG data and the ability to detect and record pacemaker pulses in accordance with appropriate AAMI pacer detection criteria.

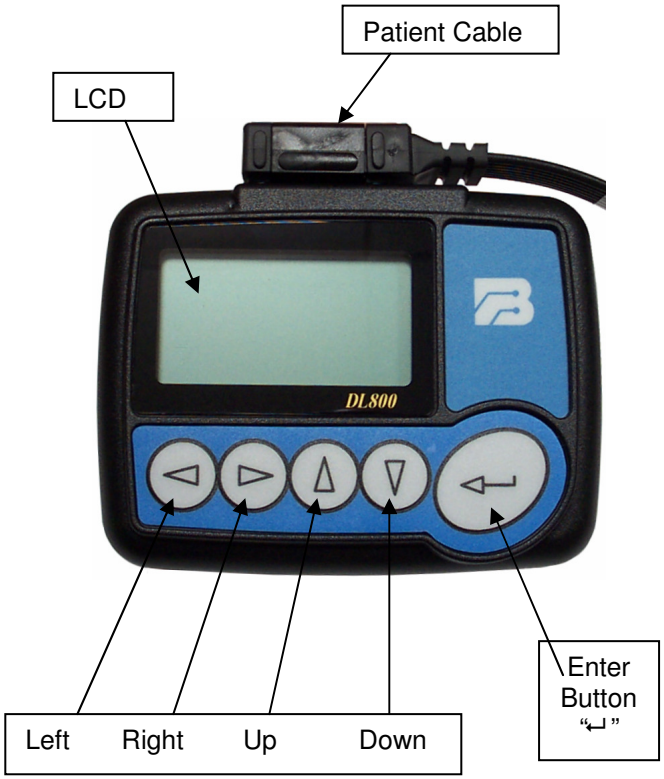
The DL800 is an AAMI Type I device, which is part of a conventional AECG monitoring system where the ECG is recorded on a Compact Flash memory card installed in the DL800. After the recording is complete, the Flash memory card is removed and placed in a Card Reader connected to the Computer Analysis System. Follow the instructions provided with your Computer Analysis System to download and analyze the recorded ECG data. The DL800 is compatible with Windows 98SE or higher and only computers complying with EN60950-1 should be used.

Indications for Use

The DL800 Holter Monitor is intended for patients requiring ambulatory (Holter) monitoring from 1 to 72 hours. 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 monitor 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.

Additional equipment classification information as required in EN 60601-1

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

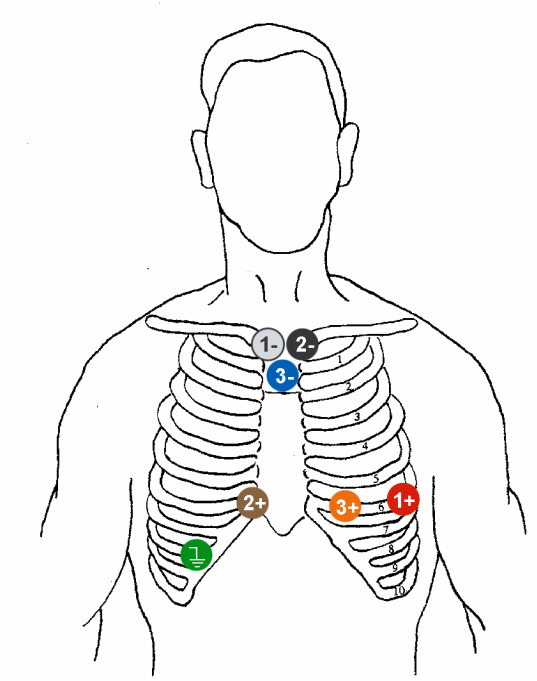
Electrode Application

- 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.

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.



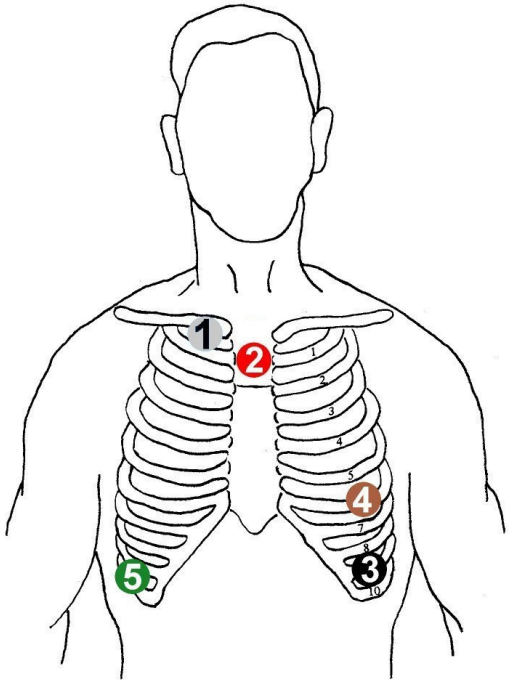
7 Lead Electrode Placement

Channel	Color	Placement
1-	White	Right Manubrial border of the Sternum.
1+	Red	Left Anterior Axillary line 6th 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 6th 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.

Caution: Use this placement and patient cable only with firmware version 4.0.3936 or greater.



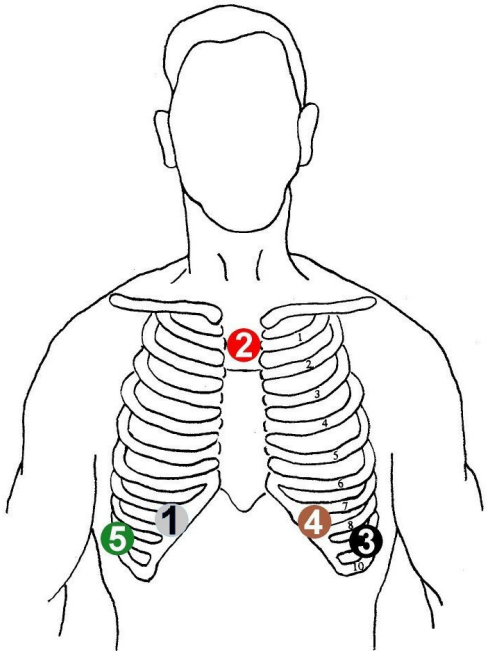
5 Lead Electrode Placement

#	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 6th 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.

Caution: Use this placement and patient cable only with firmware version 4.0.3936 or greater.

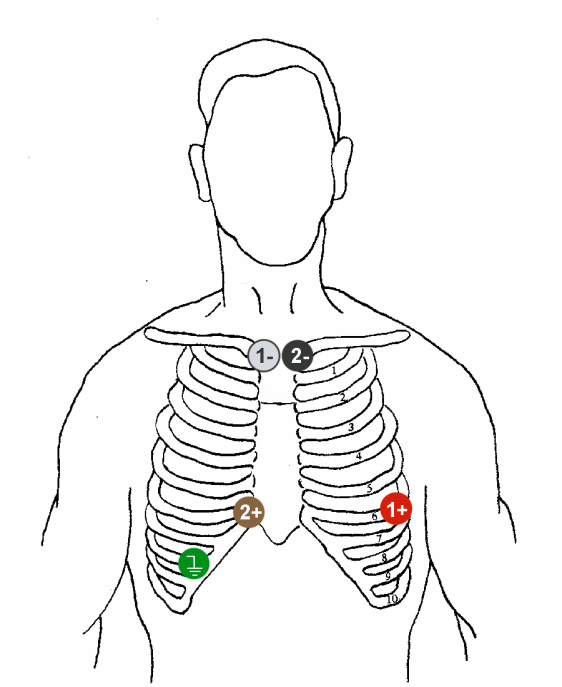


5 Lead Electrode Placement

#	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 6th 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 Flashcard observing correct insertion direction and method.

   NOTE: The DL800 is only compatible with Braemar, Inc. Certified CompactFlash Card, refer to Service & Maintenance for ordering a replacement.

2. Install fresh battery in the DL800.
   - Be sure to observe the correct battery polarity.
3. Hook up the patient to the device via the patient cable.

   NOTE: Insert patient cable in the orientation as shown in the picture on page 2. The patient cable will require a very firm squeeze on the locking clip of the cable plug in order to install or remove it from the DL800. However, it only needs to be removed in the event of damage or for convenience of storage.

4. To turn on the monitor push any one of the keypad buttons. A splash screen will be displayed for a couple seconds, then the trace screen will be displayed for CH1 through 3.
   - The device will not turn on unless a cable is plugged in.
5. Push the "◄" and "►" keypad buttons to change the active screen.
6. To input Patient ID choose "ID" from the tabs at the top of the screen. Scroll numerical line for Patient ID using ◄, ► , ▲, and ▼ buttons. "↵" button selects each entry of Patient ID.
   - The monitor will automatically start recording data 30 minutes after the battery and Compact Flash card are inserted.
7. **It is recommended that, after the patient hookup is complete, the device be inserted in the DL800 pouch to be worn by the patient either on the belt or with the shoulder strap.**

Screen	Description
ID	Used to enter the Patient ID
CH1 CH2 CH3	Displays the signal trace in real time, pacer pulse marks | if selected, and allow the gain to be set via the ▲ and ▼ buttons. There is one screen for each ECG channel. • *The gain setting is the same for all channels. Changing the gain on any channel affects all channels.* • *Pacer pulse marks | are displayed below the trace to indicate each pacer pulse detection.*
Settings	For setting the record time, user language, LCD contrast and selecting pacer detect. To change settings, Press "←" button for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◄ and ► buttons. Push "↵" again to save and exit. • *The default for pacer detect is OFF. It must be turned ON for each procedure in which it will be used.*
Date/Time	For setting the date and clock. To change the date screen, Press "↵" for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◄ and ► buttons. Press "↵" a second time to change to the time screen and follow the same procedure to set the time. Press "↵" again to save and exit. NOTE: Daylight savings time uses the USA convention.
About	Monitor information and Copyright notice
Start	After configuring or reviewing all the settings select the start screen and push the "↵" button. This will start the recording.

Previous Patient Data Erasure

Previous patient data erasure occurs when a CompactFlash Card, battery, and patient cable are properly installed and ANY button is pressed to power on the unit.

New patient data is written to the CompactFlash Card when starting a new recording. (On the "Start" tab, "Press '↵' to start recording") This is a safety design feature to ensure that recorded patient data always matches patient data and ID information.

Recording Display

During recording the DL800 displays the current time and time remaining to record.

Patient Event Marker

To register an event, push the ↵ button.

Early Out

The DL800 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◄ arrow button and ↵ button simultaneously.

Session Complete

Remove the Flash memory card and patient electrodes. Remove and properly dispose of the alkaline battery according to local laws. If it is desirable to remove the leads from the patient input connector, then, due to their snugness of fit in this connector, it is suggested that the medical technician carefully grip these leads only at the base whenever removing them. NEVER pull on the wire itself as this can easily break the wire inside the insulation causing a noisy and intermittent ECG recording.

Analyzing the ECG Data

Insert the Flash memory card into the Flash card reader of the Computer Analysis System on which the ECG analysis is to be performed.

The Computer Analysis System must have special download software installed to transfer the ambulatory ECG data from the Flash memory card to the Analysis System. Once the data transfer is complete, the previous patient's name and any other information written on the Flash memory card's label should be removed and the ECG data should be erased.
The Flash memory card is now free to be used for the next patient.

Troubleshooting

Symptom	Recommended Solution
No display	Ensure battery is inserted with correct polarity.
	Ensure patient cable is connected. Then press "↵"
	Install new battery
Low battery	Inspect battery compartment, clean contacts if necessary.
	Install new battery.
Battery does not last 24, 48, or 72 hours	Ensure new battery is being used.
	Ensure the CompactFlash card is approved by the vendor.
	Use a Lithium battery for 72 hours.
Cannot select 72 hour recording	A 256MB CompactFlash card is required for 72 hour recordings.
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to the patient.
	Replace the lead set.
Defective Card Message	The CompactFlash card is not usable by the monitor. Use a different card.
	If multiple cards are defective, call for service.

Service & Maintenance

Maintenance

Cleaning

Dampen a soft cloth with mild detergent and water to clean the monitor, lead wires, and belt clip. Remove the battery before cleaning the monitor. Battery is to be removed from the monitor when the monitor is not in use.

For best results, Braemar recommends following the ANSI/AAMI EC53 guidelines, Section 4.3.1 guidelines for cleaning our devices and cables: The device and patient leadwires should be cleaned with the following materials:

- Green soap, green soap tincture (U.S. Pharmacopeia) or alcohol-free hand soap
- Sodium hypochlorite (bleach) solution 10% in water
- Isopropyl alcohol may also be used on the monitor but **may not** be used on the lead wires.
- Odorless mineral spirits may be used to clean the lead wires.

Service

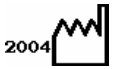
If there is a problem with the monitor, review the problem descriptions and solutions listed on the previous page. If additional assistance is required contact customer support via phone, Fax or E-mail listed on the next. Call customer support before returning a monitor to make shipping arrangements.

- Note there isn't any preventative inspection or maintenance that can be performed by the end user.

Service Items & Accessories

Description	Part Number
Battery cover	100-1654-001
Belt clip	100-1555-001
Patient cable 7 lead 3 channel	350-0235-00
Patient cable 5 lead 3 channel	350-0235-02
Patient cable 5 lead 2 channel	350-0235-01
Operator manual	600-0597-00
Braemar Certified 64 MB CF Card	350-0252-00
Braemar Certified 128 MB CF Card	350-0252-01
Braemar Certified 256 MB CF Card	350-0252-02
Pouch with shoulder strap	100-1695-001

Equipment Symbols

Symbol	Description
	Type B Applied Part
	Consult manual.
CE 0086	Complies with the Medical Device Directive of the European Union.
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
	Year of Manufacture
SN	Serial Number
REF	Not shown - catalogue number is DL800

Manufacturer:
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Authorized European Rep:
QNET BV
EC REP
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Specifications

Functional

Channels	3
Resolution	8 or 10 bits depending on config
Recording	Full disclosure
Download interface	Flash Card Reader
Sample rate	128/sec-256/sec depending on config
Frequency response	0.05Hz to 60Hz, @ -3dB
Signal verification	LCD display
Pacemaker Detection	Programmable on/off (default off)

Memory

Recording time	24, 48, 72 hours
Type	Flash
Model, **DL 800**	
Capacity	64MB Minimum

Physical

Dimensions	3.75” x 3.00” x 0.90”
Weight with batteries	4 oz. (114 grams)
Enclosure	Molded plastic (UL 94V-0)
Operating position	Any orientation

Electrical

Gain settings	1/2X, 1X and 2X
Connector	20 pin
Patient cable	7 lead

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 (qty1)	AA Alkaline IEC-LR6	AA Lithium L91
Maximum Life	48 hours	72 hours

Warranty 12 months from shipment

Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DL8 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 DL8 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
			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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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: 

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 DL8 and portable and mobile RF communications equipment.

The DL8 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the DL8 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DL8 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.

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