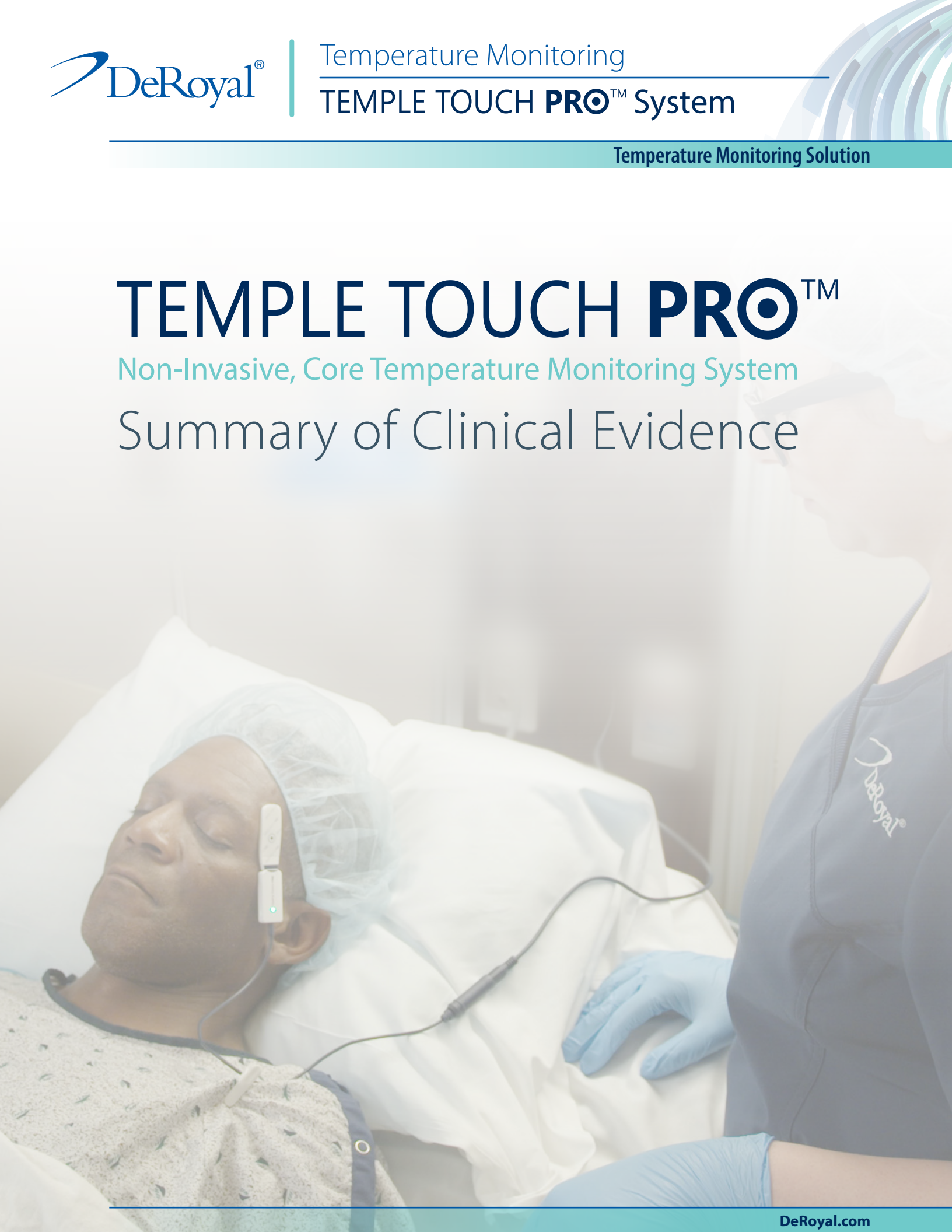
TEMPLE TOUCH PRO™

Non-Invasive, Core Temperature Monitoring System

Summary of Clinical Evidence



TEMPLE TOUCH PRO™ System Summary of Clinical Evidence

Evaluation of the Temple Touch Pro™, A Novel Non-invasive Core Monitoring System (Peer Reviewed Paper; 2017)[1]

N=50

Esophageal & Nasopharyngeal

Adult & Pediatric (Age 0-75 years)

Methods:

The study evaluates the Temple Touch Pro System compared to esophageal and nasopharyngeal temperature monitoring in adult and pediatric patients (age: 0 – 75) undergoing elective surgery.

Findings:

Paired temperature readings differed less than 0.5ºC 94% of the time, supporting the Temple Touch Pro System as an acceptable alternative to the more invasive esophageal and nasopharyngeal locations in pediatric and adult patients.

Bland Altman Analysis

- Esophageal: -0.027 bias (95% limits of agreement: -0.58 to 0.53ºC)
- Nasopharyngeal: 0.031 bias (95% limits of agreement: -0.58 to 0.64ºC)

The limits of agreement for the esophagus show less variation in temperature compared to the nasopharyngeal. Overall, the limits of agreement show clinicians that the Temple Touch Pro System provides accurate temperature measurements compared to the more established esophageal and nasopharyngeal locations.

PETER-PAN Study (Poster Presentation; 2022)[2,3]

N=100

Esophageal

Pediatric (Age <6 years)

Background:

Pediatric patients experience an increased risk of adverse perioperative thermal regulation.

Methods:

This study evaluates the Temple Touch Pro System compared to esophageal temperature monitoring in pediatric patients (< 6 years of age; > 30 minutes of general anesthesia). Surgery types include: general or urology, trauma or orthopedic, neurosurgery, and five other surgeries.

Findings:

Paired temperature readings differed less than 0.5ºC 85.3% of the time and limits of agreement indicating accuracy compared to esophageal readings, supporting the Temple Touch Pro System as an acceptable alternative to the more invasive esophageal locations in pediatric patients. Study found that accounting for a 13 minute equilibration period improved Bland-Altman analysis outcomes.

Bland-Altman Analysis

- Before Equilibration: -0.07 bias (95% limits of agreement: -1.00 to 0.85ºC)
- After Equilibration: -0.04 bias (95% limits of agreement: -0.68 to 0.60ºC)

Validation of Core Temperature Measurement with Temple Touch Pro™ Using Body Surface Sensors in Pediatric Surgery (Conference Poster 2022)[5]

N=17

Rectal

Pediatric

Background:

Non-invasive surface core temperature monitoring is ideal for small pediatric patients. Pediatric patients are at higher risk for perioperative hypothermia. However, the use of standard temperature probes involves a higher risk of iatrogenic injury (e.g., laceration) in pediatrics due to the smaller anatomy.

Methods:

This study evaluates the Temple Touch Pro System compared to rectal temperature monitoring in pediatric patients (Age: 6 months - 5 years; average of 2 years and 10 months).

Findings:

Bland Altman Analysis:

- Rectal: Bias 0.42ºC (95% Limits of Agreement: -0.32 to 1.16 ºC)

The Temple Touch Pro System measurements trend towards a higher measurement because rectal temperature measurements lag actual core temperature.

Rectal location does not represent the best location for core monitoring. Rectal location can read low during laparoscopic abdominal surgery (Laparoscopic Surgery n=8). In a single case (1 month old), the authors demonstrated the utility of the Temple Touch Pro System for monitoring a patient whose anatomy required surgery prevented rectal and esophageal temperature monitoring. The authors demonstrate that they maintained normothermia of the patient throughout the procedure to correct anatomical defects.

The authors conclude that the Temple Touch Pro System better represents core temperature compared to rectal temperature monitoring.

Comparison of Pharyngeal Temperature and Temple Touch Pro™ in Robot-assisted Laparoscopic Total Prostatectomy (Conference Poster 2020)[6]

N=55

Nasopharyngeal

Adult

Background:

Robot-assisted laparoscopic total prostatectomy prevents monitoring temperature in the bladder and rectum. Laparoscopic surgery may influence temperature readings in the esophagus, forcing the use of the nasopharyngeal cavity. The Steep Trendelenburg Positioning (STP) increases risk that the nasopharyngeal probe may shift away from correct positioning.

Methods:

The study evaluates the Temple Touch Pro System compared to nasopharyngeal temperature measurements recorded at 10 points (surgery start, start of STP, 30, 60, 90, 120, 150, and 180 minutes after STP, release of STP, and end of surgery) in surgery on adult patients.

Findings:

Thirty-one nasopharyngeal measurements compared to ten Temple Touch Pro System measurements considered outliers ($p = 0.001$). The Temple Touch Pro System and nasopharyngeal temperature readings were similar at all time points except at the 30 and 60-minute time point. Authors conclude that the Temple Touch Pro System provided more stable measurements over the course of procedures.

Verification of the Effectiveness of Body Temperature Measurement Using TEMPLE TOUCH PRO, a Continuous Body Temperature Monitoring System Using a Body Surface Sensor, in Intensive Care Management of Infants and Young Children[9]

N=29

Axillary

Newborn & Infant

Background:

Monitoring core temperature in critical care areas typically requires invasive probes placed in the rectum, esophagus, or bladder. Critical care units must use non-continuous but non-invasive methods such as axillary temperature, as used in this study, or temporal scanners. Manual, non-continuous temperature monitoring is also susceptible to human error during measurement, and its overall accuracy is questioned in the literature. In critical care, the ability to detect clinically significant changes in core temperature is essential for identifying pathological changes and allowing earlier diagnosis and treatment. The Temple Touch Pro (TTP) System offers a potential alternative to both manual non-continuous and invasive continuous temperature monitoring methods. Results from this study demonstrate that TTP can provide accurate, continuous temperature monitoring in a critical care setting, even for the smallest patients, including those requiring infant warmers for temperature management.

Methods:

The study evaluates the Temple Touch Pro (TTP) system in pediatric patients 0 -13 months admitted to a surgical intensive care unit compared to axillary temperature measurements taken every 1 – 2 hours. Patient types included sedated (n=7), awake non-intubated patients (n=12), and patients in infant warmers (n=10). Measurement pairs were analyzed using Pearson correlation and Bland-Altman Analysis.

Findings:

Overall (315 temperature pairs), the Pearson correlation coefficient was 0.830 and Bland-Altman analysis showed a bias of 0.05 OC and 95% limits of agreement (LOA): -0.72 - 0.82 OC. For awake patients with 195 temperature pairs, the Pearson correlation coefficient was 0.700 with a bias of 0.01 OC and 95% LOA:-0.81 – 0.82 OC. In infants under 5 kg and warmed in an incubator, the Pearson correlation coefficient was 0.877 with a bias of -0.02 and a 95% LOA of -0.67 – 0.64 OC.

Usefulness of Temperature Monitoring System Temple Touch Pro™ in Off-pump Coronary Artery Bypass Surgery (Conference Poster 2017)[8]

N=7

Pulmonary

Adult

Background:

Pulmonary artery represents the gold standard for core temperature and serves as reference temperature for other invasive techniques (esophagus, nasopharyngeal, rectal, bladder, tympanic).

Methods:

In seven patients, authors introduced a pulmonary artery catheter through the right internal jugular vein for routine monitoring of patients during off-pump coronary artery bypass surgery. They compared the Temple Touch Pro System readings to pulmonary artery readings every 5 minutes until the end of anesthesia.

Findings:

The Temple Touch Pro System exhibited accuracy considered acceptable compared to pulmonary artery temperature by study authors in patients undergoing off-pump coronary artery bypass surgery.

Bland Altman Analysis:

- Pulmonary: Bias 0.36ºC (95% Limits of Agreement: -0.24 to 0.96).
- A potential cause of the positive bias (higher readings) can be related to the close proximity of the pulmonary artery to surgery site.

TEMPLE TOUCH PRO™ Summary of Clinical Evidence

Evaluation of Temple Touch Pro™ Non-invasive Core-temperature Monitoring System in 100 Adults Under General Anesthesia: A Prospective Comparison with Esophageal Temperature (Peer-Reviewed Paper; 2022)[4]

N=100

Esophageal

Adult

Background:

Maintaining perioperative normothermia remains a challenge despite well-established methods for invasive temperature monitoring. Hypothermia increases the risk of increased blood loss, need for perioperative transfusion, and surgical site infections. Invasive monitoring (e.g., esophagus, nasopharyngeal, rectum) prevents continuous temperature monitoring from pre-operative through recovery.

Methods:

This study evaluates the Temple Touch Pro System compared to esophageal temperature monitoring in adults (>18 years of age; 60+ minutes of anesthesia).

The Temple Touch Pro Sensor Unit was in place before induction of anesthesia. The esophageal temperature probe was placed after induction of anesthesia.

Surgery Types:

- Vascular (n=33)
- Abdominal/urogenital (n=30)
- Orthopedic surgery (n=18)
- Breast and plastic (n=13)
- Head and neck (n=7)

Findings:

Bland-Altman Analysis:

- Esophagus: -0.04 (95% limits of agreement: -0.99 to 0.91ºC). The diverse surgery types included in the study likely influenced the wider limits of agreement.

Paired temperature readings differed less than 0.5ºC 75% of the time. The 25% of measurements outside of this range did not change the clinician's treatment. This study concludes that the Temple Touch Pro™ System represents a reasonable tool for perioperative monitoring for adults.

Comparative Study on Eardrum Temperature and Core Temperature Measured by Temple Touch Pro™ (Conference Poster 2018)[7]

N=23

Tympanic

Adult

Background:

Tympanic membrane offers the least invasive standard core temperature monitoring location but is subject to placement error. Tympanic membrane monitoring is often used in procedures with an awake patient (spinal anesthesia).

Methods:

The study evaluates the Temple Touch Pro System compared to tympanic membrane temperature monitoring in adults in laparoscopic hysterectomy procedures.

Findings:

The Temple Touch Pro System measurements exhibited a lower variation and a smaller range in temperature measurements, supporting its use over tympanic membrane temperature monitoring.

Clinical citations:

1. Evron S, Weissman A, Toivis V, Shahaf DB, You J, Sessler DI, Ezri T. Evaluation of the Temple Touch Pro, a Novel Noninvasive Core-Temperature Monitoring System. Anesth Analg. 2017 Jul;125(1):103-109. doi: 10.1213/ANE.0000000000001695. PMID: 28617697.
2. Nemeth M, Klose K, Mielke B, Fazliu A, Brauer A, Miller C. Prospective evaluation of the Temple Touch Pro temperature monitoring system compared to esophageal reference temperature in paediatric anaesthesia (PETER PAN-Study) presented at Euro Anaesthesia 2021. Munich.
3. Nemeth M, Klose K, Asendorf T, Pancaro C, Mielke B, Fazliu A, Saager L, Brauer A, Miller C. Evaluation of the noninvasive Temple Touch Pro temperature monitoring system compared with oesophageal temperature in paediatric anaesthesia (PETER PAN): A prospective observation study. Eur J Anaesthesiol. 2023 Jan. 10. DOI 10.1097/EJA.0000000000001796.
4. Bräuer A, Fazliu A, Brandes IF, Vollnhals F, Grote R, Menzel M. Evaluation of the Temple Touch Pro™ noninvasive core-temperature monitoring system in 100 adults under general anesthesia: a prospective comparison with esophageal temperature. J Clin Monit Comput. 2022 Apr 4. doi: 10.1007/s10877-022-00851-z. Epub ahead of print. PMID: 35377051.
5. Fujii Y and Nishiwaki K. Validation of Core Temperature Measurement with Temple Touch ProTM. Using Body Surface Sensors in Pediatric Surgery. Nagoya University Hospital.
6. Maruyama T. Comparison of pharyngeal temperature and Temple Touch Pro in robot assisted prostatectomy. Presented at Japan Association for Clinical Engineers 2020.
7. Sagawa M and Kitamoto. Comparative study on eardrum temperature and core temperature measured by Temple Touch ProTM. Presented at Japanese Association for Operative Medicine 2018.
8. Chida Y, Tachibana S and Yamakage M. Usefulness of temperature monitoring system Temple Touch ProTM in off-pump coronary artery bypass surgery. Presented at 22nd Japanese Society of Cardia Anesthesiologists, 2022.

Continuous ⊙ Fast ⊙ Accurate

Monitor Connecting Unit (MCU)

Features

- **Single application for entire continuum of care**
- **Continuous monitoring**
- **Intuitive setup:** quick and easy to use
- **Compatible with most multi-functional monitors and EMR Systems**
- **Small, lightweight, disposable sensor**
- **For use on patients of all ages**
- **Non-sterile**

Gown Clip | Sensor Connecting Unit | Sensor Unit

Part #	Description	Details	Qty
81-1020SU	Temple Touch Pro™ Sensor Unit	2″ x 0.7″ x 0.2″	50/Cs
81-1020TTP	**Temple Touch Pro™ Kit Includes:** Monitoring Connecting Unit Sensor Connecting Unit (81-1020SCU) USB Power Cable (81-1020PC) AC/DC USB Adapter, US Plug (81-1020A)	-	1 Ea
81-1020400	Interface Cable, ¼ Pin, 400 Series	1 m (39.4") Length	1 Ea
81-1020GE	Interface Cable, GE®/Marquette®, 400 series	1 m (39.4") Length	1 Ea
81-1020HP	Interface Cable, HP®/Philips®, 400 Series	1 m (39.4") Length	1 Ea
81-1020MR	Interface Cable, Mindray®, 400 Series	1 m (39.4") Length	1 Ea
81-1020SM	Interface Cable, Siemens®/Dräger®, 400 Series	1 m (39.4") Length	1 Ea
81-1020SL	Interface Cable, SpaceLabs®, 400 Series	1 m (39.4") Length	1 Ea
81-1020SCU	Sensor Connecting Unit	2.7 m (9′) Length	1 Ea
81-1020REF	Temple Touch Pro™ Reference Units*	-	1 Ea

** Reference Units are used to check the accuracy of the Temple Touch Pro system once every 2 years.*

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