

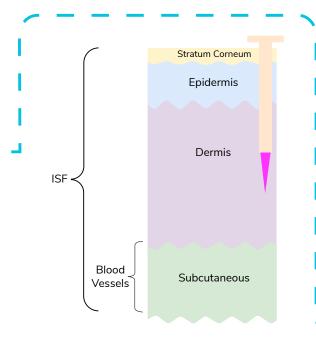
# PERFORMANCE OF A NOVEL, MINIMALLY-INVASIVE WEARABLE CGM (K'WATCH SYSTEM) IN PEOPLE WITH DIABETES: A PROSPECTIVE CLINICAL TRIAL

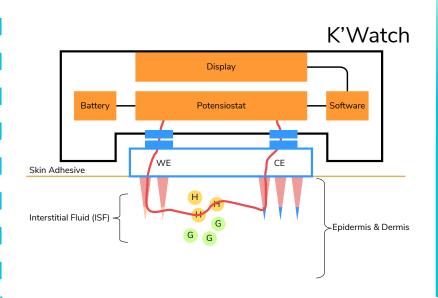


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# Background

Glucose monitoring is challenging for Type 1 & Type 2 diabetes patients











Intradermal monitoring:

- Dermal tissue (good vasculature, few nerve fibers)
- Dermal ISF correlates well with blood glucose

Glucose monitoring technology:

- Solid microneedles (< 1mm, painless)</li>
- Low-cost disposable patch
- Custom watch, designed for people with diabetes

K'Watch & sensor solution:

- Minimally invasive, wearable patch, water proof
- Consumable patch, weekly replacement
- Gentle adhesive, no shaving required, no pain or bleeding
- Continuous glucose tracking in ambulatory and home environment

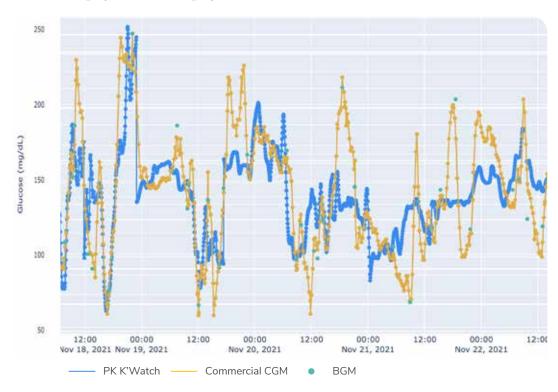
# Result - First 4 Subjects

### Feasibility clinical trial: Non-Significant Risk (NSR) study, NCT 05093569

- Study performance / safety of microneedles in dermal ISF for 7 days compared to BGM and commercial CGM
- 35 subjects T1D & T2D (BGM 7 per day/ K'Watch/ CGM Commercial 24 x 7 monitoring)
- Tolerance assessment scored 0 to 3
- Pain scored by Visual Analogic Scale (VAS)

Follow up after removal (for adverse events) Phone calls and site visit at 28 days

### **Accuracy (over 7 days)**



Four volunteers monitored in first Human trial (of 35 total)

Detection of overall glucose trend glucose compared to CGM, over 7 days

MARD 18% (calibrated with commercial CGM)

### Global observation

Disposable patch on patient



Before inserting

Patient 1



- Effective insertion into the dermis
- Needles stayed in place for 7 days
- Microneedles are not degraded after 7 days of use

**Safety** 

Patient 2

### Excursion tracking (subject #1) on first day



Day	Ref	PK	%	Missed
1	11	8	73%	3
2	12	8	66%	4
3	12	10	83%	2
4	10	7	70%	3
5	11	9	81%	2
6	14	12	85%	2
TOTAL	70	54	77%	16

Quantity of tracked excursion for Subject #1

- Excursions are sustained change in direction • Ref: excursions detected by commercial CGM
- PKvitality: excursions detected by K'Watch

# 21 days after removal

**Immediatly** after removal

1 day

after removal



Patient 3

Patient 4

No adverse events - No pain (< 3/10 on VAS) Very good tolerance - No critical irritation Great user experience

# Conclusion

- First four subjects were completed with positive outcomes (glucose tracking, needles stayed in place in the dermis, technology worked correctly)
- No pain or irritation from adhesive or microneedles
- Some limitations (only 4 subjects, missed excursions and signal amplitude issues)
- Improvements already underway and will be used for the next cohort of subjects

### K'Watch has the potential to...

- Be less invasive and eliminate the pain and discomfort of finger-sticks and invasive CGMs for people with diabetes
- Improve adherence to continuous glucose monitoring in people with diabetes.