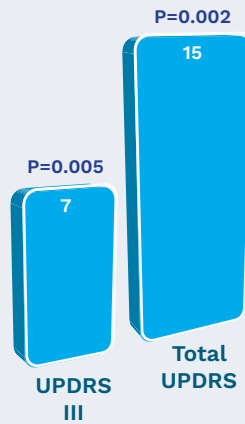


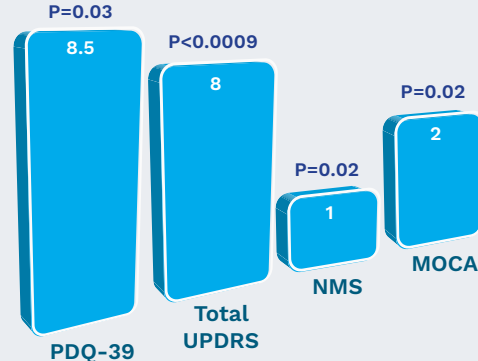
## PKG Influences a Change in Patient Outcomes

- Use of the PKG throughout PD treatment influences improved patient outcomes (both statistically significant and clinically meaningful<sup>6-7, 9, 15</sup>).

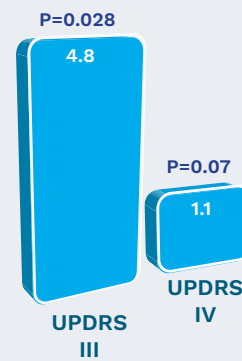
### Victoria Study - Unit Improvement



### Tasmania Study - Unit Improvement



### UCSD Study - Unit Improvement



- 64 minutes improvement in % time over target
- 43% proved quality of life with changes in oral therapies

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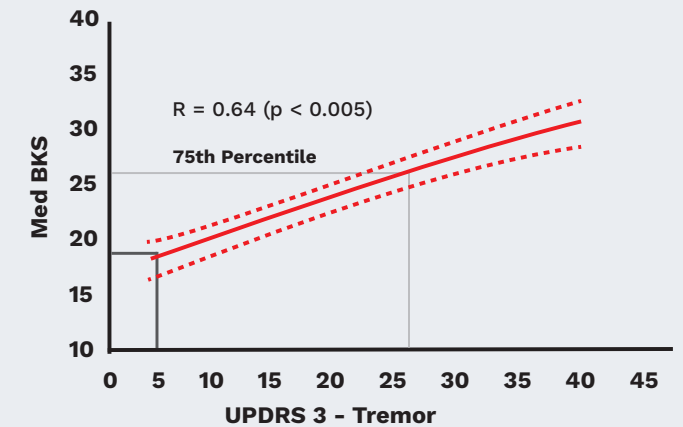
# Personal KinetiGraph® (PKG®) Summary of Clinical Evidence



## Validation of PKG Scores

### Bradykinesia Score (BKS)<sup>1</sup>

- Algorithm developed using modified Purdue Peg Board Test.
- In 79 patient cohort,  $r = 0.63$  with specificity of 88% and sensitivity of 95%.
- BKS correlated with UPDRS III (obtained while the subject was actively performing a task) while in the "On" state immediately prior to wearing the PKG Watch for 6-10 days.
- As tremor does not always accompany bradykinesia and its severity may vary independently of bradykinesia, tremor scores were removed from the UPDRS III (referred to as UPDRS III-T).
- A UPDRS III-T of 45 and above indicates very severe bradykinesia.

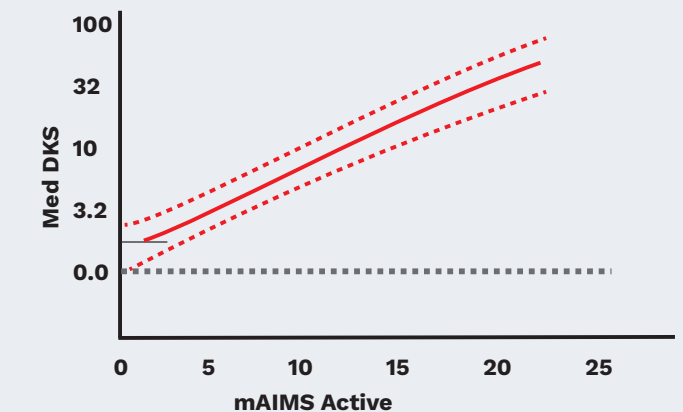


BKS	Refers to Bradykinesia Score
BKS	Approx. ~ UPDRS III
21	13
23	20
25	27
27	32

The UPDRS III-T has linear correlation with the bradykinesia score above the 50th percentile with an  $r^2$  of 0.55 and the median BKS with an  $r^2$  of 0.42 (ref. fig. a.bove).

### Dyskinesia Score (DKS)<sup>1</sup>

- Algorithm developed using observation of patients wearing PKG Watch during normal tasks.
- DKS correlated with Abnormal Involuntary Movement Scale (AIMS).
- The margin of error in predicting AIMS from DKS was 3.2 AIMS units compared to -3.4 to 4.8 AIMS units by the neurologist doing AIMS (maximum score of 20).
- Highly significant correlation of  $R = 0.80$  ( $p < 0.0001$ ).



DKS	Refers to Dykinesia Score
DKS	Approx. ~ mAIMS
5	5
9	10
15	15

The AIMS has a linear correlation with the DKS > 75th percentile of controls with an  $r^2$  of 0.49, after logarithmic transformation the median DKS has an  $r^2$  of 0.66. (ref. fig. a.bove).



## Percent Time Immobile Score (PTI)<sup>2</sup>

- Immobility is a surrogate marker of daytime sleep in PD, confirmed by correlation with PSG and ESS.
- Episodes of immobility defined as 2 minutes or greater in duration and with BKS > 80.
- PKG recordings and PSG obtained from 68 PD patients and 30 controls; 10 aged-matched with ESS performed.
  - 85.2% concordance with ambulatory Polysomnography (PSG) in detecting daytime sleep ( $p < 0.0001$  Chi Squared).
  - High Epworth Sleepiness Scores (ESS) associated with a proportion of time immobile (PTI) ( $p = 0.01$  Mann-Whitney).
  - The median PTI between 09:00 and 18:00 hours in 30 age matched control subjects was 2%, representing 10 min and PTI at or above the 75th percentile (5% or 27 min).
  - PD patients had higher PTI (median 4.8%) than controls ( $p < 0.0001$ , Mann-Whitney).

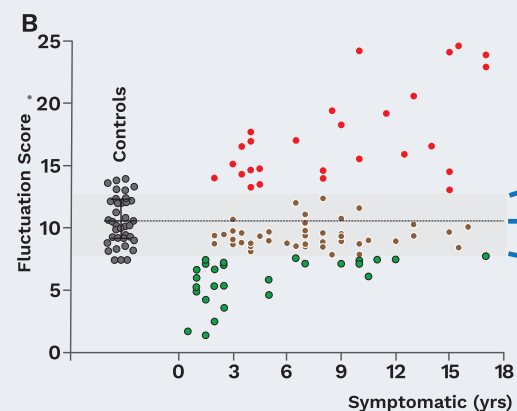
## Percent Time Tremor Score (PTT)<sup>3</sup>

- Algorithm to distinguish between subjects with a resting or postural tremor involving wrist with frequency > 3 Hz.
  - Spectrograms from accelerometry from wrist of controls and PwP with and without tremor.
  - Patients wore PKG Watch while videotaped walking and pouring water into 7 jugs.
- Receiver Operator Characteristic shown to discriminate between T+ (tremor present) and T- (no tremor).
  - PTT > 1% was accurate in predicting tremor w/ 8.8% false positives and <0.6% with 8.1% false positives.
  - Median tremor threshold BKS = 27.
- PTT score in context:
  - PTT greater than 1% indicates the presence of tremor – provides high likelihood of presence of a clinically meaningful tremor.
  - PTT less than 0.6 % indicates the absence of tremor.
  - PTT between 0.6 and 1% is not conclusive.

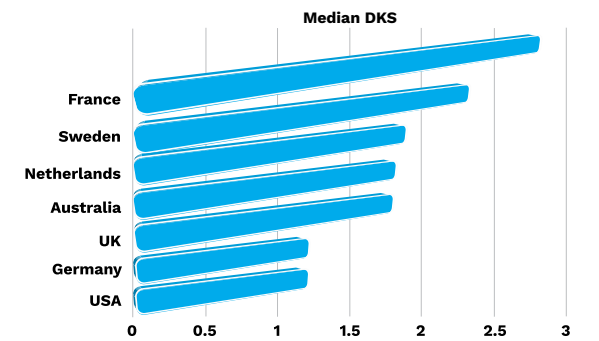
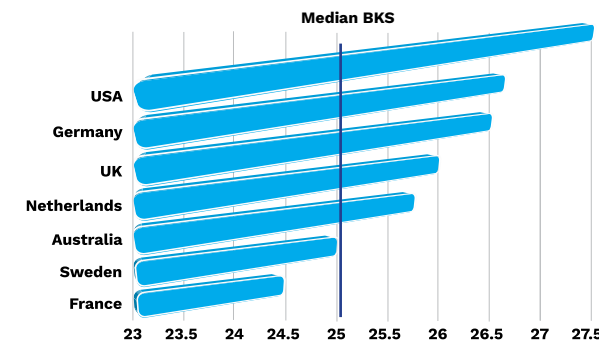
	N	Sensitivity/Selectivity
Initial Test	85	92.5% / 92.9%
Retest	87	90.3% / 92.7%
Combined Tests	172	88.7% / 89.5%

## Fluctuation and Dyskinesia Score (FDS)<sup>4</sup>

- Fluctuation score produced by summing the interquartile range of bradykinesia scores and dyskinesia scores produced every 2 minutes between 09:00-18:00 and expressed as an algorithm.
  - Score distinguishing between fluctuating and non-fluctuating patients with high sensitivity and selectivity and significantly lowered following activation of DBS.
  - Data from 527 of PD and 38 control subjects. Examined variation in distribution of BKS and DKS (as measured by their interquartile ranges).

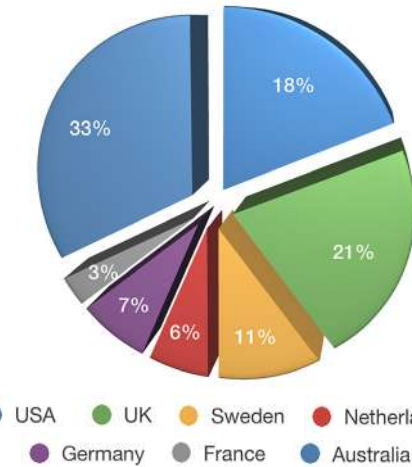


- **Green dots:** Patients whose FDS was low early in their disease course probably due to under dosing and a prevalence of bradykinesia (i.e. reduced movement)
- **Green dots:** Later on X axis - patients who have low FDS later into their disease may be poor responders or levodopa resistant.
- **Brown dots:** Patients who have a normal/expected and well controlled FDS throughout their disease.
- **Red dots:** Patients that have worsening FDS scores with increasing duration of disease probably due to higher levels of medication induced dyskinesia and unpredictable wearing "off" periods resulting in overall greater degree of symptom variability from dose-to-dose and day-to-day.



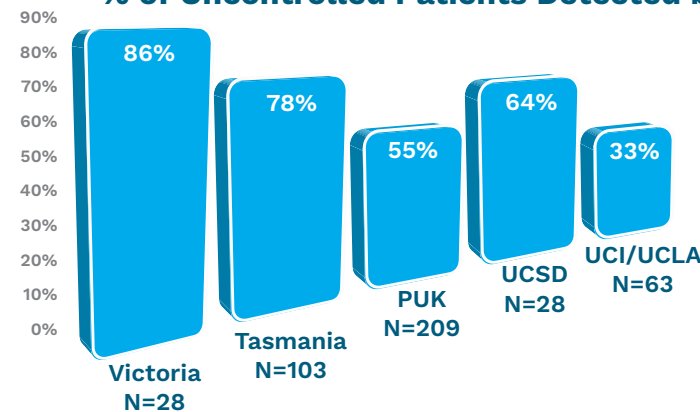
## PKG Identifies Uncontrolled Parkinson's Disease Symptoms

- Large database study of > 27K PKGs from a global cohort (2012-2018).<sup>5</sup>



- By country**
- 54% of BK scores > 25 (UPDRS III ~27) 1 ranging from 46% to 61%.
  - 10% of all DK scores > 9 (mAIMS ~10), ranging from 5-15%.
- In the U.S.**
- Median BKS of 27.5; 61.2% with BKS > 25.
  - Median DKS of 1.2; 5.4% with DKS > 9.

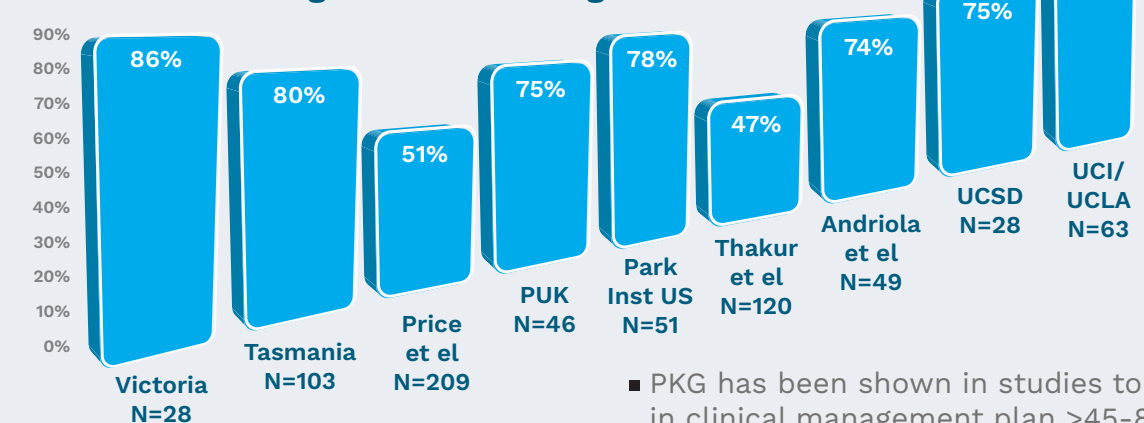
## % of Uncontrolled Patients Detected by PKG



- Studies demonstrate PKG's ability to identify uncontrolled PD patients ranging from 33-86% of the time.<sup>6-10</sup>
- Detection rates from selected U.S. studies:
  - A 28-patient study at UCSD = 64%.
  - A 63-patient, multi-center study at UCI/UCLA = 33%.

## PKG Influences a Change in Clinical Management Plan Decision

### % Time Changed Decision Using PKG



- PKG has been shown in studies to influence a change in clinical management plan >45-86% of the time.<sup>6-14</sup>
- In 5 selected U.S. studies, a clinical management plan was changed ranging from 47-79% of the time using the PKG and standard of care assessments.