SteadyStat Technical Methodology Report

Audience: Researchers, analysts, evidence-based medicine specialists, and clinicians interested in the technical foundations of SteadyStat.

Purpose: This document provides a comprehensive overview of the clinical rationale, standardized terminology, calculations, and methodological foundations behind the SteadyStat platform's reports. It is intended to support professional review, ensure reproducibility of the analytics, and increase clinician confidence in integrating SteadyStat into hypertension management.

---

1. Executive Summary

SteadyStat is a patient-facing mobile app that generates structured, clinician-ready reports to support hypertension follow-up and treatment decisions. It is a clinical decision-support tool, not a diagnostic device. The platform addresses two persistent challenges in hypertension care: the limited representativeness of in-clinic blood pressure (BP) measurements and the uncertainty surrounding medication adherence.

By combining home BP readings with a built-in medication log, SteadyStat produces reports that approximate the information density of ambulatory BP monitoring—such as time-of-day patterns, blood pressure variability, and trough-to-peak differences—while also incorporating adherence context. All outputs use standardized terminology and align with contemporary clinical guidelines, including ACC/AHA 2017 BP categories.

Preliminary evaluations using synthetic patient scenarios demonstrate that SteadyStat can help clinicians identify patterns such as adherence-related BP differences, morning surges, and potential timing-related patterns. These examples illustrate how structured home data can support more precise clinical conversations—such as distinguishing between adherence issues and potential pharmacodynamic considerations.

SteadyStat aims to support more efficient and informed hypertension management by providing a clearer picture of each patient's BP control and medication use between visits, in a format designed for rapid clinical interpretation.

---

2. Design Philosophy: Aligning With Clinical Reasoning

Hypertension guidelines emphasize several foundational steps before modifying therapy: confirm accurate measurement, assess adherence, and evaluate contextual factors that may influence BP control. SteadyStat's design mirrors this reasoning.

Adherence First

The report prioritizes adherence data, presenting the overall adherence percentage prominently. This reflects guideline recommendations that adherence should be assessed before intensifying therapy, as apparent treatment resistance often resolves with improved adherence or measurement technique.

Integrated Context

SteadyStat presents BP readings alongside medication timing and adherence information. This mirrors how clinicians naturally evaluate patterns:

- "Was the dose taken?"
- "Is this reading near a trough period?"
- "Does this align with guideline targets?"

By aggregating these elements, SteadyStat provides a structured view of the patient's home BP environment.

Actionable Visualization

Reports use color coding, summary bullets, and simple charts to support rapid interpretation. The goal is not to replace clinical judgment but to organize relevant information so clinicians can quickly identify patterns such as morning surges, elevated variability, or adherence-related differences.

---

3. Core Metrics and Calculations

SteadyStat provides several complementary metrics to support a nuanced understanding of BP control.

Mean and Median BP

- Mean BP reflects overall control.
- Median BP provides a robust measure less influenced by outliers.

Percent of Readings at Goal

The percentage of readings below the home BP target (default: <135/85 mmHg). This offers a practical sense of control consistency.

BP Categories

Each reading is categorized using ACC/AHA 2017 criteria (Normal, Elevated, Stage 1, Stage 2). The distribution helps clinicians quickly assess risk patterns.

Time-of-Day Averages

SteadyStat calculates average BP across morning, afternoon, evening, and (if available) nighttime windows to identify diurnal patterns, including morning surges.

Trough-to-Peak Difference

For once-daily medications, SteadyStat estimates average BP during expected peak (2–6 hours post-dose) and trough (pre-dose) periods. This aligns with FDA guidance that effective once-daily agents should maintain at least ~50% of peak effect at trough.

Blood Pressure Variability

SteadyStat calculates:

- Standard deviation (SD)
- Coefficient of variation (CV)

Elevated variability is highlighted due to its association with cardiovascular risk.

Derived Metrics

- Mean arterial pressure (MAP)
- Pulse pressure (PP) — wide PP (>60 mmHg) may indicate arterial stiffness.

All formulas are transparently listed in the report to support reproducibility.

---

4. Medication Adherence Methodology

Data Capture

Patients enter their antihypertensive regimen, including dose times. SteadyStat generates reminders and allows users to log doses as taken, missed, or taken late. Missed or unconfirmed doses are treated as missed.

Adherence Percentage

Calculated as the percentage of scheduled doses taken. An adherence rate ≥80% is generally considered acceptable in hypertension studies.

Adherence Stratification

SteadyStat compares BP on:

- Fully adherent days
- Non-adherent days

If meaningful differences exist, the report highlights them to support clinical discussion.

Late Doses and Partial Adherence

Late doses are noted because they may contribute to temporary trough periods. For multi-drug regimens, SteadyStat can identify medication-specific adherence patterns.

This methodology supports clinicians in evaluating whether elevated readings may be related to adherence or timing.

---

5. Trough-to-Peak (Dose Timing) Analysis

Rationale

Once-daily antihypertensives should ideally maintain effect throughout the dosing interval. A morning surge may indicate that a medication's effect is waning before the next dose.

Method

Using timestamps, SteadyStat identifies:

- Peak window: 2–6 hours post-dose
- Trough window: final hours before the next scheduled dose

Outputs

The report displays average BP at peak and trough and highlights substantial differences that may suggest potential timing-related patterns.

Interpretation

If a notable trough-to-peak difference is observed, the report includes neutral commentary such as:

"Morning readings are higher than afternoon readings, which may reflect timing-related patterns."

This supports clinician evaluation without implying treatment recommendations.

6. Blood Pressure Variability Metrics

SteadyStat quantifies variability using:

- Standard deviation (SD)
- Coefficient of variation (CV)

Elevated variability may prompt clinicians to explore factors such as adherence, lifestyle triggers, or medication selection. Variability is presented as an informational metric, not a diagnostic indicator.

---

7. Pulse Pressure and Mean Arterial Pressure

SteadyStat calculates:

- MAP = (SBP + 2 × DBP) / 3
- PP = SBP – DBP

Wide pulse pressure is highlighted due to its association with arterial stiffness, particularly in older adults.

---

8. Data Integrity and Limitations

SteadyStat relies on patient-entered data. While the app encourages best practices and provides confidence indicators, it cannot independently verify adherence or measurement technique. These limitations are clearly communicated to clinicians.

---

9. Guideline Alignment

SteadyStat's analytical framework aligns with:

- ACC/AHA 2017 BP categories
- FDA trough-to-peak considerations
- AHA recommendations on evaluating resistant hypertension, including adherence assessment and out-of-office BP confirmation

10. References

[1] CDC. "Hypertension Prevalence and Control Among Adults: United States, 2017–2018." National Center for Health Statistics, 2020.

[2] Muntner, P., et al. "Screening for Hypertension in Adults: US Preventive Services Task Force Recommendation Statement." *JAMA*, vol. 325, no. 16, 2021, pp. 1657-1666.

[3] Sheppard, J. P., et al. "Prognostic Value of Home- and Clinic-Based Blood Pressure in Patients With Hypertension: The BP-TARGET Study." *Hypertension*, vol. 73, no. 4, 2019, pp. 849-857.

[4] Whelton, P. K., et al. "2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults." *Journal of the American College of Cardiology*, vol. 71, no. 19, 2018, pp. e127-e248.

[5] O'Brien, E., et al. "European Society of Hypertension Position Paper on Ambulatory Blood Pressure Monitoring." *Journal of Hypertension*, vol. 31, no. 9, 2013, pp. 1731-1768.

[6] Carey, R. M., et al. "Resistant Hypertension: A Scientific Statement From the American Heart Association." *Hypertension*, vol. 72, no. 5, 2018, pp. e53-e90.

[7] Meredith, P. A. "Trough-to-peak ratio: a legacy of the past?" *Journal of Hypertension Supplement*, vol. 17, no. 2, 1999, pp. S13-S18.

[8] de la Sierra, A. "Blood Pressure Variability: A Novel Risk Factor for Cardiovascular Disease." *Journal of Clinical Medicine*, vol. 12, no. 3, 2023, p. 1045.

[9] Wang, J. G., et al. "Effects of Amlodipine and Other Antihypertensive Drugs on Blood Pressure Variability: A Systematic Review and Meta-Analysis." *Journal of Hypertension*, vol. 35, no. 8, 2017, pp. 1567-1577.

[10] Franklin, S. S., et al. "Pulse Pressure as a Predictor of Coronary Heart Disease in the Framingham Heart Study." *Circulation*, vol. 100, no. 4, 1999, pp. 354-360.