



# Validation of a m-Health Platform for Blood Pressure Control and Reduction

G. Peretto<sup>^</sup>, G. Del Mauro<sup>^^</sup>, T.Bordignon<sup>^^</sup>, E.Colombo<sup>^^</sup>, M.Fabi<sup>^^</sup>, S. Negri<sup>^</sup>, V. Vergani<sup>^</sup>, D.Cianflone<sup>^,^^,\*</sup>

<sup>^</sup> **Università Vita-Salute San Raffaele, Milan, Italy**

<sup>^^</sup> **AMICOMED, San Francisco, California, USA**



## ABSTRACT

**Background:** Self-measured blood pressure (BP) monitoring, has been proposed as a means of improving BP control. Lifestyle modifications are indicated in hypertension at any stage. AHA's "Life Simple 7" provide a straightforward call-to-action. mHealth services (mHs) may provide additional tools to effective BP control. **Aim:** To determine the prevalence of optimal systolic BP values in participants to a real-life digital-only BP registry and assessment service.

**Population and Methods:** We tested the reproducibility of the initial results of a mHs for remote BP monitoring and lifestyle counseling. The mHs in study is a *cloud*-based BP -recording, -interpretation and -trend evaluation service (BT) coupled with personalized lifestyle-change programs (LC). Initial results showed a significant reduction of BP at the end of the LC program. BT collects BPs, and after consistency-checks, feeds a proprietary CE-certified medical device algorithm to provide actual BP interpretation and BP trend assessment. A separate proprietary algorithm, LC provides a 3-month personalized lifestyle modification program for BP reduction, built on the AHA's "Life Simple 7", after collecting detailed clinical and lifestyle data. BP changes were evaluated comparing BPs recorded at the beginning and at 3 months in both groups. We studied all the subjects (1705M; 50±14years old) that voluntarily and unsolicited joined LC (n=717) or BT alone (2601) from June 2016 to April 2017, via App and website.

**Results:** During the study period a total 60044 BP values were collected, subjects with discontinuous BP measurements were excluded from evaluation. We hence analyzed the data of the 575 LC subjects and the 1653 BT subjects. We observed a significant BP reduction in LC subjects at the end of the program for both systolic and diastolic BP: 4.7±1.2 and 3.3±0.8 (mean±SEM, mmHg), p<0.0001, respectively. In BT subjects the reduction of BP values at 3-months was 2.5 ±0.9 and 1.7±1.0, p<0.001, respectively. The subjects of the LC group with ≥ 3 systolic BPs above normal values in the first 10 days experienced a greater BP reduction 7.9±1.4 and 4.6±1.1, p<0.0001, respectively.

**Conclusion:** The data confirm that this mHealth service provides a strong and effective adjunctive tool for BP reduction. These results support the value of the combination of algorithm based remote BP monitoring and a personalized implementation of AHA's "Life Simple 7" recommendations.

## BACKGROUND

### OUR PREVIOUS PILOT STUDY SHOWED THAT:

On 129 LC subjects and 258 "double-control" (1:2) matching BT subjects followed for 3 months (N = 15,389 BP measurements):

1. No significant difference in BP values was found in controls (BT subjects) **while**
2. LC subjects obtained a significant reduction in both systolic BP (-4.7±1.2mmHg) and diastolic BP (-3.1±0.8mmHg) – both p<0.0001

## OBJECTIVES

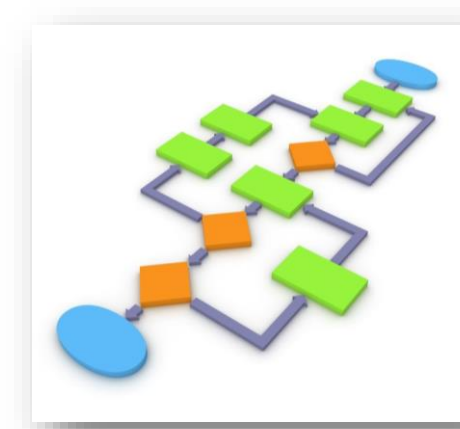
- To assess: the reproducibility of the initial results of a m-Health Service for remote BP monitoring and lifestyle counseling.
- To verify that a mHealth-mediated, digital only, personalized and actionable lifestyle change program, coupled with a medical CE certified service for BP interpretation and trend analysis provides a strong and effective adjunctive tool for BP reduction.

## SUBJECTS

- BP data were collected from June 2016 to April 2017 (study conducted in Italy)
- **3,318 consecutive subjects** that voluntarily and unsolicited joined the real-time BP -recording, - interpretation and -trend evaluation service (51% males; 50±14 years old). They discovered the service on the Web and/or AppStore/Google-Play
- **60,044 BP measurements**, validated for consistency
- **2,228 subjects** were finally analyzed (575 LC + 1,653 BT)

## METHODS

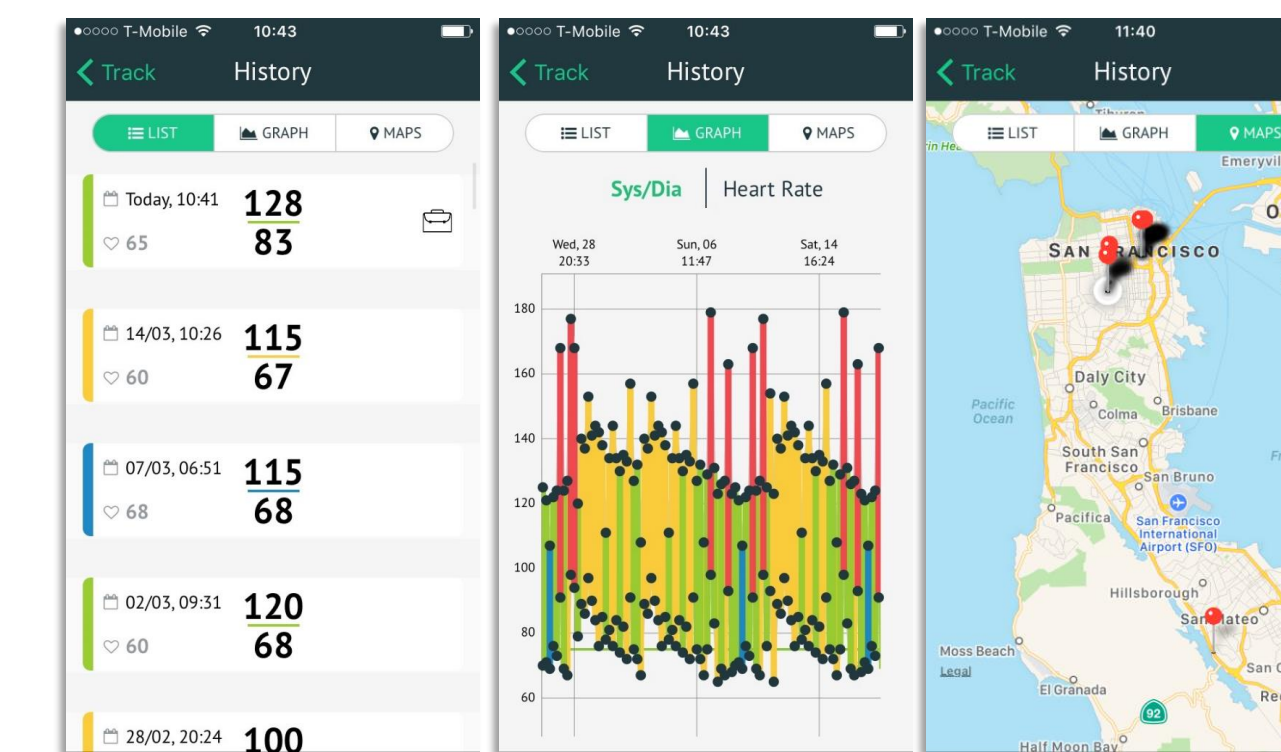
### USERS SUBSCRIBED THE AMICOMED SERVICE LEVERAGING ITS TWO FULLY AUTOMATED AND SCALABLE PROPRIETARY ALGORITHMS



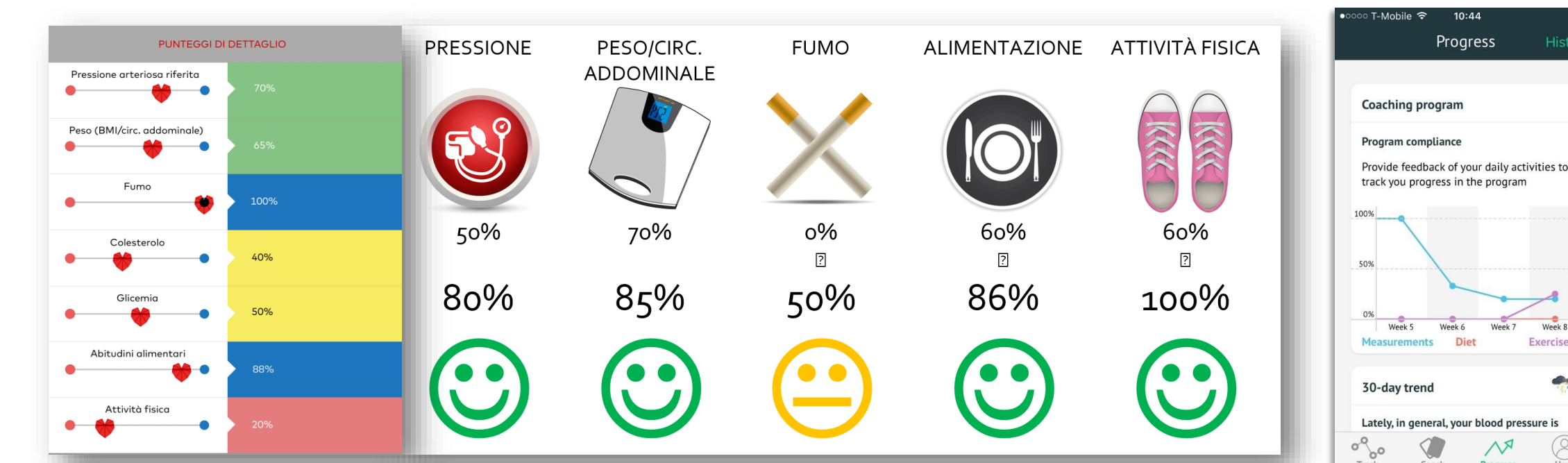
- **PASCAL** - provides instant assessment of BP evolution and variability. Patented and CE-marked as a class IIA medical device.
- **SMART PRESSURE** - provides the personalized lifestyle coaching program for BP reduction

- Real time **feedback** on each and **trend changes**
- **Visual alert** should potential clinical risk exist (e.g. very high BP)
- Ability to **separate trends** in different time bands
- Ability to distinguish between oscillation and trend
- Cloud-based storage and diary/graph accessible via App and website
- Customizable objectives and reminders
- Connection with **Apple Health App**
- Bluetooth connected with iHealth BP monitors

### HOW THE PROGRAM WORKS - DURATION 3 MONTHS

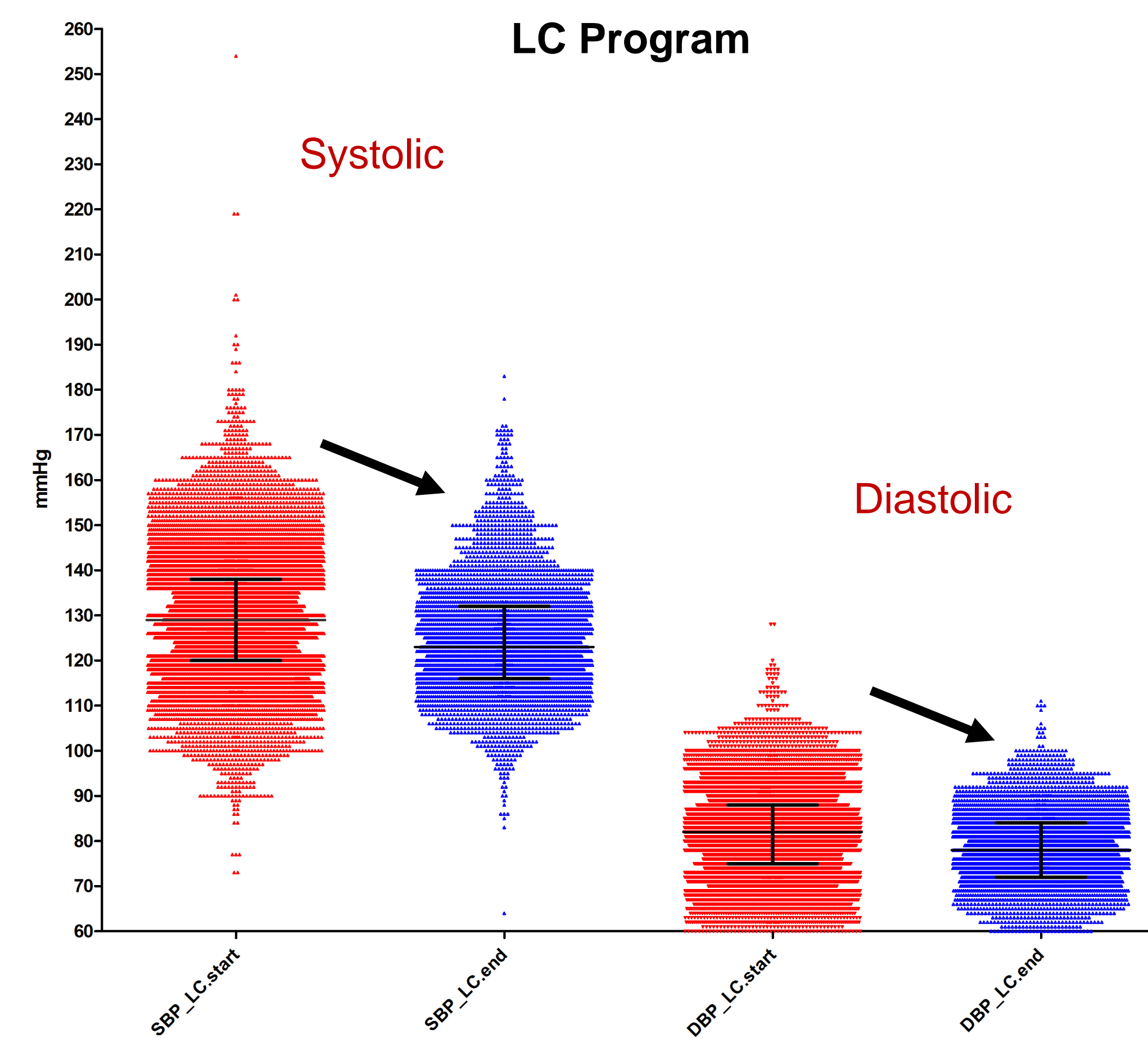


### PERSONALIZED BP REDUCTION LIFESTYLE-CHANGE PROGRAM



- App/Web-based and fully digital
- Lifestyle changes: physical activity, dietary and BP tracking coaching program
- Highly personalized on patient's clinical and lifestyle information:
  - ✓ > 70 stratification profiles
  - ✓ > 1100 3mos. dietary schemes
  - ✓ uncountable exercise programs

## RESULTS (n= 52,257 values)

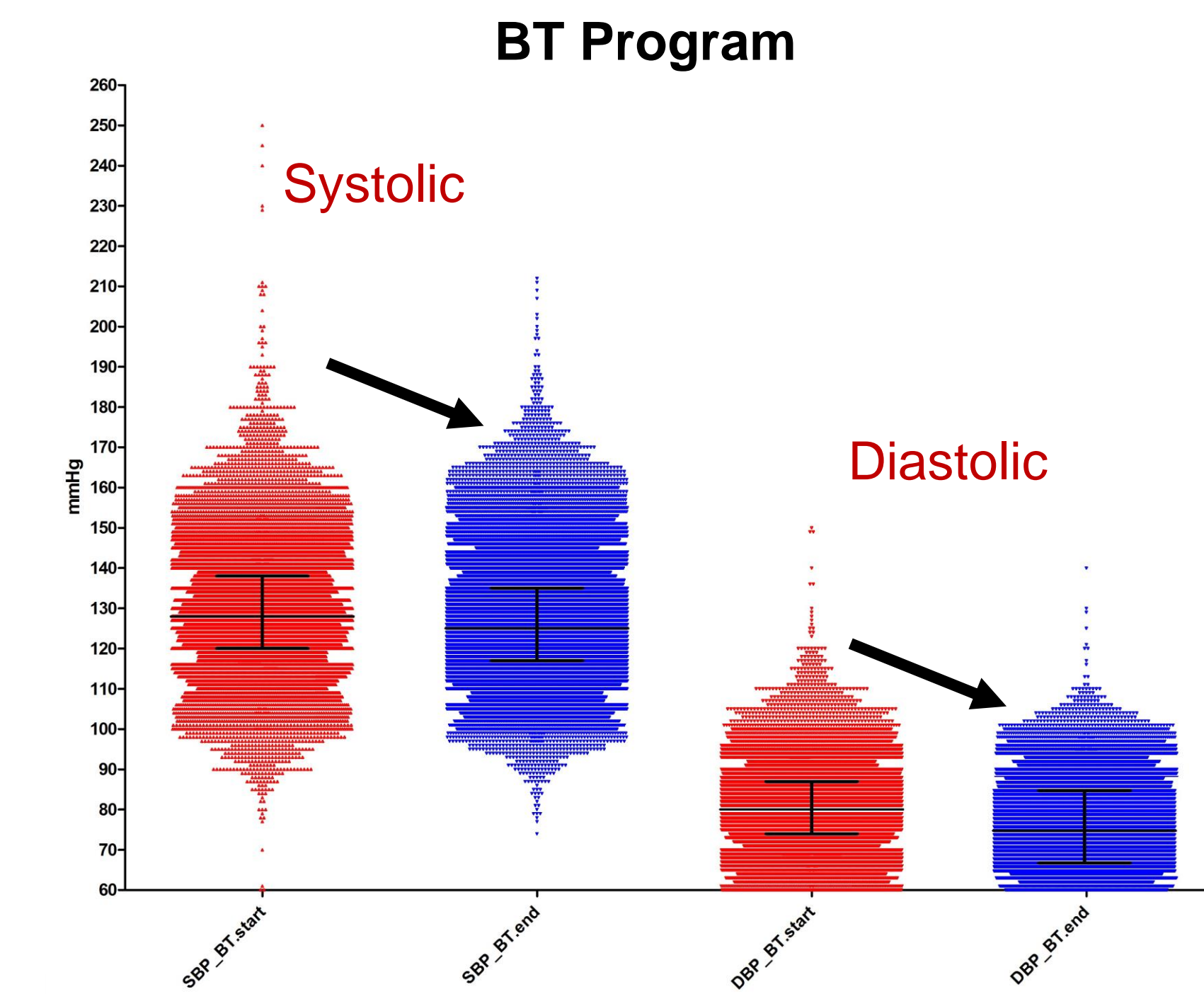


Lifestyle active program participants obtained a significant reduction of both systolic and diastolic blood pressure across the 3 months of observation:

**Systolic**  
-4.7±1.2 mmHg (p<0.0001)

**Diastolic**  
-3.3±0.8 mmHg (p<0.0001)

■ Baseline  
■ 3 months after

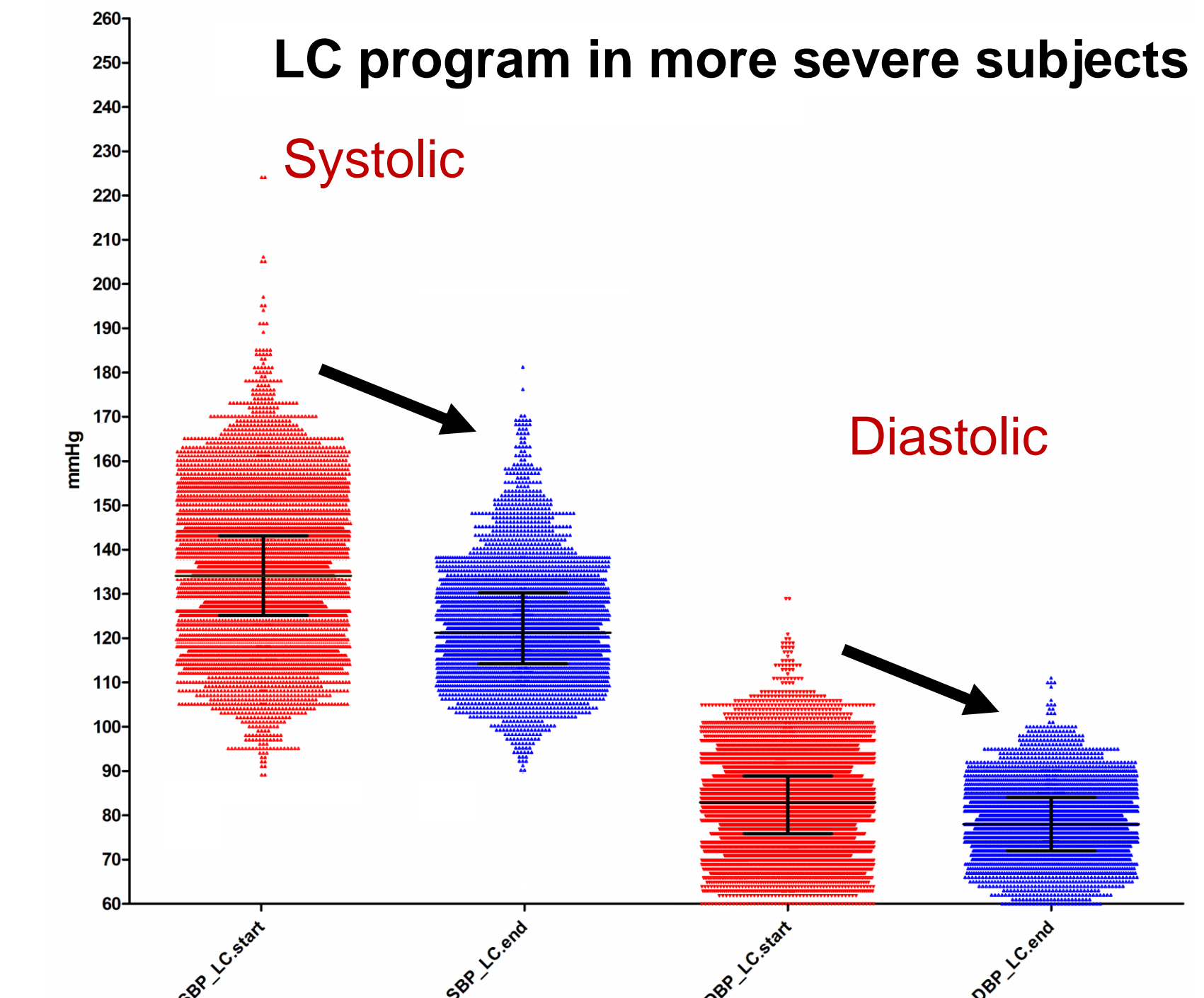


BT subjects obtained a milder but significant reduction of both systolic and diastolic blood pressure across the 3 months of observation:

**Systolic**  
-2.5±0.9 mmHg (p<0.001)

**Diastolic**  
-1.7±0.8 mmHg (p<0.001)

■ Baseline  
■ 3 months after



The subjects of the LC group with ≥ 3 systolic BPs above normal values in the first 10 days experienced a greater BP reduction

**Systolic**  
-7.9±1.4 mmHg (p<0.0001)

**Diastolic**  
-4.6±1.1 mmHg (p<0.0001)

■ Baseline  
■ 3 months after

## CONCLUSIONS

Validation data confirm that:

- A mHealth-mediated, digital only, personalized and actionable lifestyle change program,
- coupled with a medical CE certified service for BP interpretation and trend analysis...

...provides a strong and effective adjunctive tool for BP reduction

AHA Life's simple 7 are the foundation of Amicomed's programs



## DISCLOSURES & DISCLAIMERS

- <sup>^</sup> G.Peretto, S. Negri, V. Vergani: nothing to disclose
- <sup>^^</sup> G. Del Mauro, M.Fabi, T.Bordignon, E.Colombo: Employees at AMICOMED SA
- \* D.Cianflone: Co-Founder and Chief Scientific Officer – AMICOMED;

The information presented in this abstract and all statements, considerations, or data has not been evaluated by the U.S. Food and Drug Administration.