IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JEANETTE ESTRELLA, HAROLD PEERY, STEPHEN SCHNEIDER, and DENEEN POND, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

OMRON HEALTHCARE, INC.,

Defendant.

Case No. _____

CLASS ACTION COMPLAINT

Plaintiffs Jeanette Estrella, Harold Peery, Stephen Schneider, and Deneen Pond ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this class action against Defendant Omron Healthcare, Inc. ("Defendant" or "Omron"), and allege on personal knowledge as to themselves, and investigation of counsel and information and belief, as follows:

I. INTRODUCTION

1. This class action lawsuit concerns a fraud perpetrated on thousands of purchasers of the OMRON Platinum Upper Arm Blood Pressure Monitor model BP5450 (the "Product" or "Products") for personal use and not for resale.

2. The Product is marketed by Defendant as an in-home medical device capable of providing consistently accurate and reliable blood pressure readings for all users, while in truth, it is incapable. The blood pressure readings generated by the Product are wildly inaccurate for many thousands of users. For example, consecutive readings generated by the Product, and taken from the same person minutes apart, vary by 10 mmHg or more. One reviewer of the Product states it is "consistently 10+ mmHg off," making the device essentially useless. Another reviewer carefully tested his device, which involved taking nine consecutive measurements each one minute apart. Over the less than 20 minutes it took to collect these readings, the consumer's systolic blood pressure ranged from 144 mmHg to 164 mmHg. Yet another reviewer who brought the Product to a doctor's appointment said the Product's readings were as much as 91 mmHg higher than the doctor's machine and manual readings. And Plaintiffs and other class members have experienced similarly inaccurate and inconsistent readings.

3. The Product's defective nature is also a breach of express and implied warranty. The Product's user manual warrants that the device is accurate within a range of "+/- 3 mm Hg." Not only is this "range" not conspicuously disclosed at the point of sale (and such omission is misleading as described below), it is also untrue. User experience shows that the Product's

accuracy varies widely. Beyond that, Defendant commissioned a study by Northwestern researchers to validate the accuracy of the Product.[1] That study concluded that the Product was accurate within a range of ***+/- 3.7 mmHg*** for diastolic pressure—which is 23.3% greater than the ***3 mmHg*** warranted in the user manual. And for persons using the standard "wide range" cuff (22–42 cm or 9–17 inches) that comes in the box with the Product, the Product produced diastolic blood pressure readings that deviated by an average of ***4.30 mmHg*** (with a standard deviation of 5.8 mmHg) from the true level. Moreover, Defendant's +/- 3 mmHg accuracy rating is an average—meaning that for some users, the Product is decidedly incapable of providing accurate and reliable measurements—which is also not conspicuously disclosed at the point of sale. Worse, the Northwestern Study shows that the Product produces particularly inaccurate readings for users with relatively larger arm circumference (comprising a portion of users likely to monitor blood pressure), which Defendant knew, in part because it commissioned the study and tested the Product before bringing it to market.

4. Defendant's misleading representations and omissions about the Product concern its central functionality, as the Product is effectively rendered useless and unreliable. Defendant's misleading representations and omissions also pose an unreasonable safety hazard as users may incorrectly believe their blood pressure is far higher or lower than it actually is, and rely on these readings in making future decisions about their healthcare and treatment (or foregoing treatment).

5. Defendant has not recalled the Product or offered any other program to reimburse users.

[1] Peprah, Lee, and Persell, Journal of Human Hypertension, *Validation testing of five home blood pressure monitoring devices for the upper arm according to the ISO 81060-2:2018/AMD 1:2020 protocol* (submitted June 8, 2022 and published January 18, 2023) (hereinafter the "Northwestern Study").

6. As a result of Defendant's misconduct and omissions, Plaintiffs and putative Class members have suffered injury in fact.

7. Plaintiffs bring this suit to halt Defendant's unlawful sales and marketing of the Product and for economic damages sustained as a result. Given the large quantities of the Product sold nationwide, this class action is the proper vehicle for addressing Defendant's misconduct and attaining needed relief for those affected.

II. PARTIES

8. Plaintiff Jeanette Estrella is and was at all times relevant to this Complaint domiciled in and a resident of Hollywood, Florida.

9. Plaintiff Harold Peery is and was at all times relevant to this Complaint domiciled in and a resident of Cloverdale, California.

10. Plaintiff Stephen Schneider is and was at all times relevant to this Complaint domiciled in and a resident of Montara, California.

11. Plaintiff Deneen Pond is and was at all times relevant to this Complaint domiciled in and a resident of Sequim, Washington.

12. Defendant Omron Healthcare, Inc. is a Delaware corporation and headquartered in Lake Forest, Illinois. Defendant designs, manufactures, markets, and sells the Products to consumers nationwide across the United States.

III. JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) and the Class Action Fairness Act because the amount in controversy exceeds $5,000,000, and Defendant is a citizen of Illinois and is therefore diverse from at least one member of the Class.

14. This Court has personal jurisdiction over Defendant because it is headquartered in Lake Forest, Illinois. Defendant is authorized to do business in this District, conducts substantial

business in this District, and the actions giving rise to the complaint took place in part in this District as the marketing and manufacturing decisions were made from Defendant's headquarters in Illinois.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant does business throughout this District.

IV. COMMON FACTUAL ALLEGATIONS

A. Background Regarding Blood Pressure Monitors

16. Taking a blood pressure reading when visiting a primary care physician is standard practice. Blood pressure is measured in a clinical setting using a sphygmomanometer.

17. Capitalizing on the consuming public's interest in flexibility and convenience, at-home blood pressure monitors are becoming increasingly popular.

18. Accurate blood pressure measurement is critically important for proper diagnosis and treatment. When diagnosing and treating hypertension, inaccurate blood pressure measurement values can result in "over diagnoses or underdiagnoses as well as overtreatment or under treatment."[2] Inaccurate blood pressure measurements leading to untreated hypertension can cause other severe and deadly health conditions like kidney disease, heart disease, and stroke.

19. Hypertension can cause serious damage to the heart. Excessive pressure can harden arteries, decreasing the flow of blood and oxygen to the heart. This elevated pressure and reduced blood flow can cause chest pain; heart attack (which occurs when the blood supply to the heart is blocked and heart muscle cells die from lack of oxygen, and the longer the blood flow is blocked, the greater the damage to the heart); heart failure (which occurs when the heart cannot pump

[2] Northwestern Study at 134.

enough blood and oxygen to other vital body organs); and irregular heart beat which can lead to a sudden death.

20. An estimated 1.28 billion adults aged 30–79 years worldwide have hypertension and an estimated 46% of adults with hypertension are unaware that they have the condition. According to the U.S. Center for Disease Control (CDC), in 2021, hypertension was a primary or contributing cause of 691,095 deaths in the United States, and nearly half of all adults in the United States (48.1%, 119.9 million) have hypertension—defined as a systolic blood pressure greater than *130 mmHg*, or a diastolic blood pressure greater than *80 mmHg*.[3]

21. Because many doctors rely at least in part on home measurements to guide treatment, such inaccuracies could end with some people taking too much or too little blood pressure medication, seeking unnecessary treatment, or forgoing necessary treatment.[4]

22. Accordingly, it is essential that blood pressure devices provide accurate and reliable measurements.

B. The Product and Defendant's Marketing of the Product

23. Defendant is the manufacturer and distributor of healthcare devices in the United States and claims to have sold more than 300 million home-use digital blood pressure monitors worldwide as of May 2021. Among the various devices manufactured and distributed by Defendant is the Product at issue. According to Defendant's website, the Product is "exclusive to Amazon" and sold only on Amazon.com.[5]

[3] https://www.cdc.gov/bloodpressure/facts.htm.

[4] https://www.health.harvard.edu/blog/home-blood-pressure-monitors-arent-accurate-201410297494.

[5] https://omronhealthcare.com/products/platinum-wireless-upper-arm-blood-pressure-monitor-bp5450/.

24. The Amazon.com listing for the Product currently describes it as the "OMRON Platinum Blood Pressure Monitor, Upper Arm Cuff, Digital Bluetooth Blood Pressure Machine, Stores Up To 200 Readings for Two Users (100 each)."[6] The current listing further describes the Product as having the following functions and attributes[7]:

a. "Accurate. Reliable. Easy to use."

b. "The high morning average indicator alerts the user if systolic or diastolic measurements are out of normal range in the morning, when there is a higher risk for heart attack or stroke."

c. "Backed with a 6-year warranty. OMRON stands behind the accuracy and quality of our products, and believes in the longevity of our blood pressure monitors."

d. "Monitor meets the Validated Device Listing (VDL) for Clinical Accuracy as determined through an independent review process."

25. Earlier versions of the Amazon.com listing during the Class Period also included statements like "TRUSTED BRAND - OMRON is the #1 recommended home blood pressure monitor brand by doctors and pharmacists for clinically-accurate home monitoring, and the #1 selling manufacturer of home blood pressure monitors for over 40 years."

[6] https://www.amazon.com/Platinum-Pressure-Bluetooth-Storesup-Readings/dp/B07RX8WQ4K

[7] *Id.*

C. Purchasers are Misled about the Product

26. Defendant, as the manufacturer, is responsible for creating, designing, and approving the advertising shown on the Amazon website and such advertising was placed on the Amazon listing at Defendant's direction. This includes the Product name, description, attributes, features, and benefits.

27. While Defendant touts the Product on the Amazon.com listing as "accurate" and "validated" for clinical accuracy by unexplained explained standards, these representations are false, or at minimum misleading, because the Product does not in fact produce "accurate" blood pressure readings, let alone consistently for all users.

28. **First**, the Amazon.com listing does not disclose (let alone conspicuously) that, according to Defendant, the Product is at best "accurate" within a range of +/- 3 mmHg for systolic and diastolic pressure. The manual for the Product specifically states its "accuracy" is only "+/- 3 mmHg." However, based on Defendant's representations, a reasonable purchaser of the Product would believe that the Product is actually accurate and that the blood pressure value displayed by the Product is in fact the user's actual blood pressure. A Product is "accurate" and "reliable" if it produces correct results every time it is properly used.

29. **Second**, the blood pressure measurements generated by the Product are in fact regularly inaccurate by 10 mmHg to 30mmHg. The examples are many. One Amazon.com user review dated March 7, 2023 explained in detail that, based on his testing, the Product is "highly inaccurate" by +/- 10 to 12 mmHg.

Customer Review

GiggleX

★☆☆☆☆ **Highly inaccurate +10-12 mm Hg**

Reviewed in the United States on March 7, 2023

Verified Purchase

Seriously DO NOT BUY

I'm an biomedical engineer and an PhD and I will tell you that my tests with this prove it's all show and no go. Great features except readings that are 8-10% off.

The "platinum" unit reads 153/97 in the doctors office but the doctors Welch-Allyn unit reads 134/83
That is not even close. This unit is consistently 10+ mm Hg off.

The phone app and unit worked fine but inaccuracy is unacceptable. Note this unit inflates fully then decreases pressure unlike more modern units that measure as they increase pressure including the Cardiologist office (have to assume they have a great unit).

The features are great, even the optional battery powered and ac options. But functionality is a zero.

As a note I bought a $40 Walgreens model that measure on inflate and it was accurate WGNBPA-220 - it was +/- 2mm (shown in photo no bells and whistles other than a memory, but it uses a modern technique and is accurate and portable battery powered)

Same for my Omron wrist monitor from 2011 was within +/- 2-3 mm

Honestly this is garbage and the problems it takes to return the unit is ridiculous. Amazon won't return have to call manufacturer.

Update: called manufacturer and they verified unit it "overinflating" going to 205 and getting reading of 153 - this item should be taken off the market - and FDA should step up.

Do not buy - as another reviewer wrote they just subtract -10 from reading it shouldn't work that way - it's either accurate or it's garbage.

30. Over 100 other user reviews—including reviews authored by physicians—are in accord, explaining the the Product produces wildly different results within minutes of testing, the measurements are nowhere near the levels generated at a physician's office, and the Product cannot generate accurate measurements. Exemplar user reviews posted to Amazon are shown below.

Gary Lindenbaum

★☆☆☆☆ **Horribly inaccurate and inconsistent**

Reviewed in the United States on July 21, 2022

Verified Purchase

I'm an MD. I've had three of these pieces of junk and they're a waste of money. Here's why.
1-Their proprietary "Intellesense" protocol which takes 3 BP measurements 1-3 minutes apart (user defined) is not consistent at all with the American Heart or American Hypertension Association's recommendations on how to take your blood pressure.
2-The manufacturer seems to only understand arm cuff size in one dimension, that being horizontal cuff size or the length of cuff wrapped around the bicep. The vertical length of the cuff matters too because you need 2 cm clearance between the lower end of the cuff and your elbow crease. If you have a short humerus like me, you're out of luck. OMRON only makes one size in this dimension. This is interesting because OMRON does make cuffs of different lengths for the units they provide to doctors offices and hospitals.
3-As many others have pointed out, this unit is very inaccurate. I took 3 readings tonight, one minute apart after 5 minutes sitting quietly according to the AHA guidelines. My readings were 147/89, 122/76, and 138/85. These widely disparate readings are clear indication of an inaccurate device.
I have yet to find ANY machine that takes accurate BP measurements. My advice.
Find a good manual BP cuff and have your doctor show you how to use it. It's not rocket science and I've found it to be accurate and reliably consistent.
That's what this doctor does for his BP.

Paul Roberts

★☆☆☆☆ **Inaccurate**

Reviewed in the United States on January 29, 2022

Verified Purchase

I am a physician with mild hypertension and wanted to track my systolic and diastolic blood pressure several times a day over several months, as I started anti-hypertensive medication. Throughout the day, I was getting wildly different and troubling high readings, with the systolic ranging from 135-150 and the diastolic from 85-100. But when my blood pressure was checked at my primary physician's office, the readings were a steady 110-115 over 70-75. Finally, last week, I brought the OMRON in for a head to head comparison, and while my home unit indicated a blood pressure of 138 / 86, the physician's monitor indicated 105 / 70. A significant disparity, strongly suggesting the OMRON is grossly inaccurate. What is vexing is that my former OMRON, purchased several years ago, but lost during a move, was also registering similarly high readings, which I formerly believed as accurate and precise, and motivated me to reduce salt intake, lose weight, and exercise . . .and none of these 'lifestyle' measures changed the readings. So I stgarted asking around, and I have personal friends and colleagues indicate experiences with similar significant inaccuracies with the OMRON devices, despite their 'reputation' and higher cost. It would seem, given how many depend on the readings of a blood pressure monitor as matter of health, and given the sophistication of today's technology, that this should not be an issue. So buyer beware.

Irene A. Cohen, M.D.

★☆☆☆☆ **Not accurate**

Reviewed in the United States on June 25, 2023

Verified Purchase

So far this is not an accurate machine. I am a retired physician and have been taking blood pressures since 1979 in medical school. I took two readings 5-10 minutes apart without moving the cuff and got the above results. My systolic bp did not drop 13 points within 10 minutes. I then used my old school stethoscope and sphygmomanometer and got a completely different reading which was higher than these two. I will give this one more chance and then it is going back to Amazon as a return.

Mamasars

★☆☆☆☆ **Just say no**

Reviewed in the United States on April 10, 2023

Verified Purchase

I purchased this item in early January 2021. It has become very erratic in the readings, showing very high blood pressures. I reached out to Omron so they could recalibrate it. Even though on the description it says there is a six year warranty, they don't stand behind it. I was told to replace the cuff for $28!! If I used it on a regular basis, I wouldn't think much about it, but it has been rarely used. This is the last Omron unit I will buy! My family has always used Omron. I have purchased units for my parents, my daughters and friends who didn't have the funds. This is ridiculous!!

Sandrunner6

★☆☆☆☆ **Not accurate and a nightmare to set up**

Reviewed in the United States on January 16, 2023

Verified Purchase

I was excited to purchase the top of the line blood pressure monitor that would send data to my phone so I could easily share it with my health care provider. Unfortunately that's when my excitement ended in frustration in trying to get the monitor to connect with the app. The instructions are clumsy and not forgiving or intuitive. Hours later I finally got it connected and took my first reading. Much to my surprise the reading was significantly higher than the readings at my providers office. So I waited awhile and tried again. Same. Every reading I take has me T hypertension stage 1 or 2 and my providers tells me this is just not the case. I wasted a bunch of money on a piece of junk and can no longer return the product.

A.I.

★☆☆☆☆ **Does not meet specification for accuracy - Widely inaccurate! App is terrible, too.**

Reviewed in the United States on December 28, 2019

Verified Purchase

This is the latest generation of OMRON blood pressure monitors, released in 2019. Considering that OMRON is a "brand name" and that this is the latest and the greatest that they can offer, I had high hopes for this monitor. It came nicely packaged, with a soft case, batteries, and a printed manual included in the box. Unlike most consumer goods on this planet, it is not made in China but it Vietnam.

I have an elevated blood pressure and decided that I need to monitor it to find the best combination of food, exercise, and natural healing methods to keep it in control without medication. The specification of the monitor, printed in the manual, is: accuracy of measured blood pressure +/- 3 mm Hg, and +/-5% for pulse. This looks great on paper. This means, if your blood pressure is 150, the readings should be within 147 to 153 range. To validate the specified accuracy, I took 9 consecutive measurements, separated by 60 seconds between the end of the previous measurement (when the cuff deflates completely) and the beginning of the new one. I expected my blood pressure to be in the mid-140s range. Here are the 9 readings for my systolic pressure:

161 - 152 - 144 - 164 - 152 - 160 - 146 - 160 - 152

Can anyone tell me what my systolic blood pressure is? If it is 161, I have a serious problem. If it is 144, is elevated, but kind of OK. The range from 144 to 164 is 20 mm Hg. It is not anywhere close to the stated +/-3 mm Hg accuracy. Note, nothing changed in my condition within about 16-18 mins which it took to collect these 9 measurements. I did not remove or readjust the cuff. I was sitting at the same table occupied just with this test. I was just watching the time, pressing the button, and taking measurements. There is no reason to think that my blood pressure would fluctuate that much and so randomly when sit in a relaxed position. The only conclusion that I can make is that this monitor is wildly inaccurate and cannot be trusted.

Since it does not meet the spec and cannot be used to make a reasonable conclusion how high my blood pressure it, I consider it not working and sending it back. Looking at other reviews here on this Amazon page, it became clear that I made a mistake and bought a monitor which is consistently inaccurate, as reported by many users. It seems to be not a failing unit which I was lucky to get, but a systemic issue with a poorly designed product.

Not that it matters with the monitor so inaccurate that it cannot be used at all, but a few words on overall impression from its features. It has memory for 100 last readings for each of two users, which is nice. The user interface is a little primitive, for today's standards - a touch screen is definitely missing. But on the other hand, liquid crystals display might be more battery-friendly. It would be hard to set up without a manual, but since the manual in included and is very detailed, everything can be set up by pressing a sequence of buttons to set up date and time, and everything works.

The platinum version which I got also has the ability of automatically taking 3 measurements and averaging them to improve accuracy. Turning this feature on or off or changing the pause between the measurements through pressing a sequence of buttons is a pain as one has to go through the complete setup process from the very beginning. Another good reason for a lower rating. Given such wild fluctuation of readings in individual measurements, I would not trust the average, although the variability of average is, as expected, lower.

OMRON recommends that users install an application "OMRON connect", available for iPhones and Android phones. The app connects to the monitor via Bluetooth. Reportedly, one can quicker set up the monitor via the app, and one can view the history of measurements on the phone. I downloaded the app, but immediately run into a MAJOR RED FLAG when trying to start it - in order to use the app, one has to create an OMRON account, provide some personal health related data (like date of birth, weight, etc.), and agree to receive marketing information. I see absolutely no reason why OMRON should have access to my health information (this company is not my doctor) and why they should have the option of selectively spamming me based on my blood pressure readings. If I had a good level of respect for OMRON based on their "brand name" status, this respect has fallen down the cliff once I saw their app. No wonder, it has 2.1 stars rating on Google. This rating is partly affected by the problem which I outlined above, and partly by poor and unstable connection to the monitor and lack of functionality, reported by many users. Also, users report that most useful features of this app are not free.

R Smith

★☆☆☆☆ **Reading are Not correct, not even close.**

Reviewed in the United States on February 24, 2023

Verified Purchase

Warning, there is no returns / no refunds on this item.
Wish I could give this zero or negative stars.
At first look without using it, It seems to be made well.
The reason I purchased this was because my doctor wants my blood pressure a little lower. It is at the high end of the saf range, he woul like to see it closer to the middle of the safe range.
Major issues:
1) Will not stay connected with Bluetooth, keeps disconnecting, then you must go through the pairing process each time.
2) Will not stay synced. Must keep runing through the Bluetooth pairing process inorder to sync device to app. Wait a few minutes the app says it is not connected to the device, yet I am still sit at my desk with the BP monitor within two feet of my phone.
3) Worthless App, After you spent 10 to15 minutes each time, trying to get this thing to pair with the app and to so-call sync it. The app says it synced, yet the app shows no results. App does not show any reading, so what is it syncing? What the app for? I wanted to be able see past reading and to be able to shows my doctor if needed. Says it stores up to 100 reading for teo users. Where are these reading stored, not in the app. If they are, it does not show them to you. Select dashboard, white screen. Select Blood Pressure, white screen.
4) **** MAIN issue. Incorrect readings. I took this with me to my doctor's office. I wanted to make sure I was doing it correctly and that the reading were correct, or at least in the same ballpark. Why did I do this? The first two reading I too looked way off. At my doctor's office, I showed him how I was doing it. He said, that looks correct, the reedings were way off, 221/162. So my doctor took a reading with his equipment, then tested this blood pressure reader. He put the band o my arm and took the readings. He switched back and forth, three times each, between his machine and this one. My doctor even took a manual reading to ensure his equipment was correct.
Results:
My doctor's equipment reading were 128/81, 127/80 and 129/81 for the three reading. Doctor's manual reading 127/81 in the same tiny ballpark as his blood pressure machine. The difference between his machine readings were basically null within 2 points of each other on both upper and lower readings and his manual reading.
Using this blood pressure machine, my doctor took the readings. He even checking the arm band and tried repositioning Doctor's reading with this blood pressure reader were as follows: 219/152, 181/119 and 198/129 for the three readings. Please remember, my doctor was switching between his BP machine and this one for each reading.
a) Readings are WAY off, by as high as 91 points.
b) The reading are all over the place. Upper numbers are fluctuating between 91 to 54 points.
Lower reading fluctuating between 71 to 39 points.
My doctor nor I trust the readings from this machine. There is no reason for my doctor to make this fail. Besides, I took two reading the day before and they were way high (the reason I took this with me to my doctor's appointment).
Based on this machine, I have Super Hypertension Stage 3 and I should be in the hospital or dead.
My blood pressure is at the upper end of the safe range, no where need being a critical or life threatening health concern as this machine says.
I am now out $84+ on this junk. (No returns, no refunds).

If you for some reason decided to buy this Blood Pressure reader, Please, Please check and confirm the reading with a doctor's BP reader or one at your local pharmacy before you start relying on its reading for any health related issues.

32 people found this helpful

Helpful | Report

Reviewed in the United States on September 8, 2023

Verified Purchase

I've had this BPM checked by treating physician 3 times and every time reading is way off from doctor's calibrated monitor. Also off from Doctor taking manually. Never able to get good reading. Waste of money.

PL

★☆☆☆☆ **Beware!**

Reviewed in the United States on June 9, 2023

Verified Purchase

Purchased the device in December of 2022 after careful research and trust in Omron brand. When at my general physicians office a couple times since then, BP readings he has taken seemed lower than readings I was getting using the Omron device but no alarm bells went off in my head. Only when I was asked by another doctor to bring in the device to my appointment so he could compare readings he got vs. my Omron device and when he informed me that the device readings (which are set to do a set of 3 readings) were about 10 points off than his readings - his readings being 10 points less than Omron readings - I have tried reaching Omron Customer Support with whom I had registered the device. They asked a bunch of questions, rather than answer mine. When done with the 20 questions, I was informed devices are internally calibrated and cannot be manually calibrated. They would not replace the unit which has 6 year warranty on it but instead asked that I pay for shipping of device, so they could test it and if they determined device was faulty, they would send a new one. When I asked how long receiving a replacement would take, I was told at least 30 days. Needless to say, I am not a happy customer. I expected the device to be accurate. Getting a device that is off by 10 points is not acceptable. BEWARE!

Viacheslav

★☆☆☆☆ **DANGEROUSLY inaccurate**

Reviewed in the United States on September 17, 2023

Verified Purchase

The obviously invested a lot of money into marketing, as every website puts their product on top, except for one or two websites that clearly show their products are inaccurate. In my hands, five consequent readings show 125/71, 135/80. 120/72. 140/71, 161/79. The pulse measurements are also way off - at least by 10-15 bpms. But the systolic inaccuracy is the primary issue.
As a matter of fact, the main reason I got myself the monitor is because of the last two visits to see my dentist where they used OMRON and it showed me elevated blood pressure that I never experienced in my life.
This device has very serious issue, and I exclude the user-error as a different brand I just got shows very accurate numbers . If you chose to get one - make sure you read several times cause considering the deviation you may get in serious trouble or on the opposite will think you are in trouble while all the vitals are being normal.

Dr.Seuss

★☆☆☆☆ **Bad Product**

Reviewed in the United States on July 4, 2023

Verified Purchase

This product is nearly perfect, but fundamentally flawed. The product is easy to use, easy to read, the free software works very well, and will automatically collect the results. The blood pressure cuff is also a nice quality. It runs off batteries or AC power.

However, if you check the specs you will see accuracy is +/9 mmHg (about 9% at 90 mmHg...) They are right about +/- like on alternate readings. So like 18 mmHg between two readings. You also apparently can't send it back to Amazon. It is FDA approved, so I guess if you are inclined you can report it to the FDA via their consumer hotline. Alternatively you could just buy something else. I replaced this with Invaxe Automatic Blood Pressure Monitor ASIN ： B0BPPLN8FD for about $55. It has worked superbly out of the box with no issues, and stable measurements. It is not perfect but at +/- 3 mmHg it appears more accurate, but (for me) more important, the measure to measure stability, and repeatability of measure seems to be considerably better. I 'll keep as a back up, but I would not replace it with another Omron product.

Jerie

★☆☆☆☆ **Inaccurate!**

Reviewed in the United States on February 3, 2023

Verified Purchase

While very easy to read and pretty easy to use, this machine measured over 10 points higher on diastolic and 10+ points lower on systolic compared to machine at doctor's office. It was over 30 days since purchase so Amazon would not let me return. Had to go through OMRON - and have to send it back (at my expense!) for them to check. They will then send me a new machine if mine isn't reading correctly, or return this machine. For a machine of this price, I would expect it to be accurate!

Updated - On their direction, I sent this machine back to Omron. The machine was there for a full 3 weeks before I heard back that it had not passed their testing and did not meet manufacturer's specifications. Therefore, they are sending me a new cuff back with my machine. I inquired as to having my shipping cost refunded. So far the agent I had been corresponding with and his supervisor have both told me that they do not refund shipping. I am continuing to escalate this. Their approximately $90 product was found to be defective by them, and I am out the $25.79 (plus loss of the use of the machine for over 1 month) and they will not refund the shipping I incurred. If you purchase a machine from Omron, I strongly suggest that you get it checked with a professional machine within the 30 day Amazon return period! Changing rating to 1 star - nothing to do with Amazon - just poor product support.

6 people found this helpful

Gary T

★☆☆☆☆ **Inaccurate readings**

Reviewed in the United States on September 5, 2023

Verified Purchase

The doctor recommended the OMRON brand after a recent visit for a checkup. He put me on a med since mid-August and I've been using this model to monitor it since. It ready mostly at the hypertension 2 level, sometimes hypertension 1. Today was a follow-up appointment and the medical assistant took a manual reading that was at a normal range. When the doctor came in, he also took another reading and it was also normal. We did a reading with the OMRON BPM and it said hypertension 2. The readings with it were done using TruRead taking an average of 3 readings with 30 seconds in-between. He suggested not to use that feature. We took two more readings as single readings and compared against his manual readings. We did it with both arms. The readings of this unit were way too high. The chat agent here quickly issued a refund. I will be trying another OMRON model.

2 people found this helpful

Bart L. Schairer VINE VOICE

★☆☆☆☆ **Inaccurate Diastolic Readings**

Reviewed in the United States on July 3, 2023

Verified Purchase

Cons:
Not accurate

I bought this because Consumer Reports, Forbes, and many others claimed it was one of the best on the market. My former monitor of another brand, had been accurate for two years but started giving really low blood pressure readings, which didn't match the normal readings I got from doctor visits and my nurse wife's manual readings. This Omron Platinum did the same thing as my former monitor right out of the box - gave me low readings. A five point difference would have been understandable, but it consistently read 15 points lower for the diastolic reading from my nurse wife's manual readings and even my mother-in-law's wrist blood pressure monitor. My wife, my cardiologist, my family doctor, consistently get diastolic readings from 76 - 80 while the Omron reads 61 - 65. According to Omron, I am border line low blood pressure, while the rest of the world says I have normal blood pressure. I messaged Omron Support on their website, but after 13 days I have received no response, so I'm returning this to Amazon.

C. E. Smith

★☆☆☆☆ **Is not very accurate. DO not bet your life on it**

Reviewed in the United States on June 7, 2023

Verified Purchase

I bought this after I had some issues with my blood pressure and was having panic attacks. I would go to my doctor and my blood pressure would be fine, and every time I would take it at home it would be way high. A few times I got so worked up about my blood pressure I went to the ER where it was elevated (do to anxiety because it was reading wrong) but nothing to worry about. I eventually just stopped taking my blood pressure as it was just to scary every time I did and I would rather just not know. I explained this all to my doc and he said well bring in the machine and we can take them one after another and see if its accurate. Needless to say this thing was way off the mark and my doc told me not to use it. Don't trust your life on this machine.

Mary Ann Vorasky

★☆☆☆☆ **Widely divergent readings that cannot be trusted - buyer beware!**

Reviewed in the United States on March 3, 2023

Verified Purchase

I already did a written review for this product and spent the time detailing just how untrustworthy it is, and a lesser expensive version of it as well that I unfortunately did not return in time, so now I have two OMRON products that are equally bad. I guess my other review didn't pass muster because in it I wondered why OMRON is so popular and guessed at the reasons. I won't do that here. Suffice it to say I do not trust this product and could never recommend it. Even though it does a handy trick of letting you save the reports and email them, the reports themselves are not trustworthy. I have had 2 medical professionals tell me the machine needs to be "calibrated." But no one calibrates these machines. That simply means going into the doctor's office to compare the results with their blood pressure monitor. My blood pressure was excellent at the doctor's office, but on the OMRON is was at every single level possible, including crisis mode, and extremely low. Untrustworthy, unreliable, do not buy this product.

Bigmac

★☆☆☆☆ **Incredibly Inaccurate!**

Reviewed in the United States on September 29, 2023

Verified Purchase

You would probably be better off throwing a dart at a dartboard with blood pressure numbers on it while blindfolded.

Within 5 mins my pressure went from nearly 160/100 to 129/89. I wasn't exercising, not drinking or doing anything else that would cause such a change.

This thing is about as stable as a flea in a hurricane. And it is completely worthless!

Stephanye mora

★☆☆☆☆ **Garbage product**

Reviewed in the United States on August 28, 2023

Verified Purchase

As a nurse who need accurate readings. I'm disappointed. Readings are inaccurate not a reliable product. Do not waste ur money your better off with a 19.99$ wrist blood pressure machine from cvs

VUnpingco

★☆☆☆☆ **Larger Cuff Size unavailable**

Reviewed in the United States on April 25, 2020

Verified Purchase

I received the OMRON BP5450 from amazon.com with high hopes in its ability to capture Bluetooth readings. Issues: 1) The transfer of blood pressure reading requires patience, "just a couple of tries and re-pressing the Bluetooth button immediately to determine that transfer is in progress." 2) The transfer of blood pressure reading from smart phone to a PC is difficult for an average user. You will need to parse the individual reading from .txt file to a document or spreadsheet file. At times it just becomes simpler to manually transfer from unit to paper-n-pencil. 3) The blood pressure readings taken by a nurse at the doctor's office is very different from the OMRON BP5450. The nurse said that I should get and use a larger cuff size. That is a very big problem for OMRON. They have stated that their standard cuff provided with the unit, "fall within that parameter," for providing adequate blood pressure readings. Additionally, their email reply is that I need to properly adjust the cuff on my arm and troubleshoot this problem. This is not the case with their previous blood pressure units. I have been using a larger cuff size, which I bought from OMRON, and it does provide very different readings when validated against the OMRON BP5450. In fact, this older unit does match the blood pressure readings at the doctor's office. I also, compared a different blood pressure unit (A&D) using a larger cuff, and found that the nurse was right. Using a larger cuff size for me provides blood pressure readings that are similar and even matching their readings from their doctor's office grade blood pressure machines. Bottom line, for standard arms cuff size does not matter to OMRON, it falls within their parameters. "I presume that with the OMRON BP5450, you need to find a way to reduce your arm size. Or you just don't fall within their parameter.

just a consumer

★☆☆☆☆ **Bad Company Bad Product**

Reviewed in the United States on April 20, 2022

Verified Purchase

After doing extensive online research on this product including the 2022 Forbes recommendations for BP monitors, I purchased this from Amazon. Excitedly opened the package and followed all the instructions for setup and use. Downloaded the Omron app and expected the Platinum subscription benefits as advertised, not so fast son. Called the company and was told there is a problem with the app, but the engineers were on top of it and the update would fix the problem. Not yet.

The machine is difficult to setup and use the 3 readings function. Once I had it operating in the "basic features mode I attempted to use the cuff the way my cardio's office had instructed, which is the opposite of the Omron's help desk instructed me. I called to again to get a replacement for the cuff and was rejected. The readings were 20 points higher than the office readings.
Bottom line not a good choice based on price, software app, ease of use and most importantly accuracy Update Tried to get the company to replace or repair the monitor. They had more reasons not too then to live up to their warranty.

Kevin Woods

★☆☆☆☆ **The unit is inaccurate by at least 15%**

Reviewed in the United States on May 19, 2021

Verified Purchase

I had noted a blood pressure spike during an blood draw at work, where they checked blood glucose, cholesterol, and blood pressure. Alarmed that it was over my normal 120/80, I went to Amazon and found the Omron Platinum well-rated , and so it was by other sites as well. Wanting to monitor my blood pressure daily, I ordered it, it arrived quickly and I began using it. Easy to use, well manufactured and it has several good features like taking 3 readings and averaging, data tracking etc. The problem is that it is grossly inaccurate, at least the individual tester I have is. I had my pressure checked by a nurse at my doctors office and it was slightly elevated, like 127/77, but not as high as the Omron was checking at home. So I took my unit in to my doctor's office and we conducted a correlation study. She took a manual reading using the office's manual equipment, then I checked mine using the Omron immediately thereafter. We did this 4 times , and recorded the results. The Omron tested on average 15% higher than the nurse's reading. I could see 3 to 5 % difference, but 15 to 18%? So, while the unit is well built and has useful features, and is priced well , it is worse than useless at its specified uses, that of reasonably accurate blood pressure checks.

MJJ

★☆☆☆☆ **Completely in accurate**

Reviewed in the United States on October 15, 2021

Verified Purchase

I have an Omron wrist Blood pressure cuff that works perfectly with my doctors in their office. I have just gotten rid of an old Omron cough blood pressure machine that was probably eight years old and it finally just pooped out. Again it worked perfectly with the one in my doctors office within a few points. And my day-to-day blood pressure was within a few points of variation every day and was quite accurate.

This machine delivered blood pressures of 88/52, 80/60, 145/60, 110/80, over two weeks it was absolutely ridiculous it could not possibly have been correct. I took it to my doctors office yesterday and we spent a great deal of time testing it. It was within 20 points each time that I took the pressure would be the 20 points up 20 points down. The doctors blood pressure machine was quite consistent within a couple of points as usual. The last blood pressure I took was 130/75 and waiting a few minutes the one in the doctors office was again very consistent 110/68 which is very close to my usual blood pressure. I can't tell you how disappointed I am in this machine I had such good luck with the first one that I had.

PaulInNy

★☆☆☆☆ **So Inaccurate**

Reviewed in the United States on November 17, 2021

Verified Purchase

After an abnormal high blood pressure reading at my doctor she suggested I get a BP monitor to use at home and track my readings. If the abnormal number stayed high I was to visit my primary or cardiologist. Received the OMRON unit from Amazon the next day and took my readings…high again. Called cardiologist who saw me that day. They took my BP and it was normal. To be safe we scheduled a stress test and was told to bring the OMRON with me to that visit to compare. I continued daily reading with the OMRON which were similar to the high readings initially. This worried me a lot. Yesterday I had my stress test which was perfect. We then took three simultaneous BP readings. The OMRON was 30+ points too high on every reading ~150 vs 120. We then tested two other people and the numbers were equally off. The doctor said the home auto cuffs are notoriously unreliable. I researched this on Consumer Reports before purchasing and they gave it a top review. Terrible device!

31. Additionally, several reviews of the Product posted to Defendant's own website similarly conclude that the Product was wildly inaccurate when compared to a physician's clinical blood pressure reading—including where users brought the Product with them to their physician's office for a direct, side-by-side, comparison.

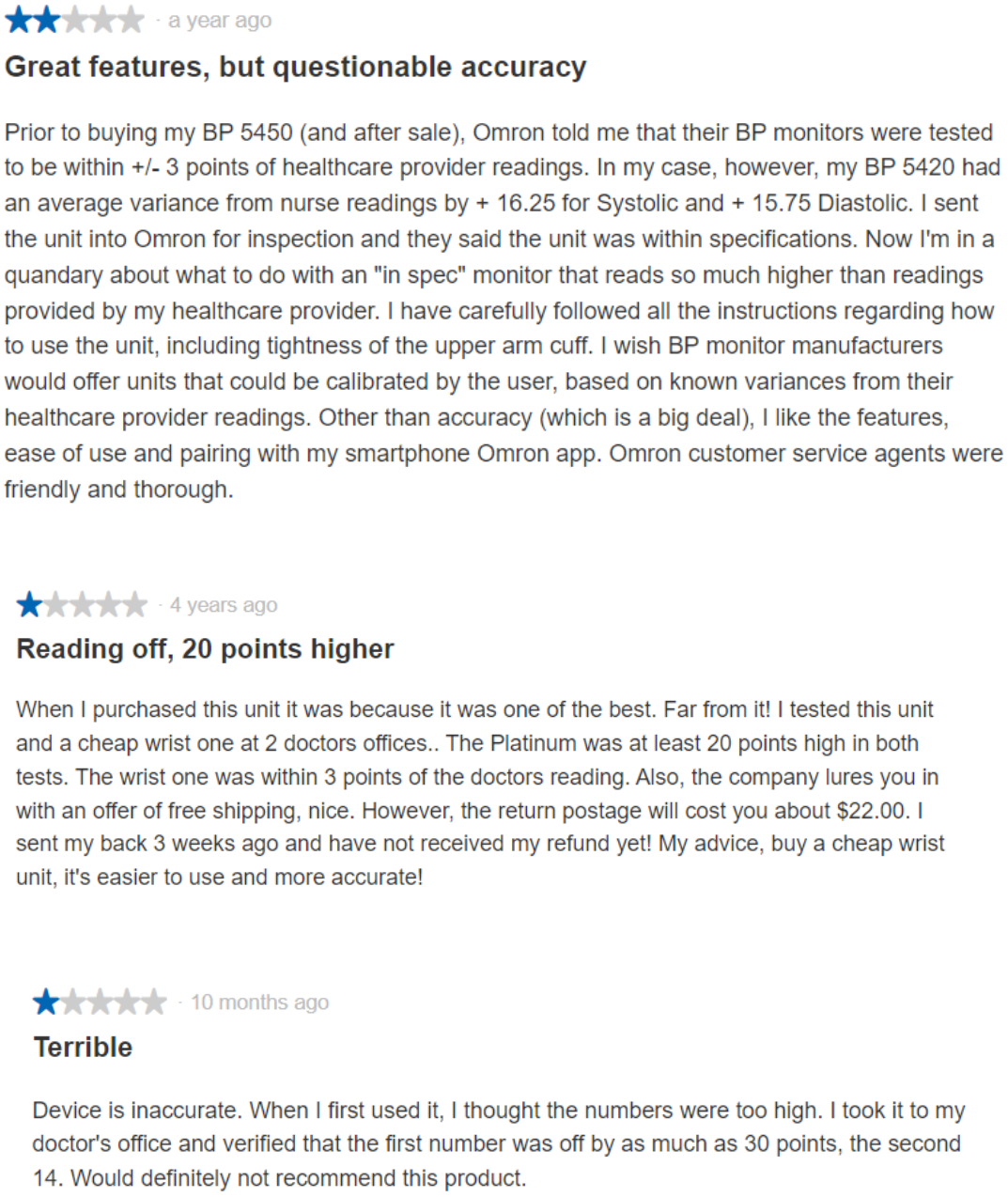
a. A review published "4 years ago" stated: "I have taken the device to compare it with two different medical checked devices as advised by my doctor to be surprised with the result and that the device is almost 10-15 points higher than the healthcare center approved devices. I have communicated with the support team during the first 30 days ***to get my money back as advertised,*** but the ***response was very bad with no follow-up at all for my case.***" The review also included pictures of the Product's reading against the healthcare provider's reading.

★★☆☆☆ · 4 years ago

Not accurate at all!

I have bought this BP monitor to check my Hypertension Stage 1 case however it was always giving high reading compared to what I have to see in my healthcare center. I have taken the device to compare it with two different medical checked devices as advised by my doctor to be surprised with the result and that the device is almost 10-15 points higher than the healthcare center approved devices (Check pictures)
I have communicated with the support team during the first 30 days to get my money back as advertised, but the response was very bad with no follow-up at all for my case.
I'm just given ** as the device has good features otherwise, I would give *.
I hope come one contact me from the support team to give me my money back or to replace the device if there is any hope for a good device.

b. Additional reviews of the Product on Defendant's website are shown below.



· a year ago

Great features, but questionable accuracy

Prior to buying my BP 5450 (and after sale), Omron told me that their BP monitors were tested to be within +/- 3 points of healthcare provider readings. In my case, however, my BP 5420 had an average variance from nurse readings by + 16.25 for Systolic and + 15.75 Diastolic. I sent the unit into Omron for inspection and they said the unit was within specifications. Now I'm in a quandary about what to do with an "in spec" monitor that reads so much higher than readings provided by my healthcare provider. I have carefully followed all the instructions regarding how to use the unit, including tightness of the upper arm cuff. I wish BP monitor manufacturers would offer units that could be calibrated by the user, based on known variances from their healthcare provider readings. Other than accuracy (which is a big deal), I like the features, ease of use and pairing with my smartphone Omron app. Omron customer service agents were friendly and thorough.

· 4 years ago

Reading off, 20 points higher

When I purchased this unit it was because it was one of the best. Far from it! I tested this unit and a cheap wrist one at 2 doctors offices.. The Platinum was at least 20 points high in both tests. The wrist one was within 3 points of the doctors reading. Also, the company lures you in with an offer of free shipping, nice. However, the return postage will cost you about $22.00. I sent my back 3 weeks ago and have not received my refund yet! My advice, buy a cheap wrist unit, it's easier to use and more accurate!

· 10 months ago

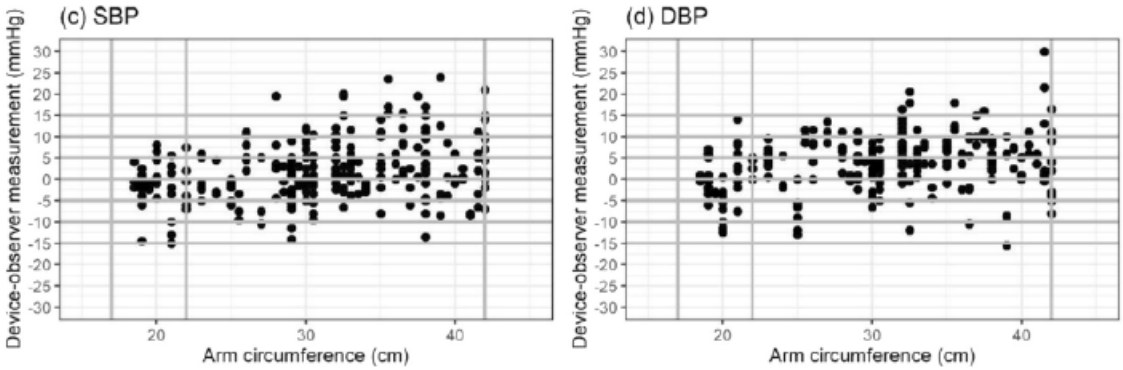
Terrible

Device is inaccurate. When I first used it, I thought the numbers were too high. I took it to my doctor's office and verified that the first number was off by as much as 30 points, the second 14. Would definitely not recommend this product.

32. **Third**, the Product's user manual warrants that the device is accurate within a range of +/- 3 mmHg. This is false and misleading because the Product generates inaccurate readings by at least 10mmHg, as shown above. Importantly, according Defendant's commissioned Northwestern Study, the Product was only accurate within a range of +/- 3.7 mmHg for diastolic

pressure—which is more than the 3 mmHg warranted in the user manual. And for persons using the standard "wide range" cuff (22–42 cm or 9–17 inches) that comes with the Product, the Product produced diastolic blood pressure readings that deviated by an average of 4.30 mmHg (standard deviation of 5.8 mmHg) from the true level.

33. **Fourth**, and critically, the Northwestern Study found that the the Products produce particularly inaccurate readings for users with a larger arm circumference, which Defendant knew because it commissioned the study. The below scatterplots from the Northwestern Study compare blood pressure readings from the Product against blood pressure readings for the same individual taken by a physician with standard mercury sphygmomanometers that were calibrated before the study began and validated against measurements generated by a dual head teaching stethoscope. As shown in the images, the larger the arm circumference, the greater the deviation from accurate readings. Individuals with an arm circumference of 30 cm or more are given completely unreliable readings that often deviate 10 mmHg or more from their actual blood pressure.



34. **Fifth**, the Product manual states it "has not be validated for use on pregnant patients"—a fact Defendant does not conspicuously disclose at the point of sale and omits from the Amazon listing—yet Defendant misleadingly advertises the Product as "validated" and "accurate" for users generally.

35. None of the above limitations were disclosed by Defendant to consumers at the point of purchase. But, again, Defendant advertises the Product as (1) "*Accurate*. Reliable. Easy to Use"; (2) "OMRON stands behind the *accuracy* and quality of our products"; (3) "OMRON is the #1 recommended home blood pressure monitor brand by doctors and pharmacists for *clinically-accurate home monitoring*"; (4) "Monitor meets the Validated Device Listing (VDL) for *Clinical Accuracy* as determined through an independent review process"; and (5) "This product meets the Validated Device Listing ('VDL') criteria for validation of *clinical accuracy*, based on the independent review and acceptance of documentation submitted by the manufacturer." By touting these positive attributes that concern the central functionality of the Product, Defendant was obligated to disclose the Product's inherent limitations.

D. Defendant Knew About the Product's Defect and Limitations

36. Defendant has been aware of the Product's inaccurate readings and the above-described limitations since the Product was launched in 2019, and years earlier.

37. As explained above, no less than fifty consumers submitted thorough and detailed reviews about the Product's consistently inaccurate readings. The volume of negative reviews raising the exact same defect is unusually large and is indicative of a widespread problem.

38. Not only does the number of complaints over the course of several years demonstrate that Defendant was on notice of the defective readings, but the substance of the complaints shows that consumers were surprised, frustrated, and disappointed with the inaccurate readings generated by the Product and would not have purchased the Product had the defect been disclosed.

39. Defendant would have seen the above-described negative reviews and complaints on its own website and third-party retailer websites. Online Reputation Management (ORM) is now a standard business practice among major companies and entails monitoring consumer

forums, social media, and other sources on the internet where consumers can review or comment on products. ORM involves the monitoring of the reputation of an individual or a brand on the internet, addressing content, which is potentially damaging to it, and using customer feedback to try to solve problems before they damage the individual's or brand's reputation. Many companies offer ORM consulting services for businesses.

40. Like most companies, Defendant cares about its reputation and regularly monitors online customer reviews because they provide valuable data regarding quality control issues, customer satisfaction, and marketing analytics. One and two-star reviews like those displayed above would be particularly attention-grabbing for Defendant's management because extreme reviews are often the result of material problems. As such, Defendant's management knew about the above-referenced consumer complaints shortly after each complaint was posted on Defendant's company website and third-party retailer websites.

41. Additionally, Defendant is experienced in designing and manufacturing medical devices like Product. As an experienced manufacturer, Defendant conducts pre-sale and post-sale safety testing to verify the accuracy of blood pressure readings. Defendant discovered the consistently inaccurate readings, including for users with a large arm circumference, during testing both before and after publicly releasing the Product for sale, but made a business decision not to take action, including recalling the Product or offering a refund. Far from it, Defendant continues to advertise the Product as "Accurate. Reliable. Easy to Use."

42. Finally, Defendant also would have had notice of the defective readings as a result of warranty claims. Before accepting a return or performing a repair, Defendant's policy is to ask each customer for a description of the request and to keep track of the reasons given. Descriptions

provided with returns and/or repair requests of the Product therefore would have disclosed the defective readings.

E. Defendant's Duty to Disclose

43. Superior Knowledge: As described above, Defendant is experienced in the design and manufacture of medical devices such as the Product. As an experienced manufacturer, Defendant conducts tests, including pre-sale testing, to verify the specifications of the products it sells. Defendant also receives, monitors, and aggregates consumer complaints. A reasonable consumer would not be on notice of the Product's inability to generate consistently accurate readings and do not have access to the granular data in Defendant's possession.

44. Active Concealment: Defendant actively concealed the Product's shortcomings as described above. Indeed, in response to consumer complaints within the warranty period regarding the Product's inaccurate readings, Defendant refused to repair the Product, told consumers it was accurate and working as designed, or replaced the defective Product with the same defective Product to make consumers believe the Product was always working and the problem lies with the consumer. Defendant also views and responds to negative reviews about the Product's inaccurate readings without publicly acknowledging the defect or the Product's limitations, and instead continues to tout the Product as accurate.

45. Partial Representations: As described above, Defendant represents on the Amazon listing, its own website, and Product packaging that each Product functions as an accurate and capable blood pressure monitor. Yet Defendant fails to disclose that the readings generated by the Product are not consistently accurate because they are at best within a range of accuracy, the Product does not meet its own +/- 3 mmHg range of accuracy according to a study it commissioned, the Product is incapable of providing accurate readings for users with a larger arm circumference, and the Product was never even tested for use by pregnant women. By disclosing some beneficial

attributes about the Product and describing its performance, Defendant is obligated to disclose material limitations that negatively affect the use of the Products.

46. The defect affects the central functionality of the Product in that it renders the Product unusable. For the same reasons, the Product presents an unreasonable safety hazard because users rely on home blood pressure devices to manage their healthcare and make medical decisions.

47. Defendant could have and should have prominently disclosed the limitations and omitted facts on product listings, on its website, on product packaging, and to third-party retailers. Had Defendant disclosed the defect in this manner, consumers would have been aware of it.

F. Plaintiffs' Purchases

Plaintiff Estrella

48. Plaintiff Estrella purchased the Product in or about June 2022 from Amazon.com while present in Florida.

49. Before purchasing the Product, Plaintiff Estrella viewed the description of the Product's features on the Amazon listing written by Defendant, including the misleading statements challenged in this action and described above regarding accuracy, performance, and reliability.

50. Plaintiff Estrella experienced inaccurate blood pressure readings with the Product by at least 10 mmHg. The Product is now non-functional and does not power on.

51. As a reasonable consumer, she believed that information regarding critical performance limitations and safety issues, like the Product's inability to generate consistently accurate blood pressure readings, would have been prominently disclosed by the manufacturer at the point of sale. Because no such limitations were disclosed, let alone prominently, she understood the Amazon listing representations made by Defendant as promising that the Product

would produce consistently accurate blood readings for all users and was safe under ordinary use. Plaintiff Estella relied on Defendant's misrepresentations and omissions in purchasing the Product.

52. Had Plaintiff Estrella known or otherwise been made aware of the Product's limitations, she would not have purchased it or would have paid significantly less for it. At a minimum, Plaintiff Estella paid a price premium for the Product based on Defendant's omission and concealment described herein.

53. Plaintiff Estrella would purchase another substantially similar product manufactured by Defendant in the future if the product was redesigned to make it 100% accurate. Plaintiff, however, faces an imminent threat of harm because she will not be able to rely on any representations or omissions of performance in the future and, thus, will not be able to purchase a device manufactured by Defendant.

Plaintiff Peery

54. Plaintiff Peery purchased the Product on November 10, 2022 from Amazon.com while present in California.

55. Before purchasing the Product, Plaintiff Peery viewed the description of the Product's features on the Amazon listing written by Defendant, including the misleading statements challenged in this action and described above regarding accuracy, performance, and reliability.

56. Plaintiff Peery experienced blood pressure readings generated by the Product within minutes of each other that differed by at least 10 mmHg.

57. As a reasonable consumer, he believed that information regarding critical performance limitations and safety issues, like the Product's inability to generate consistently accurate blood pressure readings, would have been prominently disclosed by the manufacturer at

the point of sale. Because no such limitations were disclosed, let alone prominently, he understood the Amazon listing representations made by Defendant as promising that the Product would produce consistently accurate blood readings for all users and was safe under ordinary use. Plaintiff Peery relied on Defendant's misrepresentations and omissions in purchasing the Product.

58. Had Plaintiff Peery known or otherwise been made aware of the Product's limitations, he would not have purchased it or would have paid significantly less for it. At a minimum, Plaintiff Peery paid a price premium for the Product based on Defendant's omission and concealment described herein.

59. Plaintiff would purchase another substantially similar product manufactured by Defendant in the future if the product was redesigned to make it 100% accurate. Plaintiff, however, faces an imminent threat of harm because he will not be able to rely on any representations or omissions of performance in the future and, thus, will not be able to purchase a device manufactured by Defendant.

Plaintiff Schneider

60. Plaintiff Schneider purchased the Product on October 14, 2021 from Amazon.com while present in California.

61. Before purchasing the Product, Plaintiff Schneider viewed the description of the Product's features on the Amazon listing written by Defendant, including the misleading statements challenged in this action and described above regarding accuracy, performance, and reliability.

62. Plaintiff Schneider experienced wildly fluctuating readings generated by the Product, some by as much as 30 mmHg within minutes of each other.

63. As a reasonable consumer, he believed that information regarding critical performance limitations and safety issues, like the Product's inability to generate consistently accurate blood pressure readings, would have been prominently disclosed by the manufacturer at the point of sale. Because no such limitations were disclosed, let alone prominently, he understood the Amazon listing representations made by Defendant as promising that the Product would produce consistently accurate blood pressure readings for all users and was safe under ordinary use. Plaintiff Schneider relied on Defendant's misrepresentations and omissions in purchasing the Product.

64. Had Plaintiff Schneider known or otherwise been made aware of the Product's limitations, he would not have purchased it or would have paid significantly less for it. At a minimum, Plaintiff Schneider paid a price premium for the Product based on Defendant's omission and concealment described herein.

65. Plaintiff Schneider would purchase another substantially similar product manufactured by Defendant in the future if the product was redesigned to make it 100% accurate. Plaintiff, however, faces an imminent threat of harm because he will not be able to rely on any representations or omissions of performance in the future and, thus, will not be able to purchase a device manufactured by Defendant.

Plaintiff Pond

66. Plaintiff Pond purchased the Product on or about September 26, 2022 from Amazon.com while present in Washington.

67. Before purchasing the Product, Plaintiff Pond viewed the description of the Product's features on the Amazon listing written by Defendant, including the misleading

statements challenged in this action and described above regarding accuracy, performance, and reliability.

68. Plaintiff Pond experienced wildly fluctuating readings generated by the Product, some by at least 10 mmHg within minutes of each other. She also purchased the Product, thought her individual unit was defective due to inaccurate readings and promptly returned it, and then purchased it again in hopes that the repurchased Product would work. However, the repurchased Product was equally inaccurate and defective.

69. As a reasonable consumer, she believed that information regarding critical performance limitations and safety issues, like the Product's inability to generate consistently accurate blood pressure readings, would have been prominently disclosed by the manufacturer at the point of sale. Because no such limitations were disclosed, let alone prominently, she understood the Amazon listing representations made by Defendant as promising that the Product would produce consistently accurate blood pressure readings for all users and was safe under ordinary use. Plaintiff Pond relied on Defendant's misrepresentations and omissions in purchasing the Product.

70. Had Plaintiff Pond known or otherwise been made aware of the Product's limitations, she would not have purchased it or would have paid significantly less for it. At a minimum, Plaintiff Pond paid a price premium for the Product based on Defendant's omission and concealment described herein.

71. Plaintiff Pond would purchase another substantially similar product manufactured by Defendant in the future if the product was redesigned to make it 100% accurate. Plaintiff, however, faces an imminent threat of harm because she will not be able to rely on any

representations or omissions of performance in the future and, thus, will not be able to purchase a device manufactured by Defendant.

V. TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

72. Any applicable statutes of limitation have been tolled by the discovery doctrine and Defendant's knowing and active concealment of the defect.

73. Through no fault or lack of diligence, Plaintiffs and members of the Class were deceived regarding the defect and could not reasonably discover the defect or Defendant's deception with respect to the defect.

74. Prior to purchasing and using the Product, Plaintiffs and Class members had no reasonable way of knowing about the Products' omitted limitations. Further, Plaintiffs and members of the Class did not discover and did not know facts that would have caused a reasonable person to suspect that Defendant was engaged in the conduct alleged herein.

75. By failing to provide immediate and conspicuous notice of the Product's limitations and inabilities, by responding (and refusing to respond) to negative reviews about the Product's performance without publicly acknowledging the Product's limitations, and by replacing Products under warranty with the same defective Products, Defendant actively concealed the Product's limitations from Plaintiff and Class members.

76. Plaintiffs did not learn about the Product's inability to generate accurate readings and the Product's limitations described herein until shortly before commencement of this action, or at minimum until they each purchased and used the Product .

77. Upon information and belief, Defendant intended its acts to conceal the facts and claims from Plaintiff and Class members. Plaintiff and Class members were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendant's conduct.

78. For these reasons, all applicable statutes of limitation have been tolled based on the discovery rule and Defendant's active concealment.

VI. CLASS ACTION ALLEGATIONS

79. Plaintiffs bring this action on behalf of themselves and the following classes and subclasses (collectively, the "Class") pursuant to Rule 23(b)(2), 23(b)(3), and 23(c)(4) of the Federal Rules of Civil Procedure.

a. **Nationwide class**: All persons in the United States who purchased the Product during the Class Period other than for resale.

b. **California subclass**: All persons in California who purchased the Product during the Class Period other than for resale.

c. **Florida subclass**: All persons in Florida who purchased the Product during the Class Period other than for resale.

d. **Washington subclass**: All persons in Washington who purchased the Product during the Class Period other than for resale.

e. **Multi-state subclass (Implied Warranty Non-Privity):** All persons who purchased the Product for personal use and not for resale during the Class Period in the following States: Alaska; Arkansas; California; Colorado; Connecticut; Delaware; District of Columbia; Florida; Hawaii; Indiana; Kansas; Louisiana; Maine; Maryland; Massachusetts; Michigan; Minnesota; Mississippi; Missouri; Montana; Nebraska; Nevada; New Hampshire; New Jersey; New Mexico; North Dakota; Ohio; Oklahoma; Pennsylvania; Rhode Island; South Carolina; South Dakota; Texas; Utah; Vermont; Virginia; West Virginia; Wyoming

80. Excluded from the Class are (a) any officers, directors or employees, or immediate family members of the officers, directors, or employees of any Defendant or any entity in which a Defendant has a controlling interest, (b) any legal counsel or employee of legal counsel for any Defendant, and (c) the presiding Judge in this lawsuit, as well as the Judge's staff and their immediate family members.

81. The "Class Period" begins on the date established by the Court's determination of any applicable statute of limitations, after consideration of any tolling, discovery, concealment, and accrual issues, and ending on the date of entry of judgment.

82. Plaintiffs reserve the right to amend the definition of the Class and subclasses if discovery or further investigation reveals that the Class or subclasses should be expanded or otherwise modified.

83. **Numerosity.** Class members are so numerous and geographically dispersed that joinder of all Class members is impracticable. While the exact number of Class members remains unknown at this time, there are thousands, if not hundreds of thousands, of putative Class members. Moreover, the number of members of the Class may be ascertained from Defendant's books and records. Class members may be notified of the pendency of this action by mail and/or electronic mail, which can be supplemented if deemed necessary or appropriate by the Court with published notice.

84. **Predominance of Common Questions of Law and Fact.** Common questions of law and fact exist for all Class members and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

a. Whether the Product contains the defect and performance limitations alleged herein;

b. Whether Defendant failed to appropriately warn Class members of the damage that could result from the use of the Product;

c. Whether the Defendant breached express and/or implied warranties made for the benefit of Plaintiffs and the Class;

d. Whether Defendant had actual or imputed knowledge of the defect and performance limitations but did not disclose it to Plaintiffs and the Class;

e. Whether Defendant promoted the Product with misleading statements of fact and material omissions;

f. Whether Defendant's marketing, advertising, packaging, labeling, and/or other promotional materials for the Product are deceptive, unfair, or misleading;

g. Whether Defendant's actions and omissions violate state law;

h. Whether Defendant's conduct violates public policy;

i. Whether Plaintiffs and putative members of the Class have suffered an ascertainable loss of monies or property or other value as a result of Defendant's acts and omissions of material facts;

j. Whether Defendant was unjustly enriched at the expense of Plaintiffs and members of the putative Class in connection with selling the Product;

k. Whether Plaintiffs and members of the putative Class are entitled to monetary damages and, if so, the nature of such relief; and

l. Whether Plaintiffs and members of the putative Class are entitled to equitable or injunctive relief and, if so, the nature of such relief.

85. Defendant has acted or refused to act on grounds generally applicable to the putative Class, thereby making final injunctive relief appropriate concerning the putative Class as a whole. In particular, Defendant manufactured, marketed, advertised, distributed, and sold the Products that are deceptively misrepresented, including by omission.

86. **Typicality.** Plaintiffs' claims are typical of those of the absent Class members in that Plaintiffs and the Class members each purchased and used the Product, and each sustained damages arising from Defendant's wrongful conduct, as alleged more fully herein. Plaintiffs share the aforementioned facts and legal claims or questions with putative members of the Class. Plaintiffs and all members of the putative Class have been similarly affected by Defendant's common course of conduct alleged herein. Plaintiff and all members of the putative Class sustained monetary and economic injuries including, but not limited to, ascertainable loss arising out of Defendant's misrepresentations and omissions regarding the Product's performance.

87. **Adequacy.** Plaintiffs will fairly and adequately represent and protect the interests of the members of the putative Class. Plaintiffs have retained counsel with substantial experience in handling complex class action litigation, including complex questions that arise in this type of consumer protection litigation. Further, Plaintiffs and their counsel are committed to the vigorous prosecution of this action. Plaintiffs have no conflicts of interest or interests adverse to those of putative Class.

88. **Insufficiency of Separate Actions.** Absent a class action, Plaintiffs and members of the Class will continue to suffer the harm described herein, for which they would have no remedy. Even if individual consumers could bring separate actions, the resulting multiplicity of lawsuits would cause undue burden and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated consumers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendant.

89. **Injunctive Relief.** Defendant has acted or refused to act on grounds generally applicable to Plaintiffs and all members of the Class, thereby making appropriate final injunctive relief, as described below, concerning the members of the Class as a whole.

90. **Superiority.** A class action is superior to any other available methods for the fair and efficient adjudication of the present controversy for at least the following reasons:

a. The damages suffered by each individual member of the putative Class do not justify the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct;

b. Even if individual members of the Class had the resources to pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed;

c. The claims presented in this case predominate over any questions of law or fact affecting individual members of the Class;

d. Individual joinder of all members of the Class is impracticable;

e. Absent a class action, Plaintiffs and members of the putative Class will continue to suffer harm as a result of Defendant's unlawful conduct; and

f. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiffs and members of the putative Class can seek redress for the harm caused by Defendant.

91. In the alternative, the Class may be certified for the following reasons:

a. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudication concerning individual members of the Class, which would establish incompatible standards of conduct for Defendant;

b. Adjudications of claims of the individual members of the Class against Defendant would, as a practical matter, be dispositive of the interests of other members of the putative Class who are not parties to the adjudication and may substantially impair or impede the ability of other putative Class Members to protect their interests; and

c. Defendant has acted or refused to act on grounds generally applicable to the members of the putative Class, thereby making appropriate final and injunctive relief concerning the putative Class as a whole.

VII. INADEQUACY OF LEGAL REMEDIES

92. In the alternative to those claims seeking remedies at law, Plaintiffs and Class members allege that no plain, adequate, and complete remedy exists at law to address Defendant's unlawful and unfair business practices. The legal remedies available to Plaintiffs are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to

the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

93. Additionally, unlike damages, the Court's discretion in fashioning equitable relief is very broad and can be awarded when the entitlement to damages may prove difficult. *Cortez v. Purolator Air Filtration Products Co.*, 23 Cal.4th 163, 177-180 (2000) (restitution under the UCL can be awarded "even absent individualized proof that the claimant lacked knowledge of the overcharge when the transaction occurred.").

94. Thus, restitution would allow recovery even when normal consideration associated with damages would not. *See, e.g., Fladeboe v. Am. Isuzu Motors Inc.*, 150 Cal. App. 4th 42, 68 (2007) (noting that restitution is available even when damages are unavailable). Furthermore, the standard and necessary elements for a violation of the UCL "unfair" prong and for quasi-contract/unjust enrichment are different from the standard that governs a legal claim.

CLAIMS FOR RELIEF

COUNT I
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf of the Multi-State Class, California Class, Florida Class, and Washington Class)

95. Plaintiffs re-allege and incorporate by reference the preceding allegations as though set forth fully herein.

96. Plaintiffs' individual claims are brought under the laws of the state in which they purchased their Products. See Cal. Commercial Code § 2314; Fla. Stat. §672.314; and RCW Section 62.A.2-314(2)(f). The claims of absent members of the California Class, Florida Class, and Washington Class are brought under California, Florida, and Washington law, respectively. The claims of absent members of the Multi-State Class are brought under the state's laws in which they purchased their Product and identified below.

a. Alaska Stat. §§ 45.02.314, et seq.;

b. Ark. Code Ann. §§ 4-2-314, et seq.;

c. Cal. Commercial Code § 2314 et seq[8];

d. Colo. Rev. Stat. Ann. §§ 4-2-314, et seq.;

e. Conn. Gen. Stat. §§ 42a-2-314, et seq.;

f. Del. Code Ann. Tit. 6, §§ 2-314, et seq.;

g. D.C. Code §§ 28:2-314, et seq.;

h. Haw. Rev. Stat. §§ 490:2-314, et seq.;

i. Ind. Code §§ 26-1-2-314, et seq.;

j. Kan. Stat. Ann. §§ 84-2-314, et seq.;

k. La. Civ. Code Ann. Art. 2520, et seq.;

l. Md. Code Ann., Com. Law §§ 2-314, et seq.;

m. Me. Rev. Stat. Ann. Tit. 11, §§ 2-314, et seq.;

n. Mass. Gen. Laws ch. 106, §§ 2-314, et seq.;

o. Mich. Comp. Laws Ann. §§ 440.2314, et seq.;

p. Minn. Stat. §§ 336.2-314, et seq.;

q. Miss. Code Ann. §§ 75-2-314, et seq.;

r. Mo. Rev. Stat. §§ 400.2-314, et seq.;

s. Mont. Code Ann. §§ 30-2-314, et seq.;

t. Neb. Rev. Stat. Ann. §§ 2-314, et seq.;

u. Nev. Rev. Stat. §§ 104.2314, et seq.;

v. N.H. Rev. Stat. Ann. §§ 382-A:2-314, et seq.;

[8] *See also* Count II (Song-Beverly Act), *infra*.

w. N.J. Stat. Ann. §§ 12A:2-314, et seq.;

x. N.M. Stat. Ann. §§ 55-2-314, et seq.

y. N.D. Cent. Code §§ 41-02-31, et seq.;

z. Ohio Rev. Code Ann. §§ 1302.27, et seq.;

aa. Okla. Stat. Tit. 12A, §§ 2-314, et seq.;

bb. 13 Pa. Stat. Ann. §§ 2314, et seq.;

cc. R.I. Gen. Laws §§ 6A-2-314, et seq.;

dd. S.C. Code Ann. §§ 36-2-314, et seq.;

ee. S.D. Codified Laws §§ 57A-2-314, et seq.;

ff. Tex. Bus. & Com. Code Ann. §§ 2.314, et seq.;

gg. Utah Code Ann. §§ 70A-2-314, et seq.;

hh. Va. Code Ann. §§ 8.2-314, et seq.;

ii. Vt. Stat. Ann. Tit. 9A, §§ 2-314, et seq.;

jj. W. Va. Code §§ 46-2-314, et seq.; and

kk. Wyo. Stat. Ann. §§ 34.1-2-314, et seq.

97. Defendant manufactured and distributed Products for sale to Plaintiffs and the Class members.

98. Defendant impliedly warranted to Plaintiffs and Class members that the Product was free of defects and was merchantable and fit for its ordinary purpose for which such goods are used.

99. As alleged herein, Defendant breached the implied warranty of merchantability because the Product suffers from a central and material defect in that it is incapable of producing

consistently accurate blood pressure readings for all users. The Product is, therefore, defective, unmerchantable, and unfit for its ordinary, intended purpose.

100. Plaintiffs further allege that the Product is not merchantable because at the time of sale and all times thereafter:

a. The Product as advertised would not pass without objection in the medical device trade given the defect;

b. The defect renders the Product unsafe and unfit for its ordinary purpose;

c. The Product were inadequately labeled as consistently accurate, reliable, and capable of producing blood pressure readings, and the labeling failed to disclose the Product' limitations described herein; and

d. The Product does not conform to its labeling, which represents that it is safe and suitable for its intended use.

101. Due to the defect, Plaintiffs and the Class members cannot operate their Product as intended, substantially free from defects. The Product does not provide accurate and reliable blood pressure readings which poses a serious safety risk as users rely on the Product for medical treatment and management. As a result, Plaintiffs and members of the Class cannot use their Product for the purposes for which they purchased them.

102. Privity of contract is not required here because Plaintiffs and Class members were each intended third-party beneficiaries of the Product sold through independent retailers. The retailers were not intended to be the ultimate consumers of the Product and have no rights under the implied warranty provided with the Product. Plaintiffs and Class members are intended third-party beneficiaries of contracts between Defendant and its retailer agents, specifically the intended beneficiaries of Defendant's implied warranties.

103. Plaintiffs did not receive or otherwise have the opportunity to review, at or before the time of sale, any purported warranty exclusions and limitations of remedies. Accordingly, any such exclusions and limitations of remedies are unconscionable and unenforceable. As a direct and proximate result of the breach of implied warranty of merchantability, Plaintiffs and Class members have been injured in an amount to be proven at trial.

104. Plaintiffs and the Class members timely provided Defendant notice of the issues raised in this count and Complaint, and an opportunity to cure, by letter dated September 13, 2023 with a courtesy email copy the following day. No response was given. Alternatively, Plaintiffs and Class members were excused from providing Defendant with notice and an opportunity to cure because it would have been futile. As described above, Defendant knew about the defective and misrepresented nature of the Product for years.

COUNT II
VIOLATION OF SONG-BEVERLY CONSUMER WARRANTY ACT - BREACH OF IMPLIED WARRANTY
Cal. Civ. Code §§ 1791.1 & 1792
(On Behalf of the California Class)

105. Plaintiffs re-alleges and incorporates by reference the preceding allegations as though set forth fully herein.

106. For purposes of this count, Plaintiffs refers to the California Plaintiffs Peery and Schneider. Plaintiffs bring this claim on behalf of themselves and behalf of the California Class against Defendant.

107. Plaintiffs and the other Class members who purchased the Products in California are "buyers" within the meaning of Cal. Civ. Code § 1791(b).

108. The Products are "consumer goods" within the meaning of Cal. Civ. Code § 1791(a).

109. Defendant is a "manufacturer" of the Products within the meaning of Cal. Civ. Code § 1791(j).

110. Defendant impliedly warranted to Plaintiffs and the other Class Members that the Products were "merchantable" within the meaning of Cal. Civ. Code §§ 1791.1 & 1792.

111. However, the Products do not have the quality that a reasonable purchaser would expect.

112. Cal. Civ. Code § 1791.1(a) states: "Implied warranty of merchantability" or "implied warranty that goods are merchantable" means that the consumer goods meet each of the following: "(1) pass without objection in the trade under the contract description; (2) are fit for the ordinary purposes for which such goods are used; … and (4) conform to the promises or affirmations of fact made on the container or label."

113. The Products would not pass without objection in the trade because they are incapable of providing consistently accurate and reliable blood pressure readings, particularly for users with a larger arm circumference, and none of this information is conspicuously disclosed at the point of sale.

114. The Products are not fit for the ordinary purpose they are used because of the inaccurate blood pressure readings and defect as alleged herein.

115. The defect in the Products is latent. Though the Products appear operable when new, the defect existed at the time of sale and throughout the one year period under the Song-Beverly Act. Accordingly, any subsequent discovery of the defect by Class members beyond that time does not bar an implied warranty claim under the Song-Beverly Act.

116. Further, despite due diligence, Plaintiffs and Class Members could not have discovered the defect before the manifestation of its symptoms in the form wildly inaccurate

readings. Those Class members whose claims would have otherwise expired allege that the discovery rule and doctrine of fraudulent concealment tolls them.

117. Defendant breached the implied warranty of merchantability by manufacturing and selling Products containing the defect. The existence of the defect has caused Plaintiff and the other Class members not to receive the benefit of their bargain and have caused Products to depreciate in value.

118. As a direct and proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiffs and the other Class members received goods whose defective condition substantially impairs their value to Plaintiffs and the other Class members. Plaintiffs and the other Class members have been damaged as a result of the diminished value of the Products.

119. Plaintiffs and the other Class members are entitled to damages and other legal and equitable relief, including, at their election, the purchase price of their Products or the overpayment or diminution in value of their Products.

120. Pursuant to Cal. Civ. Code § 1794, Plaintiffs and the other Class members are entitled to costs and attorneys' fees.

COUNT III
VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW
Cal. Bus. & Prof. Code § 17200 et seq. ("UCL")
(On Behalf of the California Class)

121. Plaintiffs re-allege and incorporate by reference the preceding allegations as though set forth fully herein.

122. For purposes of this count, Plaintiffs refers to the California Plaintiffs Peery and Schneider.

123. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200.

124. Defendant's acts and omissions as alleged herein constitute business acts and practices.

125. Unlawful: The acts alleged herein are "unlawful" under the UCL in that they violate at least the following laws:

a. The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq.;

b. Implied warranty of merchantability under the Commercial Code and Song-Beverly Act.

126. Unfair: Defendant's conduct concerning the labeling, advertising, and sale of the Products was "unfair" because Defendant's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of their conduct, if any, does not outweigh the gravity of the harm to their victims. Distributing materially unsafe blood pressure monitors because they cannot generate consistently accurate readings has no public utility at all.

127. Any countervailing benefits to consumers or competition did not outweigh this injury. Selling products unsafe and unfit for their intended purposes only injures healthy competition and harms consumers. Defendant also minimizes the scope of the defect despite knowing the Products are unreasonably dangerous, made repairs and/or replacements during the warranty period that unbeknownst to consumers did not provide a permanent fix, and knowingly sold defective products in hopes of forcing consumers to purchase replacement products.

128. Defendant's conduct concerning the labeling, advertising, and sale of the Products was and is also unfair because it violates public policy as declared by specific constitutional, statutory, or regulatory provisions, including but not limited to the applicable sections of the Consumers Legal Remedies Act and the Song-Beverly Consumer Warranty Act.

129. Fraudulent: A statement or practice is "fraudulent" under the UCL if it is likely to mislead or deceive the public, applying an objective reasonable consumer test.

130. As set forth herein, Defendant engaged in deceptive acts by knowingly omitting from Plaintiffs and Class members the Products' performance limitations, which is a material safety defect, including the Products' inability to generate consistently accurate readings, the reading shown on the Product is not the user's actual blood pressure but is only accurate within an undisclosed range, the Products are useless for persons with a larger arm circumference, and the Products have never been tested for use by pregnant persons. Defendant knew that the Products were defectively designed, posed an unreasonable safety risk, and unsuitable for their intended use.

131. Defendant was under a duty to Plaintiffs and the Class members to disclose the defective nature of the Products because:

a. Defendant was in a superior position to know the true state of facts about the defect and the Product's limitations;

b. Plaintiffs and the Class members could not reasonably have been expected to learn or discover that the Products had a safety defect and were incapable of generating accurate blood pressure readings for all users before purchase;

c. Defendant knew that Plaintiffs and Class members could not reasonably have been expected to learn or discover the defect and performance limitations;

d. Defendant made partial representations regarding conceptually related attributes and benefits of the Products on advertising/labeling at the point

of sale while deceptively omitting the existence of the defect and performance limitations; and

e. Defendant actively concealed the defect in part because, in response to consumer complaints within the warranty period regarding the Product's inaccurate readings, Defendant refused to repair the Product, told consumers it was accurate and working as designed, or replaced the defective Product with the same defective Product to make consumers believe the Product was always working and the problem lies with the consumer. Defendant also views and responds to negative reviews about the Product's inaccurate readings without publicly acknowledging the defect or the Product's limitations, and instead continues to tout the Product as accurate.

132. Defendant could have and should have prominently disclosed the reliability, safety, and performance limitations of the Products on the listings on its website, on product packaging, and to third-party retailers. Had Defendant disclosed the defect in this manner, Plaintiffs and reasonable consumers would have been aware of it.

133. The facts concealed or not disclosed by Defendant to Plaintiffs and Class members are material in that a reasonable consumer would have considered them important in deciding whether to purchase Defendant's Products or pay a lesser price. Had Plaintiffs and the Class known about the defective nature of the Products, they would not have purchased them or paid less for them.

134. Defendant also misrepresented the Products as generating "accurate" blood pressure readings as described above.

135. Defendant profited from selling the falsely, deceptively, and unlawfully advertised Products to unwary purchasers.

136. Plaintiffs and Class Members will likely continue to be damaged by Defendant's deceptive trade practices because Defendant continues disseminating misleading information on the Products' packaging and online retail listings. Thus, injunctive relief enjoining Defendant's deceptive practices is proper.

137. Defendant's conduct caused and continues to cause substantial injury to Plaintiff and the other Class members. Plaintiff has suffered injury in fact as a result of Defendant's unlawful conduct.

138. Under Bus. & Prof. Code § 17203, Plaintiff seeks an order requiring that Defendant correct its misleading labeling and commence a corrective advertising campaign.

139. Plaintiffs and the Class also seek an order for and restitution of all monies from the sale of the Products, which were unjustly acquired through acts of unlawful competition.

COUNT IV
VIOLATION OF CALIFORNIA'S CONSUMER LEGAL REMEDIES ACT
Cal. Civ. Code § 1750 et seq. ("CLRA")
(On Behalf of the California Class)

140. Plaintiffs repeat and reallege the preceding allegations as if fully set forth herein.

141. For purposes of this count, Plaintiffs refers to the California Plaintiffs Peery and Schneider.

142. The CLRA prohibits deceptive practices concerning the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

143. Defendant's omissions were designed to, and did, induce the purchase and use of the Products for personal, family, or household purposes by Plaintiffs and Class members, and violated and continue to violate the following sections of the CLRA:

a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits that they do not have;

b. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;

c. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and

d. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

144. As set forth herein, Defendant engaged in deceptive acts by knowingly omitting from Plaintiffs and Class members the Products' performance limitations, which is a material safety defect, including the Products' inability to generate consistently accurate readings, the reading shown on the Product is not the user's actual blood pressure but is only accurate within an undisclosed range, the Products are useless for persons with a larger arm circumference, and the Products have never been tested for use by pregnant persons. Defendant knew that the Products were defectively designed, posed an unreasonable safety risk, and unsuitable for their intended use.

145. Defendant was under a duty to Plaintiffs and the Class members to disclose the defective nature of the Products because:

a. Defendant was in a superior position to know the true state of facts about the defect and the Product's limitations;

b. Plaintiffs and the Class members could not reasonably have been expected to learn or discover that the Products had a safety defect and were incapable of generating accurate blood pressure readings for all users before purchase;

c. Defendant knew that Plaintiffs and Class members could not reasonably have been expected to learn or discover the defect and performance limitations;

d. Defendant made partial representations regarding the attributes and benefits of the Products on advertising/labeling at the point of sale while deceptively omitting the existence of the defect and performance limitations; and

e. Defendant actively concealed the defect in part because, in response to consumer complaints within the warranty period regarding the Product's inaccurate readings, Defendant refused to repair the Product, told consumers it was accurate and working as designed, or replaced the defective Product with the same defective Product to make consumers believe the Product was always working and the problem lies with the consumer. Defendant also views and responds to negative reviews about the Product's inaccurate readings without publicly acknowledging the defect or the Product's limitations, and instead continues to tout the Product as accurate.

146. Defendant could have and should have prominently disclosed the reliability, safety, and performance limitations of the Products on the listings on its website, on product packaging, and to third-party retailers. Had Defendant disclosed the defect in this manner, Plaintiffs and reasonable consumers would have been aware of it.

147. The facts concealed or not disclosed by Defendant to Plaintiffs and Class members are material in that a reasonable consumer would have considered them important in deciding whether to purchase Defendant's Products or pay a lesser price. Had Plaintiffs and the Class known

about the defective nature of the Products, they would not have purchased them or paid less for them.

148. Defendant also misrepresented the Products as generating "accurate" blood pressure readings as described above.

149. Defendant profited from selling the falsely, deceptively, and unlawfully advertised Products to unwary purchasers.

150. Plaintiffs and Class Members will likely continue to be damaged by Defendant's deceptive trade practices because Defendant continues disseminating misleading information on the Products' packaging and online retail listings. Thus, injunctive relief enjoining Defendant's deceptive practices is proper.

151. Defendant's conduct caused and continues to cause substantial injury to Plaintiffs and the other Class members. Plaintiffs have suffered injury in fact as a result of Defendant's unlawful conduct.

152. On September 13, 2023, a CLRA demand letter was sent to Defendant pursuant to Cal. Civ. Code § 1782. This letter provided notice of Defendant's violation of the CLRA and demanded that Defendant correct the unlawful and deceptive practices alleged herein. Defendant did not offer any remedy to Plaintiffs and each Class member. Accordingly, Plaintiffs seek all monetary relief available under the CLRA.

153. Pursuant to California Civil Code § 1780, Plaintiff also seeks money damages, injunctive relief, reasonable attorney fees and costs, punitive damages, and any other relief the Court deems proper.

COUNT V
VIOLATION OF THE FLORIDA DECEPTIVE & UNFAIR TRADE PRACTICES ACT
Fla. Stat. §§501.201, et seq. ("FDUTPA")
(On Behalf of the Florida Class)

154. Plaintiffs repeat and reallege the preceding allegations as if fully set forth herein.

155. For purposes of this count, Plaintiff refers to the Florida Plaintiff Estrella.

156. Plaintiff and the other Class members are "consumers" under Fla. Stat. §501.203(7) because they purchased the Products primarily for personal, family, or household use.

157. Defendant was and is engaged in "trade or commerce" under the meaning of Fla. Stat. §501.203(8).

158. The FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. §501.204(1).

159. Defendant's violations of the FDUTPA occurred repeatedly in their trade or practice – including the design, manufacture, distribution, marketing, and sale of the Products.

160. Defendant violated the FDUTPA by knowingly and intentionally misrepresenting, omitting, concealing, and/or failing to disclose material facts regarding the reliability, safety, and performance of the Products as detailed above.

161. As set forth herein, Defendant engaged in deceptive acts by knowingly omitting from Plaintiff and Class members the Products' performance limitations, which is a material safety defect, including the Products' inability to generate consistently accurate readings, the reading shown on the Product is not the user's actual blood pressure but is only accurate within an undisclosed range, the Products are useless for persons with a larger arm circumference, and the Products have never been tested for use by pregnant persons. Defendant knew that the Products

were defectively designed, posed an unreasonable safety risk, and unsuitable for their intended use.

162. Defendant was under a duty to Plaintiff and the Class members to disclose the defective nature of the Products because:

a. Defendant was in a superior position to know the true state of facts about the defect and the Product's limitations;

b. Plaintiff and the Class members could not reasonably have been expected to learn or discover that the Products had a safety defect and were incapable of generating accurate blood pressure readings for all users before purchase;

c. Defendant knew that Plaintiff and Class members could not reasonably have been expected to learn or discover the defect and performance limitations;

d. Defendant made partial representations regarding the attributes and benefits of the Products on advertising/labeling at the point of sale while deceptively omitting the existence of the defect and performance limitations; and

e. Defendant actively concealed the defect in part because, in response to consumer complaints within the warranty period regarding the Product's inaccurate readings, Defendant refused to repair the Product, told consumers it was accurate and working as designed, or replaced the defective Product with the same defective Product to make consumers believe the Product was always working and the problem lies with the consumer. Defendant also views and responds to negative reviews about the Product's inaccurate readings without publicly acknowledging the

defect or the Product's limitations, and instead continues to tout the Product as accurate.

163. Defendant could have and should have prominently disclosed the reliability, safety, and performance limitations of the Products on the listings on its website, on product packaging, and to third-party retailers. Had Defendant disclosed the defect in this manner, Plaintiffs and reasonable consumers would have been aware of it.

164. The facts concealed or not disclosed by Defendant to Plaintiff and Class members are material in that a reasonable consumer would have considered them important in deciding whether to purchase Defendant's Products or pay a lesser price. Had Plaintiff and the Class known about the defective nature of the Products, they would not have purchased them or paid less for them.

165. Defendant also misrepresented the Products as generating "accurate" blood pressure readings as described above.

166. Defendant's unfair or deceptive acts or practices, specifically their misrepresentations, concealments, omissions, and/or suppressions of material facts, were designed to mislead and had a tendency or capacity to mislead and create a false impression in consumers that the Products were properly-functioning and reliable.

167. Defendant profited from selling the falsely, deceptively, and unlawfully advertised Products to unwary purchasers.

168. Plaintiff and Class Members will likely continue to be damaged by Defendant's deceptive trade practices because Defendant continues disseminating misleading information on the Products' packaging and online retail listings. Thus, injunctive relief enjoining Defendant's deceptive practices is proper.

169. Defendant's conduct caused and continues to cause substantial injury to Plaintiff and the other Class members. Plaintiff and the Class have suffered injury in fact as a result of Defendant's unlawful conduct.

170. Pursuant to Fla. Stat. §501.211, Plaintiff and the other Class members seek an order enjoining the above unfair or deceptive acts or practices and awarding actual damages, treble damages, restitution, attorneys' fees, and any other just and proper relief available under the FDUTPA.

COUNT VI
BREACH OF EXPRESS WARRANTY
(On Behalf of the Nationwide Class, California Class, Florida Class, and Washington Class)

171. Plaintiffs re-allege and incorporate by reference the preceding allegations as though set forth fully herein.

172. Plaintiffs' individual claims are brought under the laws of the state in which they purchased their Products. The claims of absent members of the Nationwide Class, California Class, Florida Class, and Washington Class are brought under the state's laws in which they purchased their Products.

173. In connection with the sale of the Products, Defendant issued an express warranty in user manuals stating the Products' "Specifications" for "Accuracy" include "Pressure: +/- 3 mmHg."

174. Defendant also issued an express warranty on the Amazon.com listing page stating that the Products would generate "accurate" blood pressure readings.

175. Defendant's affirmation of fact made to Plaintiffs and the Class became a part of the basis of the bargain between Defendant and Plaintiffs and Class members, thereby creating warranties that the Products would conform to Defendant's affirmations of fact.

176. Defendant breached its express warranties because the Products are not in fact accurate for blood pressure readings, let alone within a margin of +/- 3 mmHg. In truth, the Products generate blood pressure readings far in excess of that level of accuracy as explained above. Further, Defendant's own commissioned study concluded that the Products do not meet that level of accuracy. That study concluded that the Product was accurate within a range of +/- 3.7 mmHg for diastolic pressure—which is 23.3% greater than the 3 mmHg warranted in the user manual. And for persons using the standard "wide range" cuff (22–42 cm or 9–17 inches) that comes with the Product, the Product produced diastolic blood pressure readings that deviated by an average of 4.30 mmHg from the true level with a standard deviation of 5.8 mmHG.

177. Plaintiffs and the Class members timely provided Defendant notice of the issues raised in this count and Complaint, and an opportunity to cure, by letter dated September 13, 2023 with a courtesy email copy the following day. No response was given. Alternatively, Plaintiffs and Class members were excused from providing Defendant with notice and an opportunity to cure because it would have been futile. As described above, Defendant knew about the defective and misrepresented nature of the Products for years.

178. Plaintiffs and the Class were injured as a direct and proximate result of Defendant's breach because they would not have purchased the Products if they had known the true facts, or would have paid less for the Products, and the Products did not have the quality, effectiveness, or value as promised.

179. As a result, Plaintiffs and the Class have been damaged in the full amount of the purchase price of the Products, or at minimum a portion of the purchase price of the Products.

COUNT VII
VIOLATION OF THE WASHINGTON UNFAIR BUSINESS PRACTICES AND CONSUMER PROTECTION ACT
RCW Section 19.86.010 et seq.
(On Behalf of the Washington Class)

180. Plaintiffs repeat and reallege the allegations in the preceding paragraphs as if fully set forth herein.

181. For purposes of this count, Plaintiff refers to the Washington Plaintiff Pond.

182. Defendant's deceptive conduct alleged herein violated the following provisions of Washington's Consumer Protection Act:

a. RCW section 19.86.020, by negligently, recklessly, and/or intentionally misrepresenting, omitting, concealing, and/or failing to disclose material facts regarding the reliability, safety, and performance of the Products as detailed above.

183. As set forth herein, Defendant engaged in deceptive acts by knowingly omitting from Plaintiff and Class members the Products' performance limitations, which is a material safety defect, including the Products' inability to generate consistently accurate readings, the reading shown on the Products is not the user's actual blood pressure but is only accurate within an undisclosed range, the Products are useless for persons with a larger arm circumference, and the Products have never been tested for use by pregnant persons. Defendant knew that the Products were defectively designed, posed an unreasonable safety risk, and unsuitable for their intended use.

184. Defendant also misrepresented the Products as generating "accurate" blood pressure readings as described above.

185. Defendant misrepresented and omitted this material information with the intent to induce consumers, such as Plaintiff, to purchase the Products.

186. Defendant engaged in deceptive trade practices in the conduct of its trade or commerce.

187. Defendant's deceptive trade practices significantly affected the public interest.

188. Plaintiff and the Washington Class were purchasers of Defendant's goods.

189. Plaintiff and the Washington Class were deceived by Defendant's deceptive trade practices and purchased the Products due to Defendant's deceptive trade practices.

190. Defendant's deceptive marketing practices implicated the public as consumers because Defendant directed its misrepresentations at the market generally.

191. Plaintiff and the Washington Class suffered damages and losses as described above as a result of Defendant's deceptive trade practices.

192. Plaintiff and the Washington Class seek actual damages, treble damages, attorneys' fees, costs, and any other just and proper relief available thereunder.

193. Plaintiff and the Washington Class seek injunctive relief and any other just and proper relief available.

COUNT VIII
Unjust Enrichment
(On Behalf of the Nationwide Class, California Class, and Florida Class)

194. Plaintiffs repeat and reallege the allegations in the preceding paragraphs as if fully set forth herein.

195. Plaintiffs' individual claims are brought under the laws of the state in which they purchased their Products (California and Florida). The claims of absent members of the Nationwide Class, California Class, and Florida Class are brought under the state's laws in which they purchased their Product.

196. Plaintiffs and putative Class members conferred a benefit on Defendant when they purchased the Products.

197. Defendant knew or should have known that the payments rendered by Plaintiffs and the Class were given with the expectation that the Products would have the qualities, characteristics, and suitability for use represented and warranted by Defendant. As such, it would be inequitable for Defendant to retain the benefit of the payments under these circumstances.

198. By its wrongful acts and omissions described herein, including selling the Products which contain the safety defect and performance limitations described in detail above and did not otherwise perform as represented and for the particular purpose for which they were intended, Defendant was unjustly enriched at the expense of Plaintiffs and putative Class members.

199. Plaintiffs' detriment and Defendant's enrichment were related to and flowed from the wrongful conduct challenged in this Complaint.

200. Defendant has profited from its unlawful, unfair, misleading, and deceptive practices at the expense of Plaintiffs and putative Class members when it would be unjust for Defendant to be permitted to retain the benefit. It would be inequitable for Defendant to retain the profits, benefits, and other compensation obtained from its wrongful conduct described herein in connection with selling the Products.

201. Defendant has been unjustly enriched in retaining the revenues derived from Class members' purchases of the Products, which retention of such revenues under these circumstances

is unjust and inequitable because Defendant manufactured the defective Products, and Defendant misrepresented by omission the nature of the Products and knowingly marketed and promoted dangerous and defective Products, which caused injuries to Plaintiff and the Class because they would not have purchased the Products based on the exact representations if the true facts concerning the Products had been known.

202. Plaintiffs and putative Class members are entitled to recover from Defendant all amounts wrongfully collected and improperly retained by Defendant.

203. As a direct and proximate result of Defendant's wrongful conduct and unjust enrichment, Plaintiffs and putative Class members are entitled to restitution of, disgorgement of, and/or imposition of a constructive trust upon all profits, benefits, and other compensation obtained by Defendant for their inequitable and unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated members of the Class, pray for relief and judgment, including entry of an order:

A. Declaring that this action is properly maintained as a class action, certifying the proposed Class(es), appointing Plaintiffs as Class Representative, and appointing Plaintiffs' counsel as Class Counsel;

B. Directing that Defendant bear the costs of any notice sent to the Class(es);

C. Declaring that Defendant must disgorge, for the benefit of the Class(es), all or part of the ill-gotten profits they received from the sale of the Products or order Defendant to make full restitution to Plaintiffs and the members of the Class(es).

D. Awarding money damages;

E. Awarding restitution and other appropriate equitable relief;

F. Granting an injunction against Defendant to enjoin it from conducting its business through the unlawful, unfair, and fraudulent acts or practices set forth herein;

G. Granting an Order requiring Defendant to fully and adequately disclose the safety risks and performance limitations associated with the Products to anyone who may still be at risk of buying and using the Products;

H. Ordering a jury trial and damages according to proof;

I. Awarding attorneys' fees and litigation costs to Plaintiffs and members of the Class(es);

J. Awarding prejudgment interest, and punitive damages as permitted by law; and

K. Ordering such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

Dated: October 25, 2023

Respectfully submitted,

/s/ Gary M. Klinger

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Attorneys for Plaintiffs and the Proposed Class

DECLARATION OF ALEXANDER E. WOLF

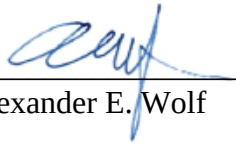
I, Alexander E. Wolf, declare as follows:

1. I am an attorney with the firm of Milberg Coleman Bryson Phillips Grossman PLLC, counsel of record for Plaintiffs in the instant action, and an individual over eighteen years of age. I make this declaration as required by California Civil Code § 1780(d).

2. The Complaint in this action is filed in a proper place for the trial of this action because a substantial portion of the events alleged in the Complaint occurred in this district. Defendant Omron Healthcare, Inc. has a substantial presence in Illinois, and conduct relating to this action, including directing and managing the distribution, sale, marketing, and design of the Product, took place in this county and district. As such, it is my understanding that Defendant does business in this county and district.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: October 25, 2023



Alexander E. Wolf