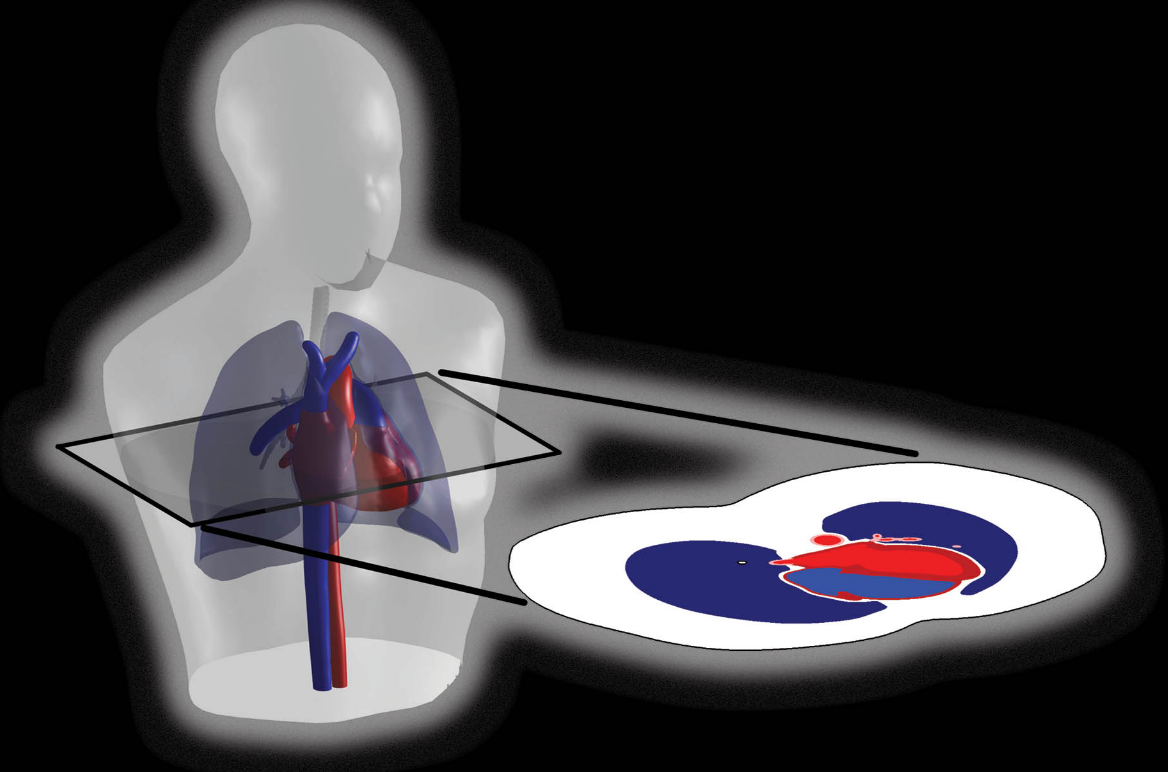
MEDICAL DEVICES AND DATA

Technology to Instrument the Body and Its Interpretation



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Medical Devices and Data

The miniaturization of electronics has driven a huge innovation in medical instruments. Medical-grade systems are now able to be sent home with patients, alongside small, portable devices for monitoring sports performance, stress, and lifestyle.

The core ideas behind these devices originated about 130 years ago, but they are now made cheaply and are readily available in consumer devices like smart watches, as well as in new diagnostic instruments.

Medical Devices and Data: Technology to Instrument the Body and Its Interpretation focuses on three key questions: How do these new instruments work? How do they interpret their data? And when do they err? It also identifies the key factors that are driving this innovation further.

This text is written for those who would like to understand non-invasive medical instruments in more detail. It is written in an accessible manner, and no formal background in science, engineering, or medicine is required. Some equations are used where necessary, but calculus is avoided. This book explains the key ideas behind the advanced techniques used. All data, software, and figures used in this book are made available online at the following link: https//bitbucket.org/biomedical-instrumentation/book.

Key features:

- Explores the design and use of medical instrumentation, seeking to explain the data measured and how it relates to body processes.
- Discusses what these devices mean: modern instruments give a whole range of indications: from basic (heart rate) to much more complicated (sleep quality score). For users of these devices, this book hopes to shed some light on the information available.
- Details when results can be trusted and how to cast a critical eye over the accuracy and interpretation of these instruments.

Andy Adler is a Canada Research Professor in Biomedical Engineering in Systems and Computer Engineering at Carleton University in Ottawa, Canada. His research interests are broadly in the area of biomedical measurement and robust data analysis. He is the author of ten book chapters, four patents, eighty-eight journals, and 190 conference papers. A main focus of his work is technologies for imaging the body using small applied electrical currents. He has also been active in translation of the technology to the bedside, working with both start-up and established med-tech companies. He is the editor of *Electrical Impedance Tomography, Second Edition* (CRC Press, 2021).

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Contents

Foreword

The 21st century has seen an incredible and accelerating miniaturization of computers. Complete computers are available on single chips costing a few dollars and weighing less than a gram.

This book is about non-invasive medical instruments. As we will see, the earliest ideas of recording the heart rate as a numerical value were from renaissance Europe. Instruments were bulky and inconvenient. However, numerical medical data provides big benefits. Most importantly, tracking health over time allows us to monitor the progress and remission of diseases. In addition, instruments make healthcare more affordable. A doctor can interpret the numbers and ask a technician, or the equipment itself, to make the recording.

The miniaturization of electronics has driven a huge innovation in medical instruments. Medical-grade systems are sent home with patients. We also see sports monitoring and lifestyle and stress devices. Most smart matches now include these instruments.

This text is written for those who would like to understand these instruments in more detail. It is written for a general science audience. Equations are used where necessary, but we avoid calculus. The goal is not to explain the advanced techniques used. Instead, we hope to clarify the key ideas that motivate the many ideas out there.

Your author is naturally sceptical and tends to focus on the downsides and problems with any technology. However, it's valuable to first underline the amazing benefits of our "data revolution". Medical data and knowledge have been democratized! Individuals are now able to make measurements for themselves, just as they are able to read open science papers. More likely, the average person will ask an AI agent to summarize the science and to purchase devices that perform the analysis for them. Beyond simply making medical information available to average citizens, the knowledge is immediate. Your blood pressure measured at the doctor's office is a rare measurement when you may feel unwell; your – repeated – blood pressure measured at home is a better reflection of your lived condition.

For these reasons, we want to understand these instruments better:

- *Design and use of medical instrumentation*: non-invasive medical instruments are used not only in medicine, but for health, stress, and environmental monitoring. We seek to explain how the data are measured and how they relate to the body processes.
- *Understanding what the measurements mean*: modern instruments give a whole range of indications: from the basic (heart rate) to much more

complicated (sleep quality score). For users of these devices, we hope to shed some light on what information is available.

- *When can the results be trusted*: there is a tendency to find numerical results inherently trustworthy. But the best any instrument can do – with a system as complex as the body – is to create an estimate. When are these estimates useful?

In addition to the advantages, there are many reasons to worry about the accuracy of the results and interpretations of many of these instruments. In several fields of science, this has been called the "reproducibility crisis" – where key findings cannot be repeated by future experiments. As algorithms become increasingly more complex, the systems become fragile: this is increasingly true with modern machine-learning approaches, as powerful as they are.

The key advice to conducting reproducible research is "open science" [5]. This means documenting and recording each step in the process. To encourage this, all data, software, and figures used in this book are made available. Software, data, and other source code at bitbucket.org,[1] and figures (under a creative-commons CC license) at zenodo.[2] For those who wish to use this as a textbook for a course on medical instrumentation, a set of questions for each chapter is provided.[3]

We underline the importance of *interpretation*. As you read this text, each receptor cell in your eyes detects dots of light. In order to *see*, we need our brain to interpret this mass of signals as words and sentences. To clarify this process, we begin the next chapter with Plato.

This book represents many years of trying to explain and work with these concepts with students and colleagues. The author would like to thank all of them for insightful conversations, suggestions, and criticism.

Andy Adler
Ottawa, November 2025

NOTES

1 bitbucket.org/biomedical-instrumentation/book
2 doi.org/10.5281/zenodo.16732424
3 bitbucket.org/biomedical-instrumentation/book/src/main/questions

CHAPTER 1

Introduction

THREE INNOVATIONS AT THE TURN of the 20th century changed medicine. In 1895, Wilhelm Rontgen discovered X-rays and founded the field of medical imaging. In 1896, Scipione Riva Rocci developed the mercury Sphygmomanometer – allowing blood pressure measurement with a rubber cuff (Chapter 9). In 1901, Willem Einthoven refined the string galvanometer to measure the heart's electrical activity (Chapter 11).

All these innovations had one thing in common. They were *non-invasive*, meaning that information about the inside of the body could be obtained from the measurement on the outside. No cutting required!

The value is obvious: patient measurements were now much easier. We could also measure repeatedly to monitor the effects of treatment. Unfortunately, X-rays weren't really non-invasive. X-rays were even used for fitting shoes from the 1920s, until it was realized that there were long-term risks from radiation exposure. Of course, the shoe retail industry initially argued that X-ray harm was offset by preventing harm to customers' feet from poorly fitting shoes. Many other industries – like tobacco – have followed in these "shoes".

These innovations changed medicine in another way. They were bulky and initially expensive. A home-calling doctor could not carry the machines to patients. Instead, patients visited the hospital for assessment. This was part of the hospitalization of health care, a big trend of 20th-century medicine. The discovery of antibiotics a few decades later addressed the main risk of hospitals – infection from other patients and staff.

We are now witnessing a dramatic new phase in this trend: *small, portable, non-invasive medical instruments.* The core ideas of these pioneers 130 years ago are now made cheaply and are available in consumer devices like watches as well as in new diagnostic instruments.

This is the focus of this book: how do these new instruments work, how do they interpret their data, and when do they err? We identify two factors that are driving this innovation:

- *Electronics miniaturization:* we now have small and cheap instruments to measure light, voltage, sound, as well as to acquire the data and process the results.

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- *Advanced analysis:* developments in computer algorithms to process and interpret the measured data.

Miniaturization and advanced analysis techniques mean we are increasingly seeing non-medical uses, for fitness and lifestyle applications, such as stress and sleep monitors. But also – more ominously – security and tracking devices. For example, a driver-drowsiness monitor provides useful information not only to a driver but also to the vendor of automobile insurance and a driver's licensing agency.

These instruments don't directly measure the variables of interest. A stethoscope with a pressure cuff measures the sound generated by moving blood; the blood pressure must be interpreted by a trained technician. This type of interpretation is now done by computer algorithm. But of course, algorithms don't always give the right answer.

Advanced instruments and analysis allow high-level parameters, such as a "stress level" or a "sleep quality score". But there is a key problem. We know what heart rate (HR) means, and that HR can be elevated because of stress, disease or recovering from exercise. By contrast, high-level parameters are hard to interpret. What is a "sleep score"? Is it ever "bad", and what should we do about it?

To begin, let's look at the most important allegory about the human quest to measure and interpret the world.

1.1 DATA INTERPRETATION

Plato gave us one of the most vivid metaphors for the human condition. In the parable of the cave (Figure 1.1), we are invited to imagine ourselves chained to a wall, unable to sense the "real" world [82]. All we can see are shadows cast against the wall by the light of flickering fires that illuminate the world's objects. We are not content with this fate, however, but long to be free: to escape our chains and live in the outside world – where we can see and interact with things as they really are.

FIGURE 1.1 Illustration of Plato's parable of the cave. At left, slaves see only flickering shadows. At right, the free see things as they are.

This parable has been interpreted in two primary ways: telling us about how we learn about what is real (the philosophical term is *epistemology*) and about the human quest for freedom (thus a political interpretation). This is a book about medical data and its interpretation, and we will focus on the first aspect.

However, it is interesting to note that the two interpretations are not completely independent. One common policy of dictators is to obscure citizens' access to the facts. Often this is done by making much contradictory "noise" in the public space. All of the noise obscures the truth and leads citizens to feel anything – and nothing – could be true [96]. In this sense, freedom and access to truth are closely related.

Returning to our poor slaves who see only shadows, this is the case of any scientist or doctor: the things we would really like to know are hidden from us, except by the traces left in the measurements from our instruments.

A historian would love to walk on ancient Athens' streets and watch Plato talk; unfortunately, he can only read old texts and pottery. A cardiologist would want to know the beat-by-beat flows and pressures in each blood vessel and throughout a patient's day. Instead, she can read measurements made on the body surface or a scan made when the patient visits a clinic.

To gain more detailed knowledge, we can add more and invasive instruments. For example, complex physiological changes occur at birth, and these are affected by clinical treatment decisions. These changes can be understood in animal models. For example, in [99], both sheep mothers and the in-utero lambs were instrumented, and, using these instruments, continuous measurements were made in the mother and newborn during and after birth. But, of course, this only tells us about those lambs' birth. It doesn't quite tell us what we really want to know: how to improve treatments for human babies.

Clearly, we need to extrapolate: how similar (and different) is this lamb from human babies? But even if we make measurements on human babies, we can't – ethically – measure all the quantities we would like to. And even if we could have all the measurements we would like on human babies, there is tremendous variability between individuals, and the data we have don't necessarily tell us about the individual baby we are interested in.

We are thus, always, to some extent, in Plato's shadows. The remainder of this chapter considers the "shadows". In what ways do they perturb our access to the real, and in what ways are we still able to make reasonably reliable conclusions?

1.2 SENSE AND SENSITIVITY

This book is concerned with instrumentation, measurement, and interpretation of the resulting data. Our slaves have an instrument, the projection of the world (the models of horses and people) onto the shadows, and from this they try to make sense of the world.

The concept of *sensitivity* is the key characteristic of a measurement system. To be *sensitive* is to be aware of others. By analogy, a sensitive instrument responds to its *measurand*, x, the quantity subject to measurement. Our instrument $f(\cdot)$

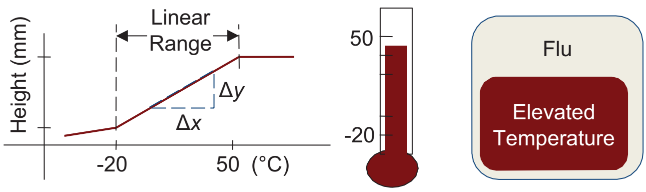

FIGURE 1.2 In a liquid thermometer (centre), the liquid expands with temperature (right). Within the linear range, (left) it has a sensitivity, $S = \Delta y/\Delta x$. The thermometer can be used to make a decision, such as whether a person has the flu, but only some people (red) have elevated temperature. In this case, sensitivity is the true positive rate.

produces an output $y = f(x)$, determined by the value of the measurand, but it may also be sensitive to other variables $x_2, x_3, \ldots$ in which case we would write $y = f(x, x_2, x_3, \ldots)$.

Sensitivity, S, is defined in two ways. The first way is useful to characterize instrument output, y, over the range of input values. For example, a liquid thermometer (Figure 1.2) has a useful linear range where the height of the column y is directly proportional to the temperature x. For example, when the temperature changes from x =10 to 16 °C, the height of the mercury column may increase from y =8 to 11 mm. In this case, the sensitivity, $S = \Delta y/\Delta x$ is constant in this linear range: $S = \frac{11-8\,\mathrm{mm}}{16-10\,^\circ\mathrm{C}} = 0.5\,\frac{\mathrm{mm}}{^\circ\mathrm{C}}$.

Below a certain temperature, S is low as the all the liquid is in bulb. Since the bulb is large, changes in the volume of the liquid only make small changes in liquid height. Above a maximum temperature, the liquid will leak out of the tube and the sensitivity is zero; there is no longer a change in y with x. These high temperatures will also ruin our instrument!

Typically, we don't just measure for fun; rather we use our instrument to make a decision – a *diagnosis*: for example, does a patient have the flu? The decision may be right or wrong, and in this case, the sensitivity is the fraction of times we are right S = (# cases of flu with elevated T)/(# cases of flu). This can also be called the true-positive rate (see Chapter 5).

1.3 MOVEMENTS IN THE SHADOWS

The cave allegory is useful to illustrate many ways in which measurement-system characteristics affect the interpretation. We will illustrate the issues here; see [41] for a mathematical treatment. Figure 1.3 illustrates the fire, the movement of a horse model, and the slaves' view of the shadows.

In this case, the sensitivity corresponds to the magnification, M =(size on shadow)/(size on horse).

We have an *magnification*, defined by the geometry, $M = d_i/d_o$. In an instrumentation system, M, in most cases, can be determined by

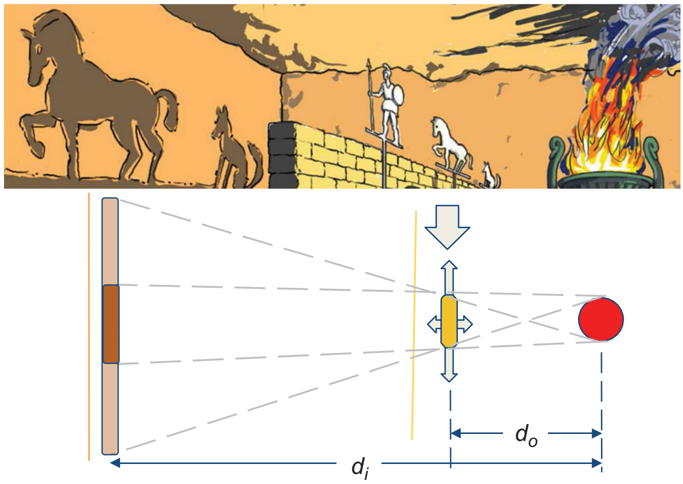

FIGURE 1.3 Uncertainties in information from the shadows. Dark and light boxes illustrate the depth of shadow. The horse model can move different directions, while the fire flickers.

calibration. An object with a known size is measured and the value of M determined.

The value of M may be unknown, and its value may change over time. Sometimes it's important to know M exactly. On the other hand, we are often more interested in changes (trends) than the absolute measurements, in which case an uncertain value of M is not a problem, as long as its value is not changing over time.

Next, we consider the movement of the horse. Movements in the plane (up-down and left-right) lead to large changes in the shadows, with the same M as the overall image. For example, if we have a horse model $d_o = 2\,\text{m}$ from the fire and a shadow $d_i = 8\,\text{m}$, here $M = 8\,\text{m}/2\,\text{m} = 4$. This value of M means a side-to-side movement of the model by 1 cm will move each corresponding part of the shadows by $M \times 1\,\text{cm} = 4\,\text{cm}$.

However, the shadows are not equally sensitive to all types of movements. Out-of-plane movements (forward-backward) have much lower sensitivity than in-plane movements. Movement of the model towards the fire will make the shadow increase in size[1]. For a 1 cm movement towards the fire M, increases by $0.01\,\text{m} \times \frac{1}{2} 6\,\text{m}/2\,\text{m}^2 = 0.01$. Thus our 1 cm movement leads to a corresponding movement of the shadow by 0.1 mm.

Using our analogy, the slaves cannot perceive nature directly, but have an instrument to make measurements. The instrument can be characterized by a sensitivity, where certain characteristics of nature (side-to-side movements) can be measured more easily and lead to large observed changes in measurements. On the other hand, not all characteristics can be measured, or if they can be measured, sensitivity is low: backward-forward movement only leads to small observed changes; the colour of the horse model cannot be seen at all.

In general then, to interpret an instrument's measurements, we need to understand its sensitivity: what characteristics can it measure well, which are poorly measured or not measured at all, and which lead to distorted representations?

1.4 BLURRY SHADOWS OF A FLICKERING FIRE

Our slaves' view of the world is actually worse than we considered in the previous section. In addition to the limitations of the shadows' sensitivity, the shadows are blurry and unstable.

The blur of the shadows is caused by the size of the fire as a source of light and would not be present for a point light source. In Figure 1.3, each shadow is shown in two parts, at the centre, the *umbra*, where all light is blocked, and on the sides, the *penumbra*, where only some light is blocked. This partial shadow is not uniform, but slowly varies from dark to light as one moves from umbra outside the shadow.

How does the blur affect our slaves' perceptions? By reducing the ease with which small movements and small objects can be detected. In our example, if the fire is 20 cm wide, the penumbra width will be $20\,\mathrm{cm} \times (d_i - d_o)/d_o = 60\,\mathrm{cm}$. A small movement of the horse model will not lead to movement of a clean, easily-visible edge. Instead, there are gradual changes of light intensity in the partially shadowed region, which is much more difficult to interpret. Similarly a very small object will be lost in the blurred region: it would not be easy for the slaves to see if the horse has saddle bags.

Even worse for the slaves, the fire flickers; the flames dance around and the illumination is constantly changing. These changes in illumination mean that the shadows keep moving, even if the horse model does not. The situation seems impossible: how can the slaves know if the horse is moving if any movement could either be real or just from the defects of the fire as our instrument. As we will see later, there is much that can be done with these measurements. First, large movement cannot be due to the fire, they must be the horse. Additionally, we can learn about the characteristics of the flickering. The fire, while random, moves in typical ways. With a knowledge of these patterns, we can better filter flickering from real movement (Chapter 19).

The previous section characterized this instrument using the first meaning of sensitivity, instrument output/input. However, the effect of blur and flickering is best understood in the second sense – the ability to make correct predictions. We may wish to determine which horse has saddle bags; if the blurring and flickering were reduced, then our guesses would be more accurate, and our instrument would have higher sensitivity.

1.5 DISCUSSION

Plato's cave is a profound philosophical analogy, and it may at first seem unrelated to medical data and its interpretation. Nevertheless, it is a useful introduction to many of the key concerns we consider later.

- *Measurements vs measurand*: We almost never have access to the information we want, but instead have an instrument that gives us partial information. Understanding the defects of the instrument is vital to correct interpretation.
- *Partial sensitivity*: Instruments are sensitive to some aspects of the world, but less or not at all sensitive to others. Additionally, some changes lead to distortions (movement to magnifications), which are then mixed with other measurements.
- *Calibration and trending*: It is not always possible to get an absolute calibration (we may never know the size of the horse) but often what we want is the changes over time (trending).
- *Blurring and noise*: Instruments have inaccuracies. Blurring makes it difficult to detect small features, and noise (flickering) means measurements change over time. These inaccuracies decrease our ability to make predictions using the instrument (the second *sensitivity*).

A note on the terms "real" and "truth". Of course there is no such easy-to-describe thing. Full information would only come from a quantum-level uncertainty model of each atom in the horse. We will never have the full information; we need to settle for less – perhaps the outline of the body.

When we discuss instruments and their errors, we will be interested in how close the reported value is to the correct one. Various terms are used for the correct value: the "ground truth", a "gold standard" (Chapter 5).

This chapter illustrates a key theme of this book: we don't have access to the "true" information, but rather to our measurements of it, which are typically distorted in various ways. The challenge is twofold: first, we want to learn as much as possible from the distorted measurements we have, and second, we want to be aware of the ways in which we might still be wrong.

This quantity is a model, a substitute, for the real thing, which hopefully tells us enough to answer the questions we care about. "All models are wrong, but some are useful"[14]. This issue is an important one: can we know when our models are so wrong that they are no longer useful?

1.6 SUMMARY

- Three key inventions in 1895–1901 changed medicine by allowing non-invasive investigation of the body: X-rays, blood pressure cuff, and electrocardiogram.
- Current innovations in sensors and computer processing are leading another era of big changes in medical instruments and interpretations.