MDEXPO
Dallas • April 16-17, 2021

The Realities and Irrelevance of Medical Device Leakage Currents

April 17, 2021

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How did leakage current measurements become such a sacred cow ?

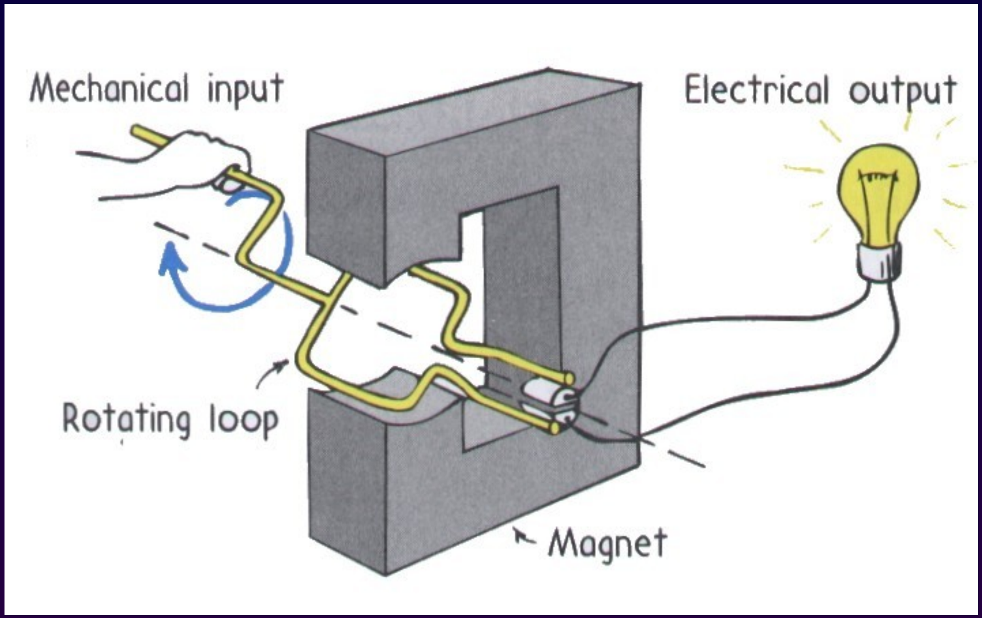
Topics:

- Origin of 60 Hz leakage currents
  - Electrical behavior in AC circuits
  - AC electrical power distribution systems
- Physiological effects of AC current
- Electrical safety in hospitals – birth of the sacred cow (circa 1970's)
- Why leakage current measurements are no longer necessary.

Faraday's Law of Induction:

A voltage is induced across a rotating coil of wire when it is rotated in a magnetic field.

$$V = N \frac{d\phi}{dt}$$



Where:

V = induced AC voltage appearing across the coil

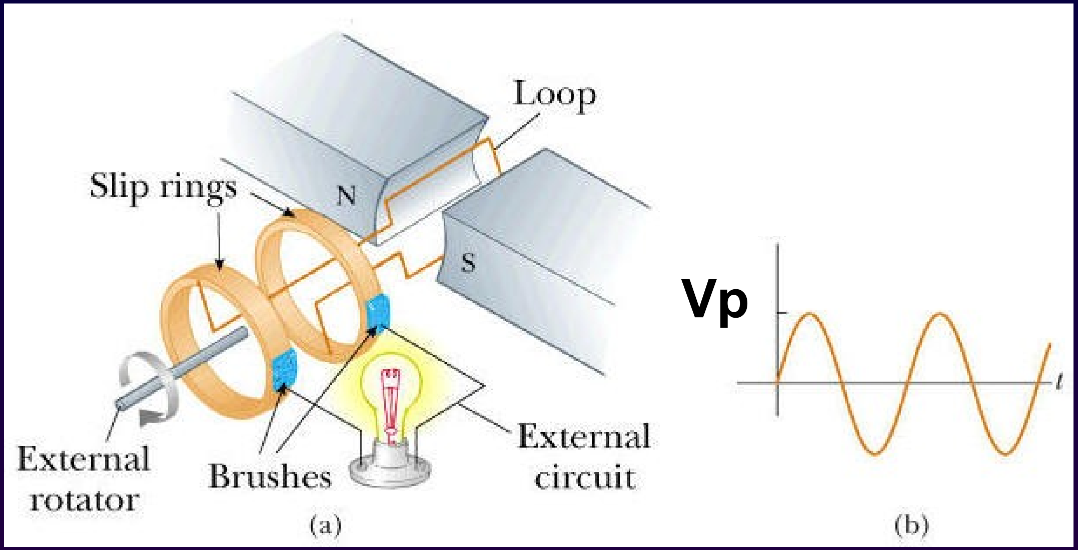
N = number of wire turns in the coil

$\frac{d\phi}{dt}$ **= relative change in magnetic flux through the coil**

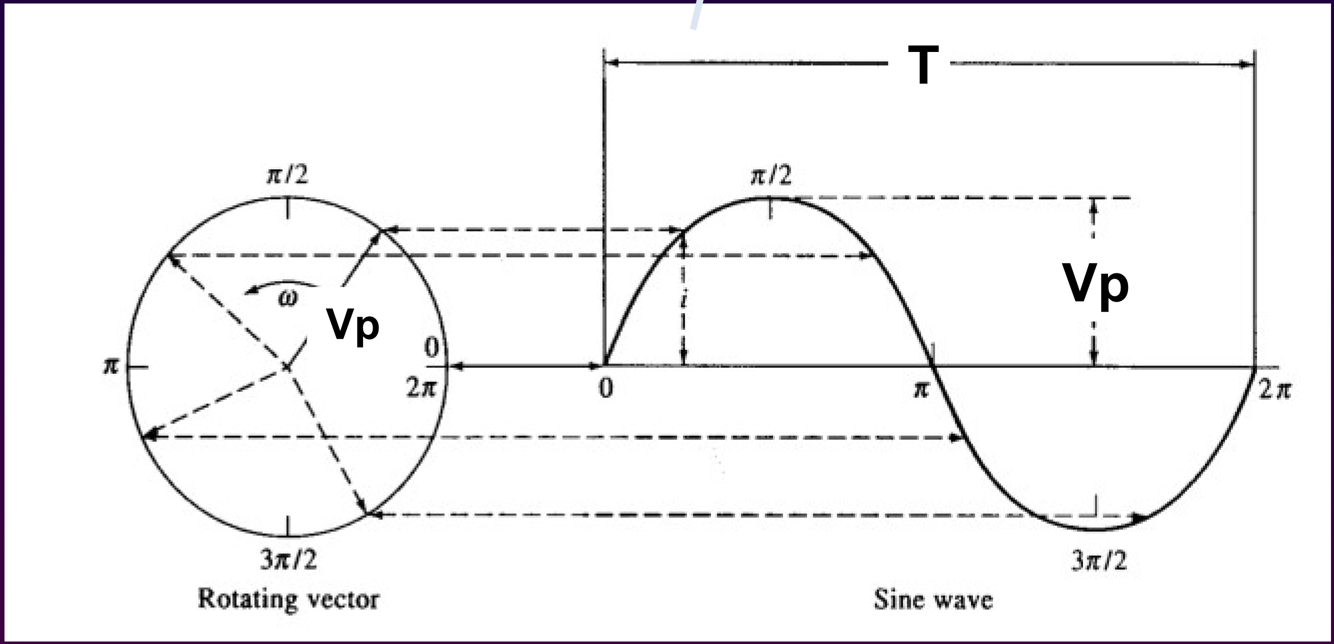
Michael Faraday
1791 - 1867

Faraday's Law of Induction:

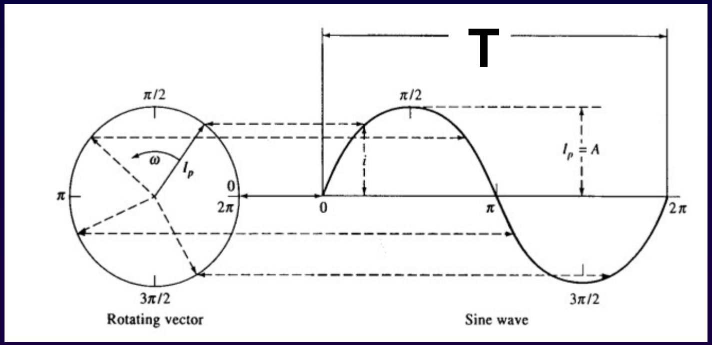
AC Voltages & Currents:

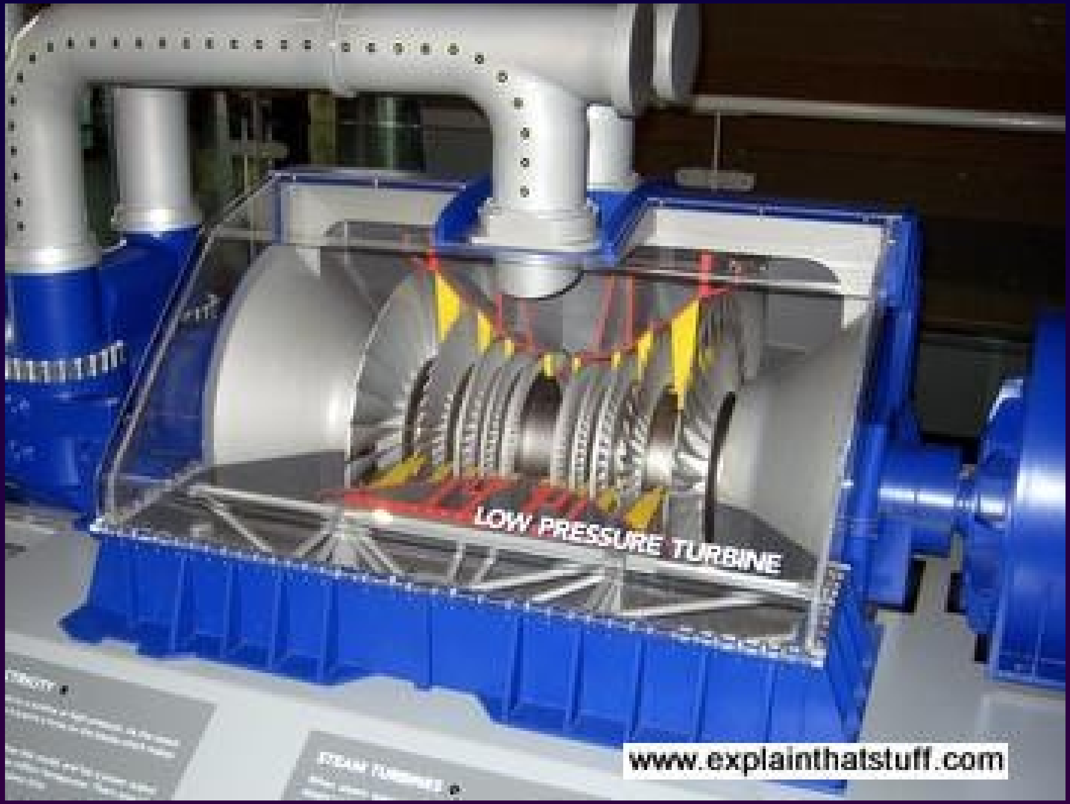


The period, T, of the resulting sinusoidal waveform is determined by the angular velocity or speed of the rotating coil.



AC Voltages & Currents:

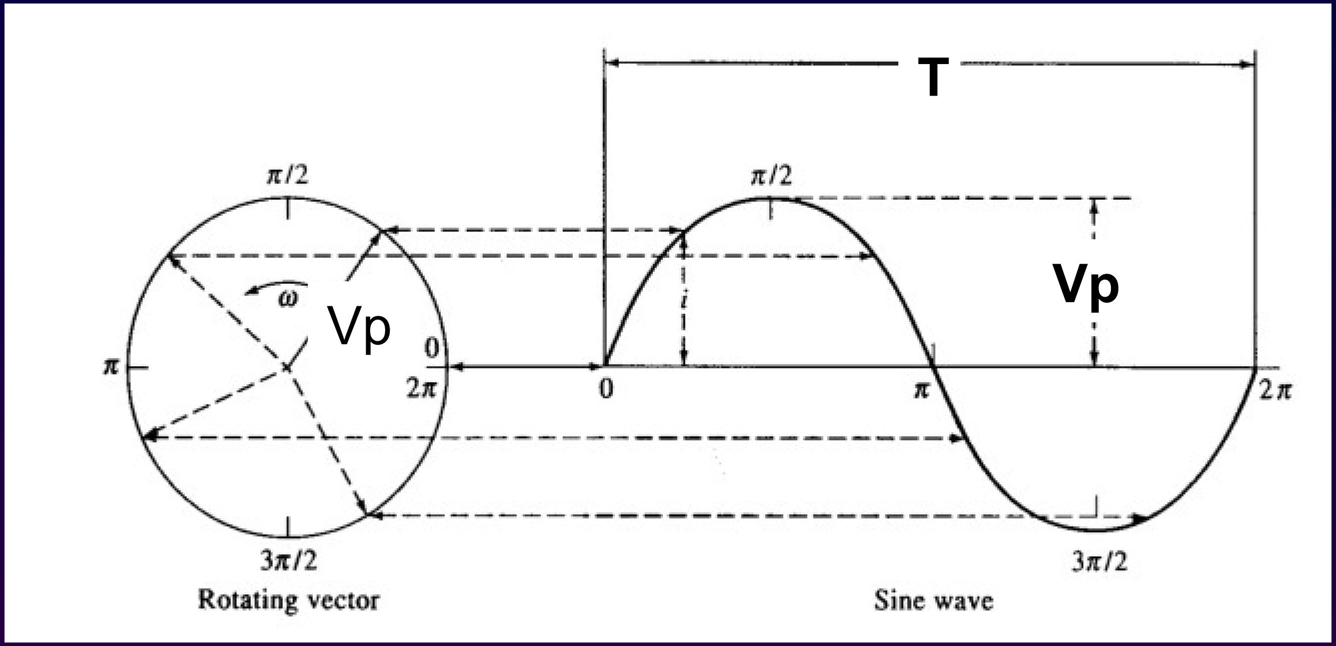




$$\omega = 2\pi f = \frac{2\pi}{T} = 377 rad/\sec = 3600 rpm$$

Speed of rotating turbine generator at power plant

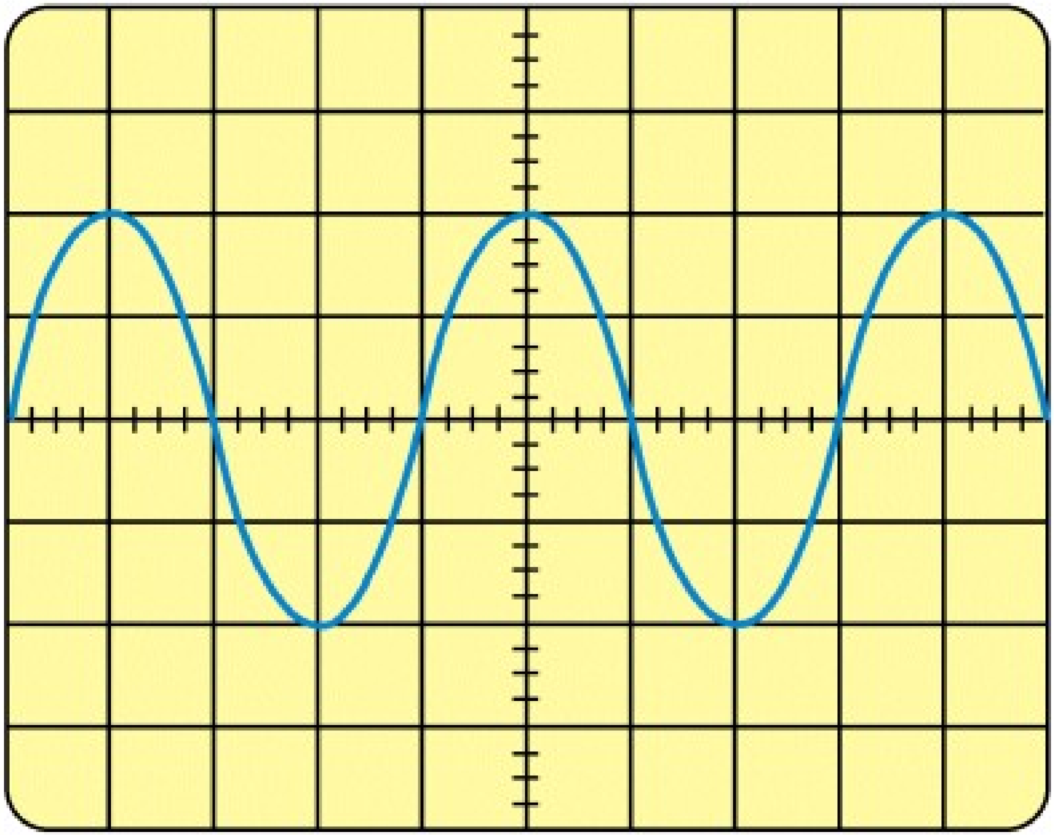
AC Voltages & Currents:



Where:

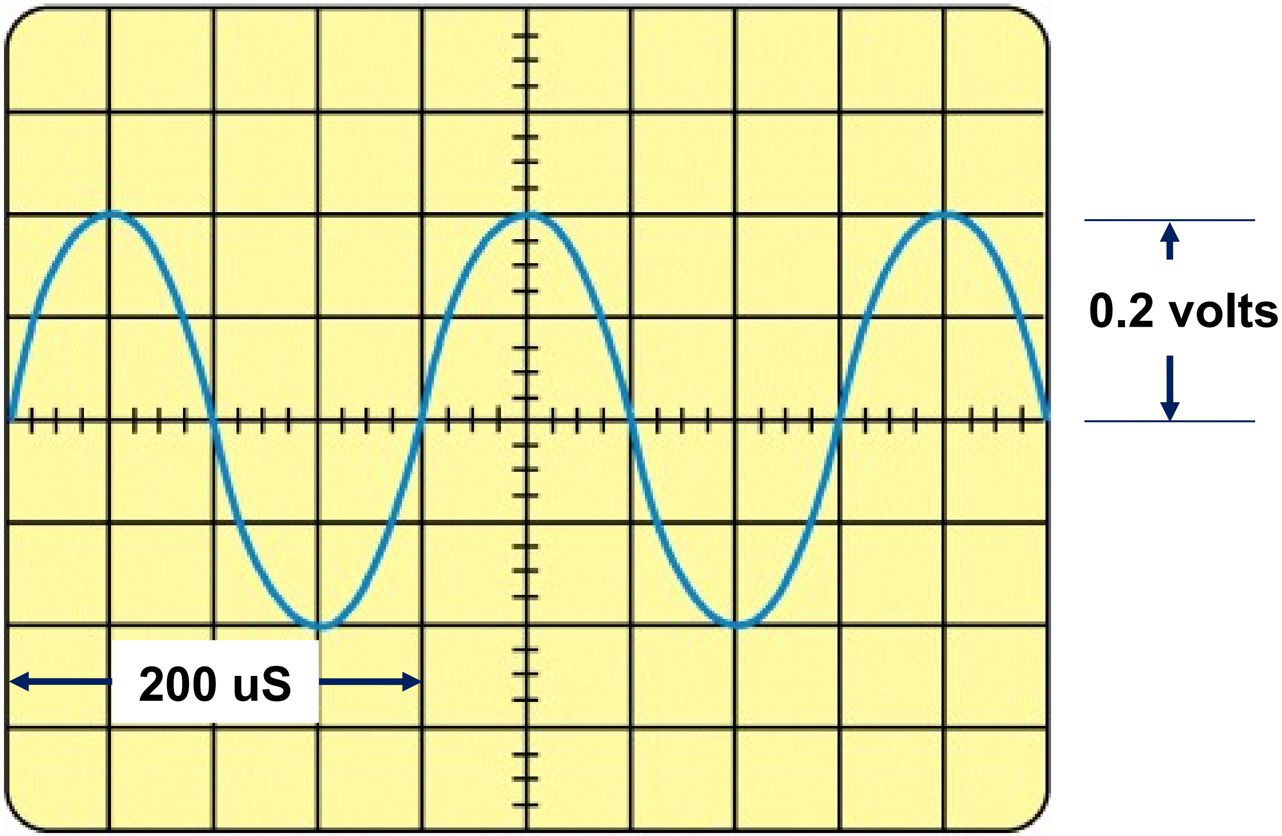
$$T = \frac{2\pi}{\omega} = \frac{1}{f} = \frac{1}{60} = 16.66\text{milliseconds}$$

Sine wave viewed on an oscilloscope



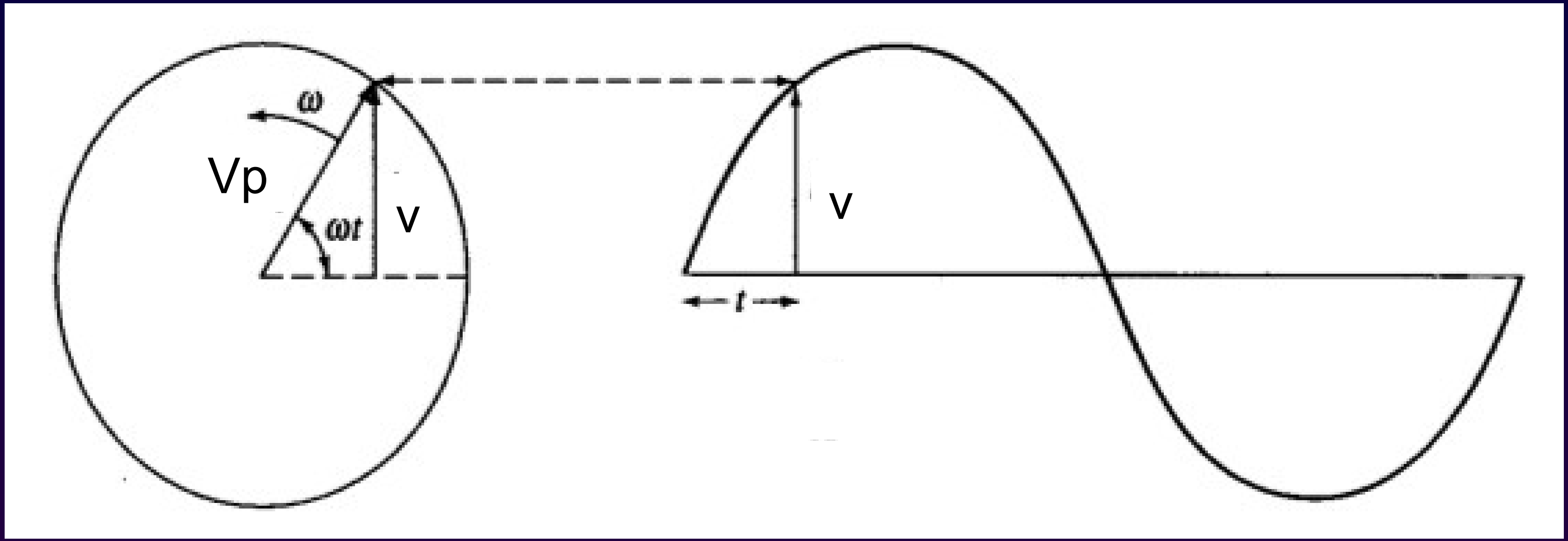
Vertical sensitivity = 0.1 V/div.
Horizontal sensitivity = 50 μs/div

Sine wave viewed on an oscilloscope



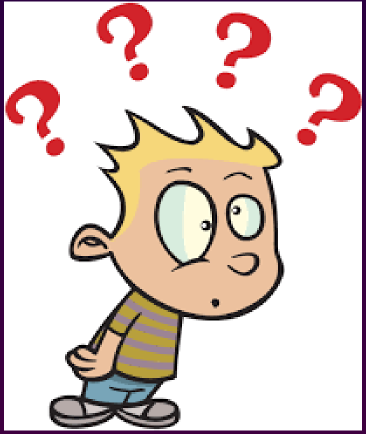
Vertical sensitivity = 0.1 V/div.
Horizontal sensitivity = 50 μs/div

AC Voltages & Currents:



With the instantaneous voltage amplitude, v, given by:

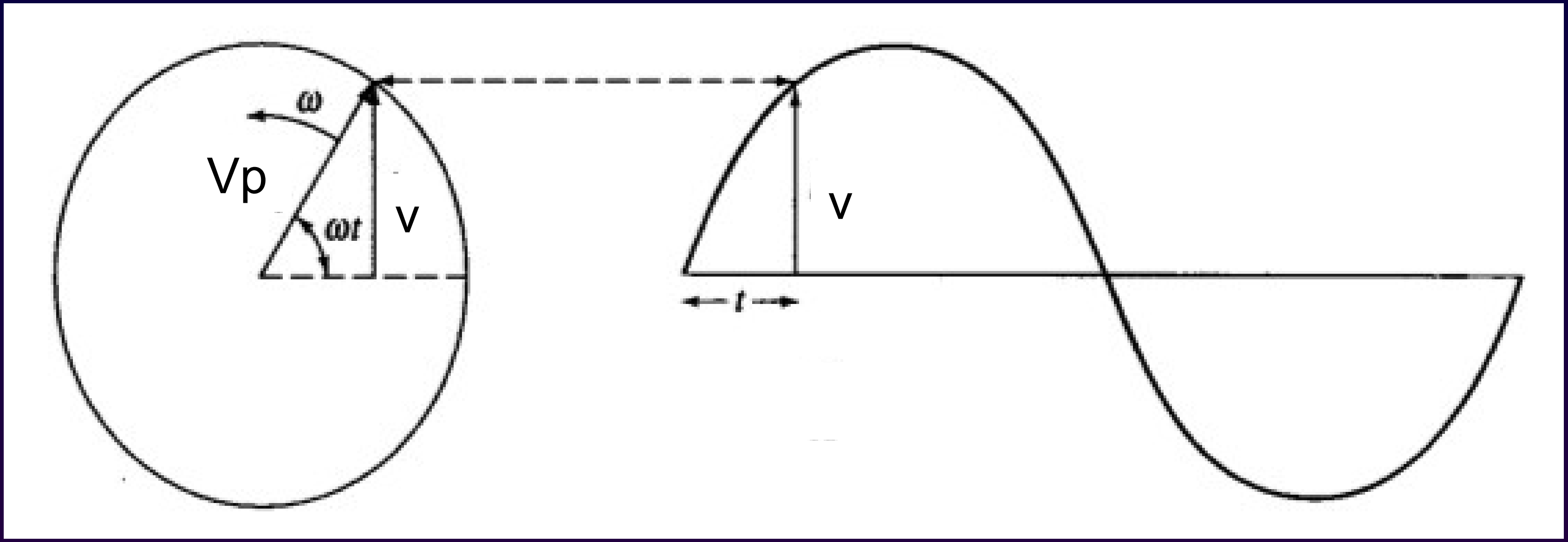
$$v = V_p \sin \omega t = V_p \sin 2\pi f t$$



Or, from the oscilloscope waveform:

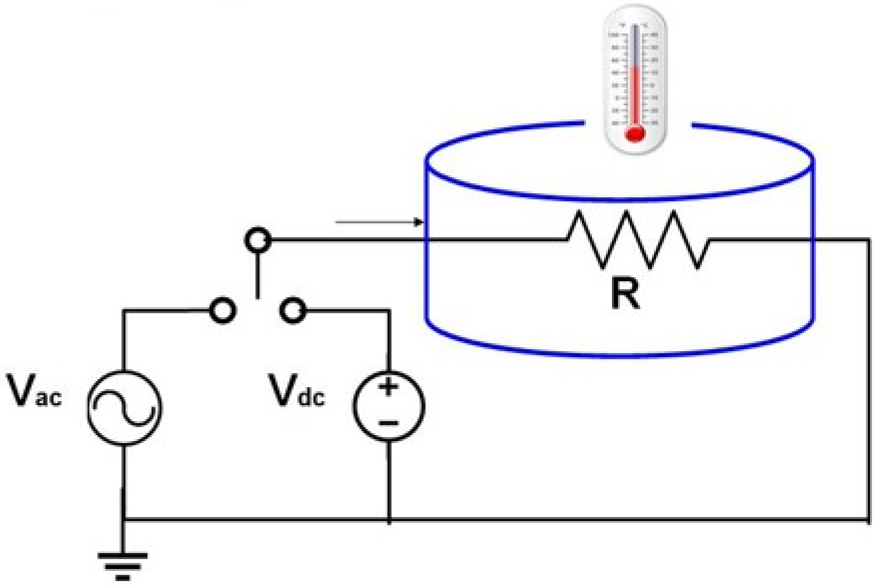
$$v = 0.2 \sin 31400t$$

AC Voltages & Currents:



Fortunately, we have a easier, short-hand method of describing AC currents and voltages: by their *RMS* value.

AC Voltages & Currents: RMS Value



The RMS value of a sinusoidal (or any periodic) waveform is that value of AC that produces the same heating effect as an equivalent value of DC.

AC multimeters display RMS values .

AC Voltages & Currents: RMS Value

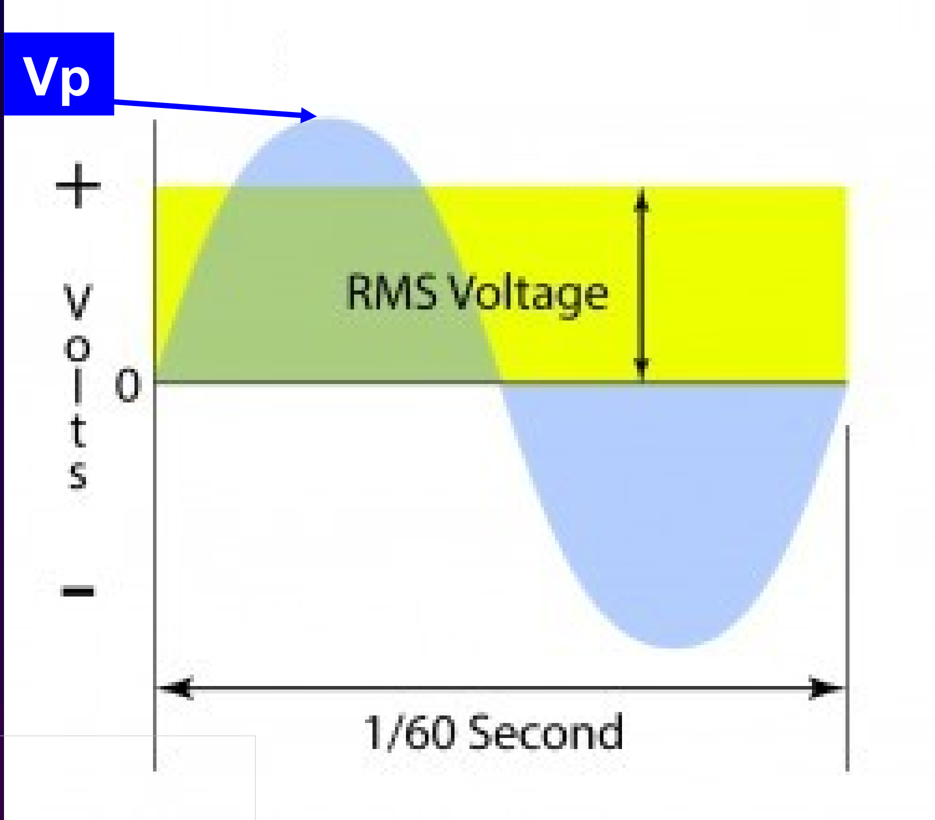
$$v = V_p \sin \omega t$$

Fully defines the amplitude and frequency of a sinusoidal waveform.

The equivalent RMS value of a sinusoidal waveform is given by:

$$V_{rms} = V_p \cdot \frac{\sqrt{2}}{2} = V_p \cdot 0.707, or$$

$$V_p = V_{rms} \cdot \sqrt{2} = V_{rms} \cdot 1.414$$



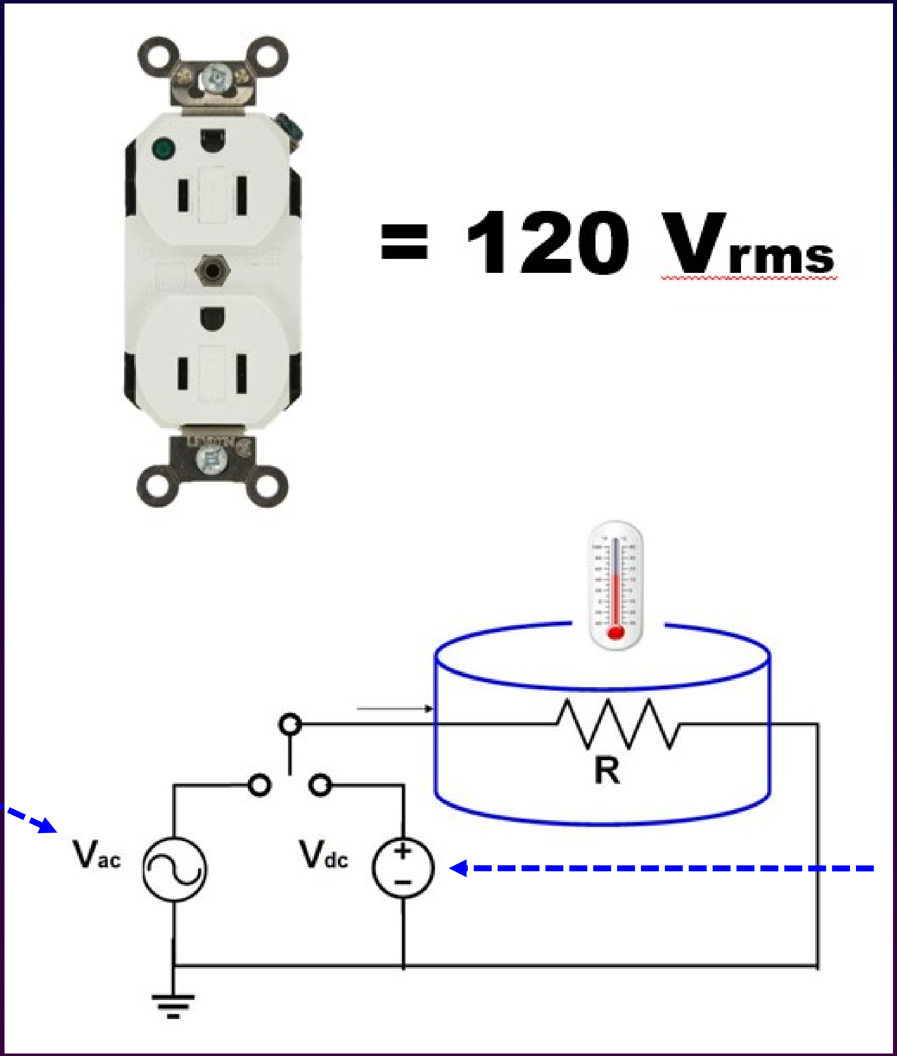
Leakage current is measured in RMS uA.

AC Voltages & Currents: RMS Value

Or, a sinusoidal voltage at 60 Hz and described by:

$170 \sin 377t$

volts,



will produce the same heating effect as 120 volts of DC.

AC Voltages & Currents: RMS Value

General equation for the RMS value of a periodic function.

$$V_{RMS} = \sqrt{\frac{1}{T}\int_0^T [V(t)]^2\, dt}$$

Square

Mean

Root

A

waveform

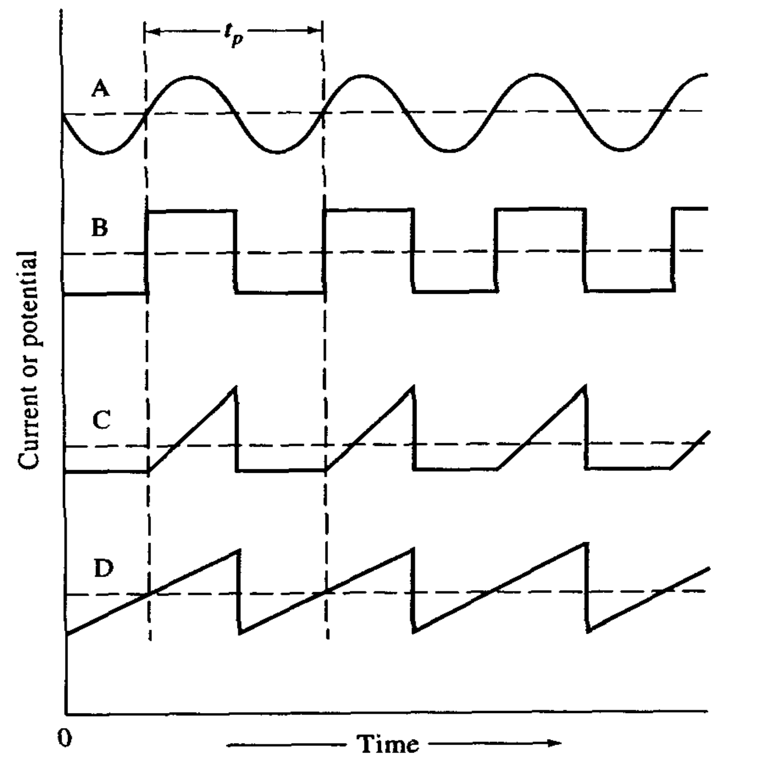
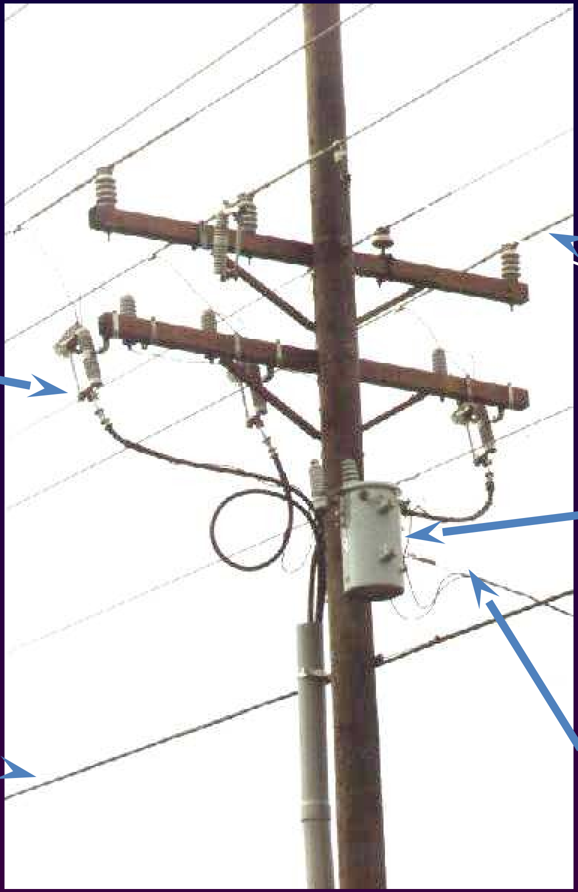


Figure 2-5 Examples of periodic signals: *(A)* sinusoidal, *(B)* square wave, *(C)* ramp, and *(D)* sawtooth.

Sub-transmission and Distribution line:

Fuse and disconnector

Telephone line

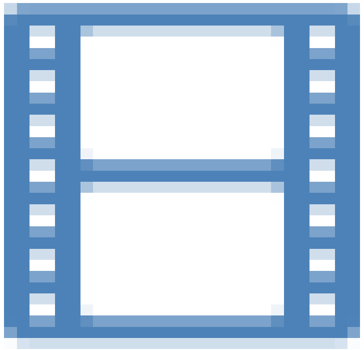


Distribution line
14 kV

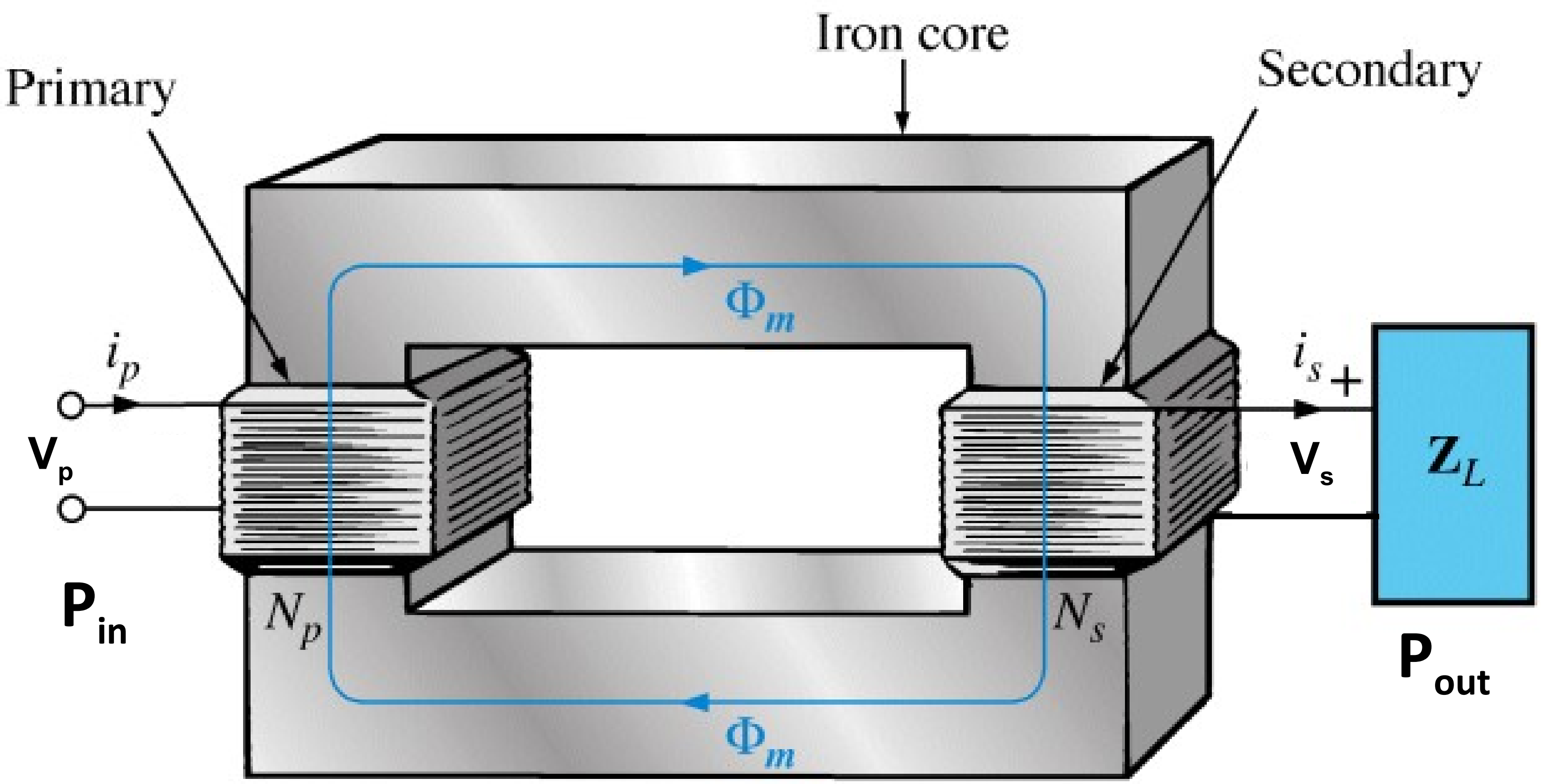
Transformer

240/120V line

How transformers work



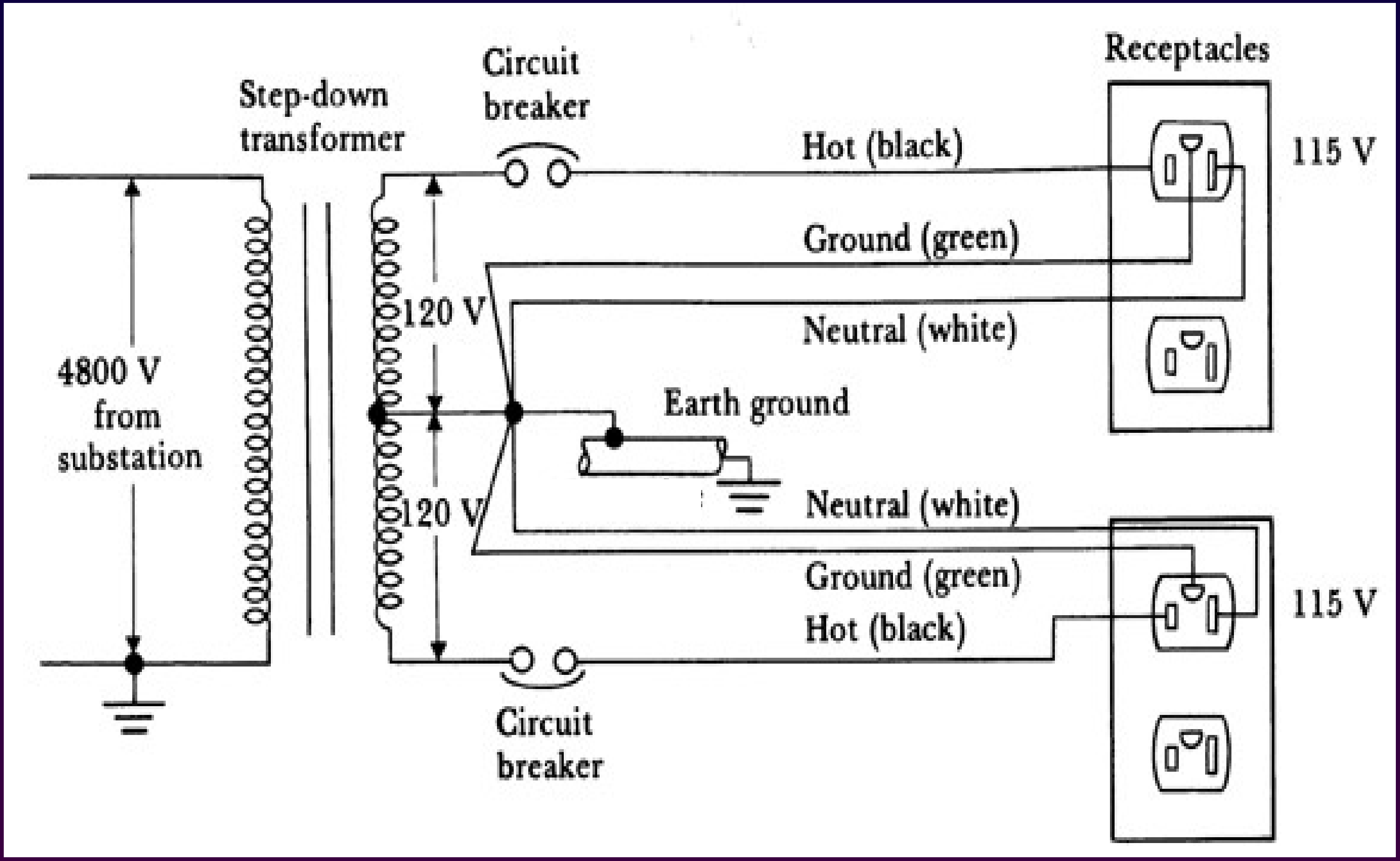
Basic transformer relationships



$$\frac{V_p}{V_s} = \frac{N_p}{N_S} = \frac{I_s}{I_p} = \sqrt{\frac{Z_p}{Z_s}}$$

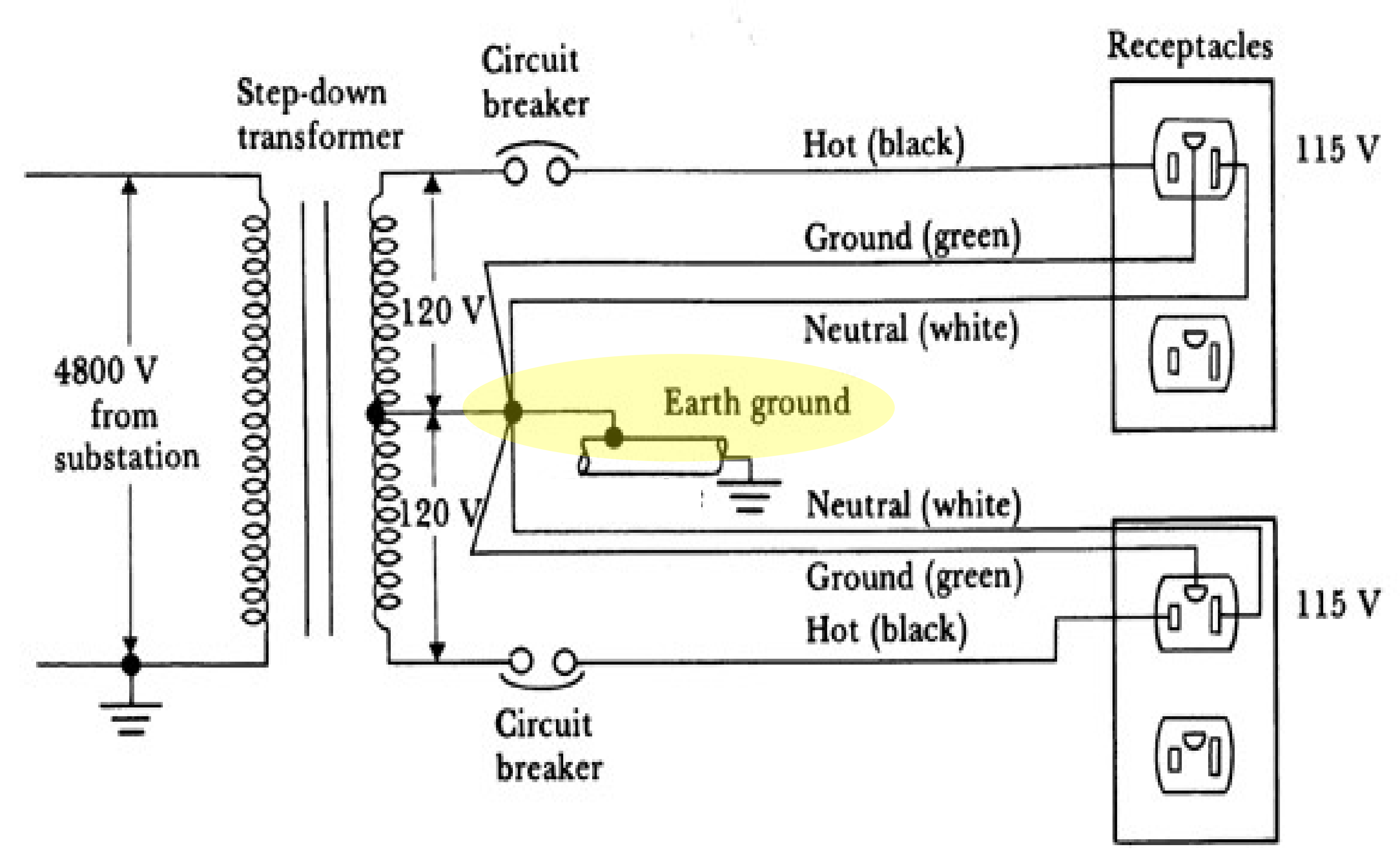
Ideally, $P_{in} = P_{out}$

Distribution of Electrical Power



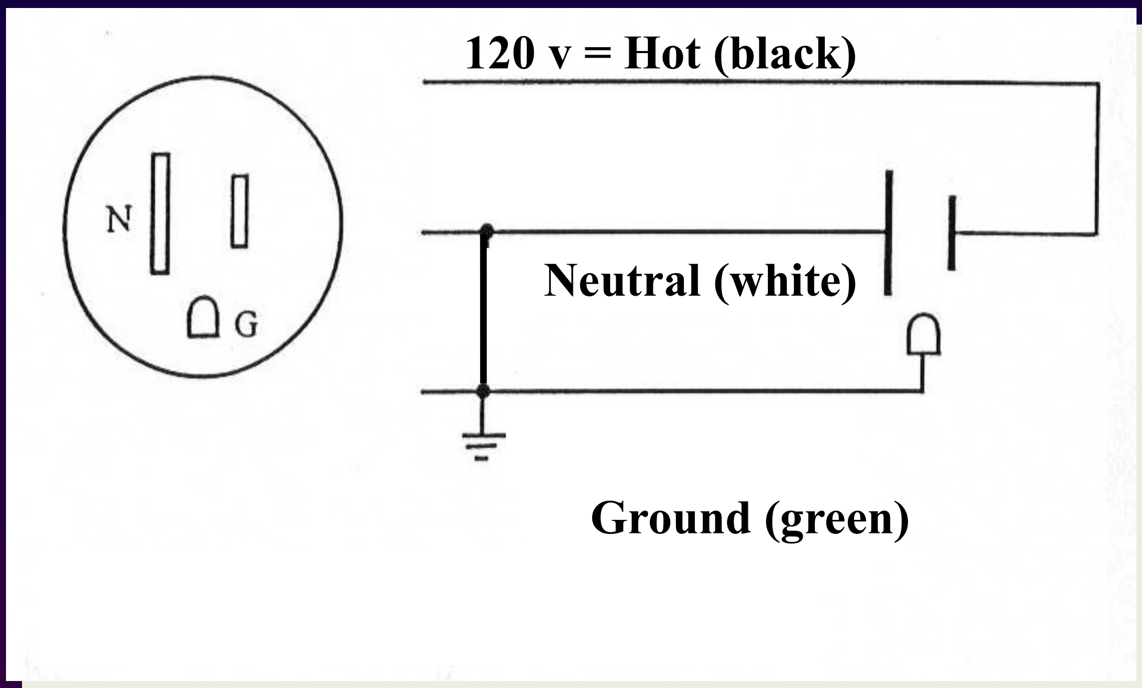
From W. Olson in J. G. Webster (1998). Medical Instrumentation and Design, 3rd ed. Wiley. p. 631.

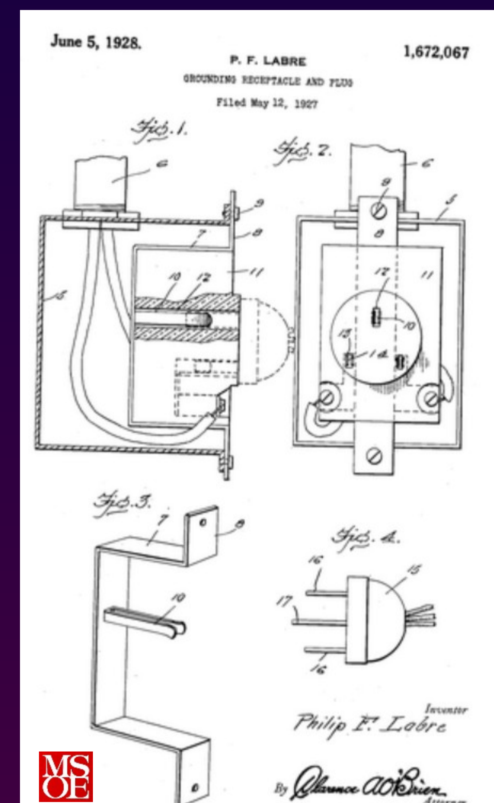
Distribution of Electrical Power



From W. Olson in J. G. Webster (1998). Medical Instrumentation and Design, 3rd ed. Wiley. p. 631.

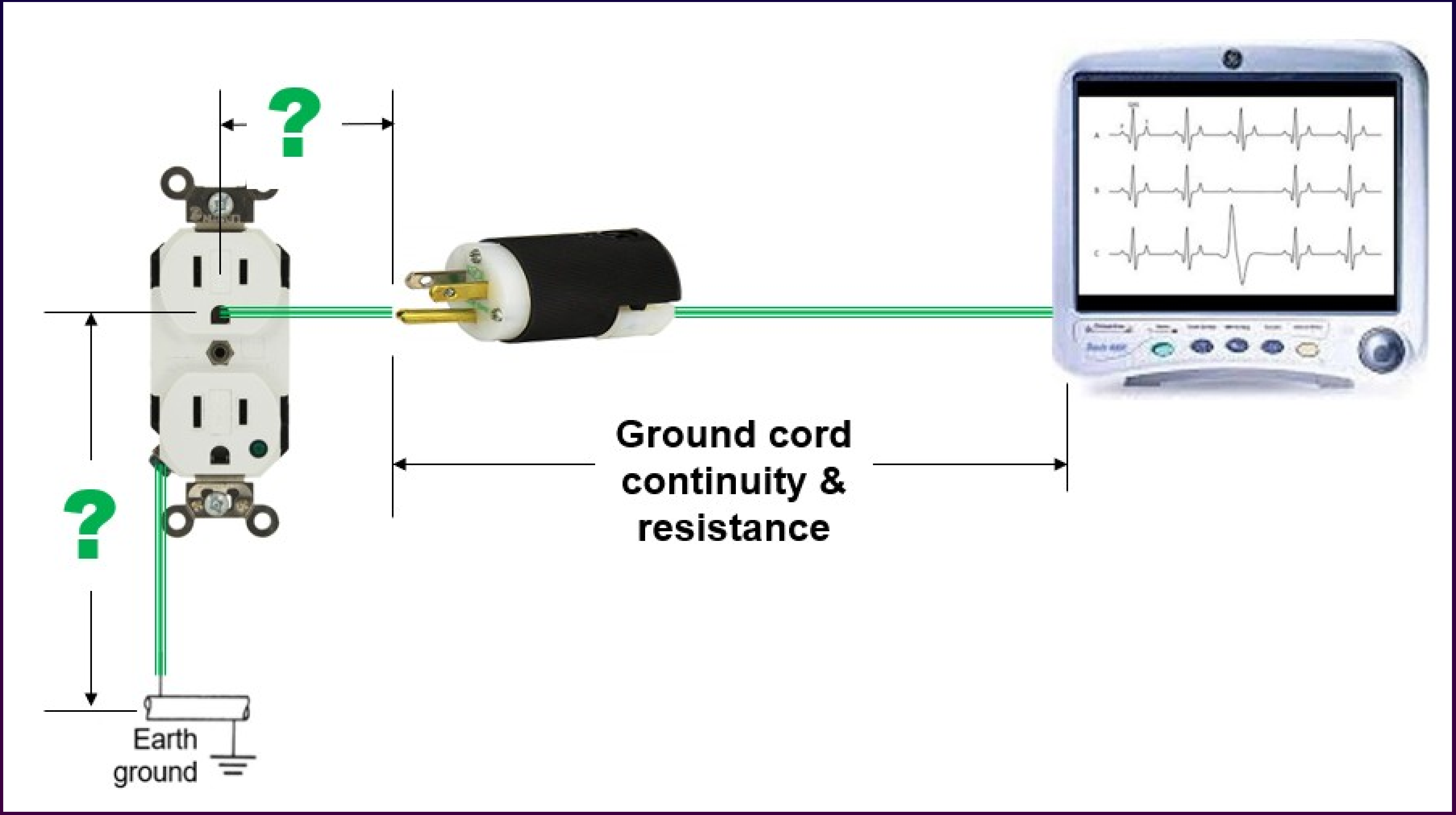
The grounded 120-volt receptacle





Invented by an MSOE student, Philip Labre, 1928.

Ground connection quality includes continuity and low ohmic resistance between the device case and earth ground.



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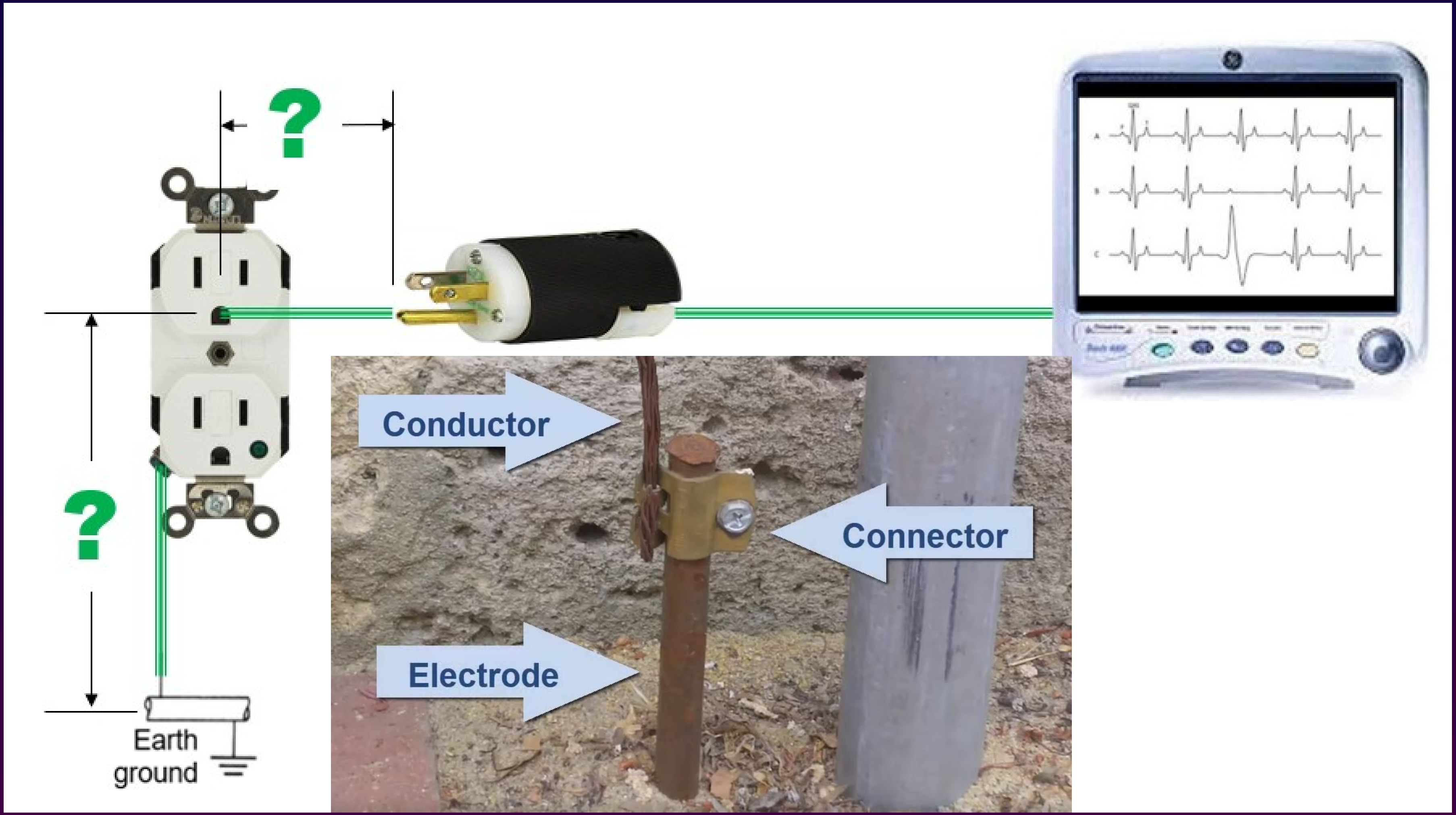
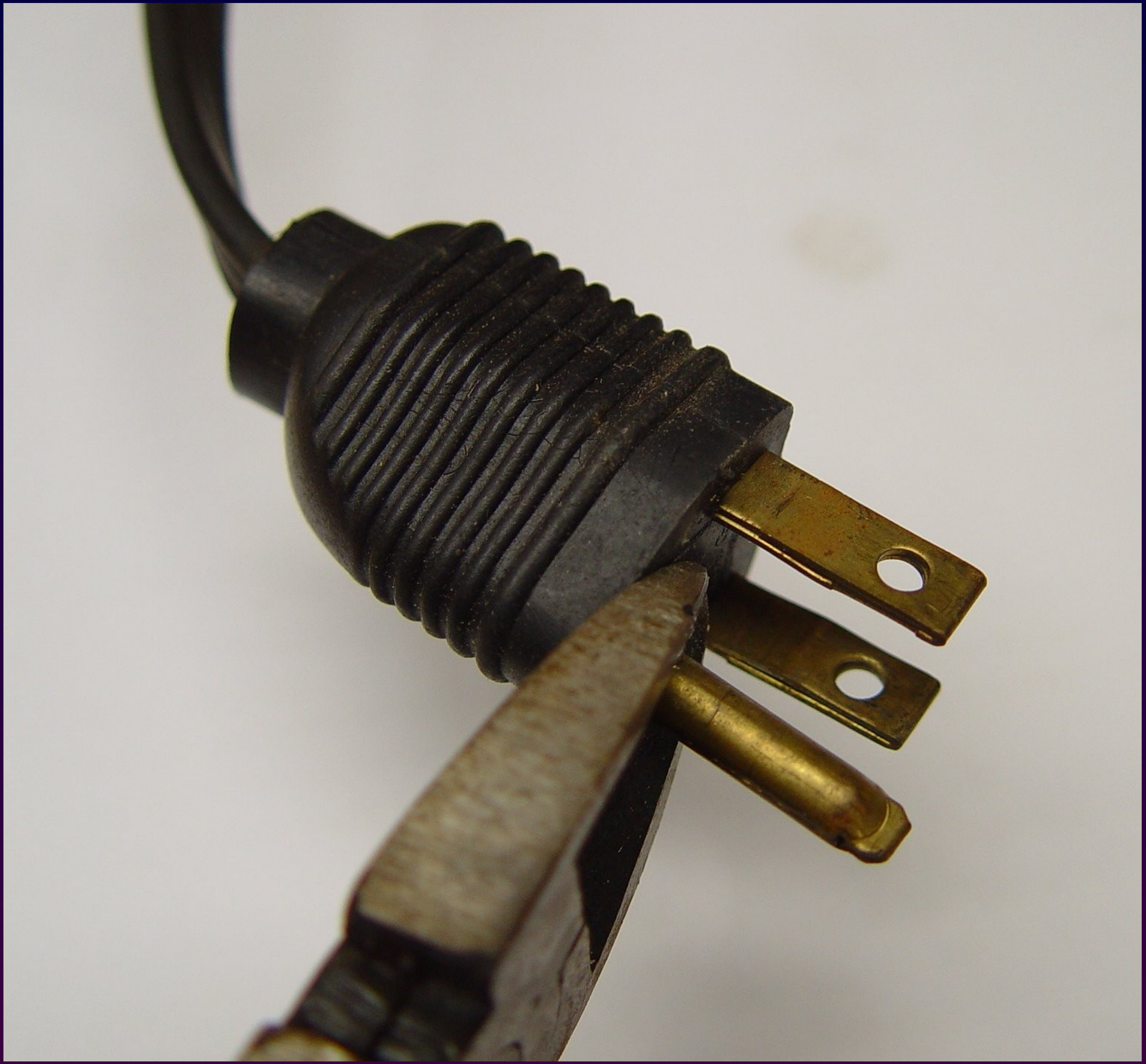


So, don’t ever do this !!!



All electrical circuit behavior follows:

- Ohm's Law
- Kirchhoff's Voltage Law
- Kirchhoff's Current Law

Georg Ohm

(1789 – 1854)

Gustav Kirchhoff

(1824 – 1887)

Ohm's Law . . . in DC circuits:

- Defines the relationship between current, voltage, and resistance;

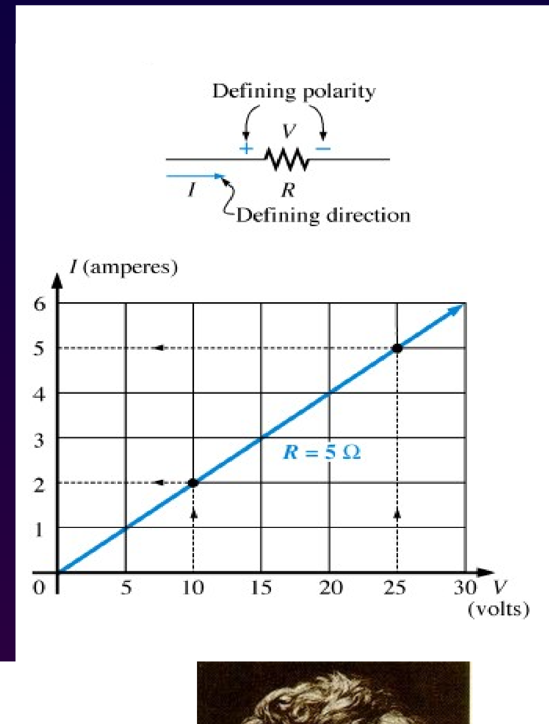
$$I = \frac{V}{R}$$

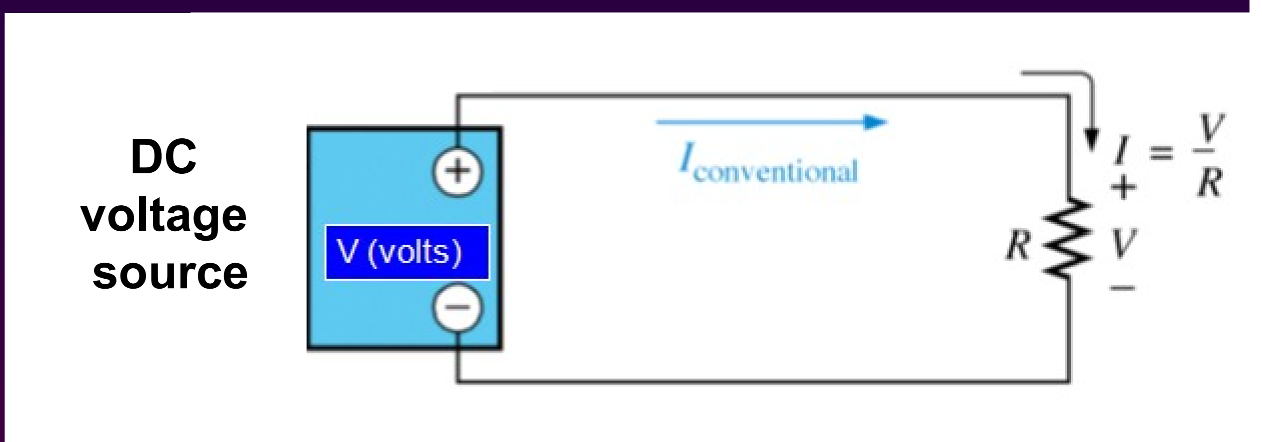
Where:

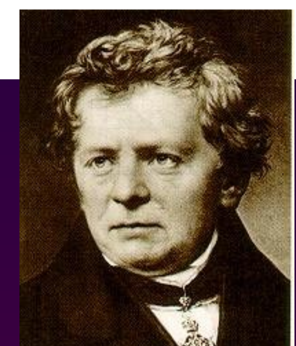
V is in volts

I is current in amperes

R is resistance in ohms







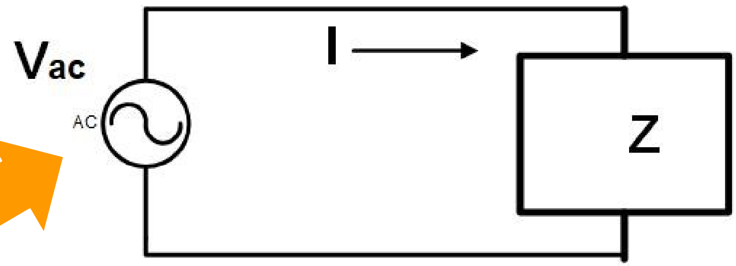
Georg Ohm

(1789 – 1854)

Ohm's Law . . . in AC circuits:

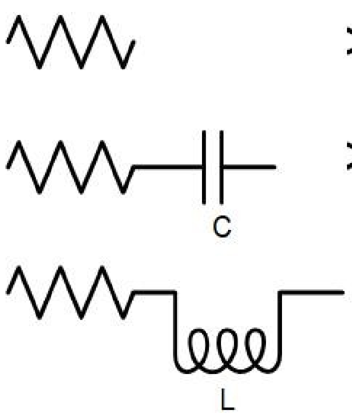
- Defines the relationship between current, voltage, and impedance;

$$I = \frac{V}{Z}$$



$$I = \frac{V}{Z}$$

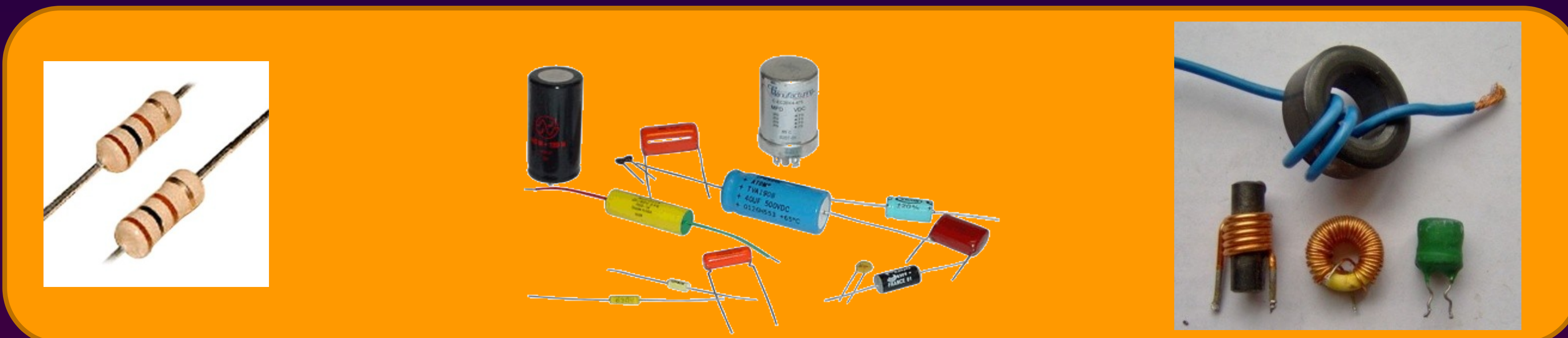
Where Z = impedance (in ohms) and may be represented as one of the following:



- Pure resistance > > $Z = R$
- Series R-C network > > $Z = R - jX_C$
- Series R-L network > > $Z = R + jX_L$

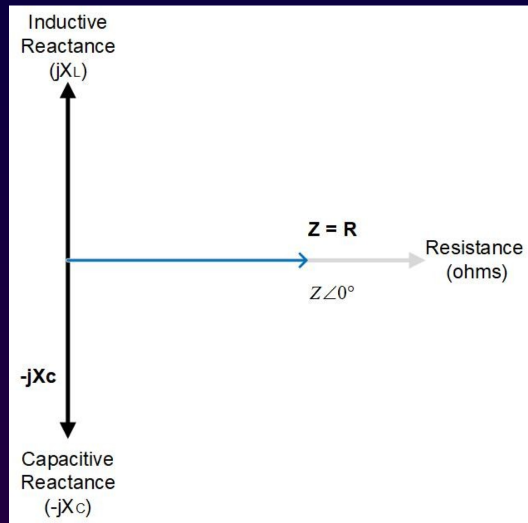
Resistance in an AC circuit = Impedance

- Impedance, Z, represents the opposition to the flow of current in an AC circuit due to the combi individual effects of resistance, capacitive, and inductive reactances. Loosely, think of impedance as a frequency-dependent resistance. Impedance is also measured in ohms. Impedance also has an associated phase angle (θ) which tells us if an impedance is predominately resistive (θ=0º), inductive (+ θ), or capacitive (- θ).

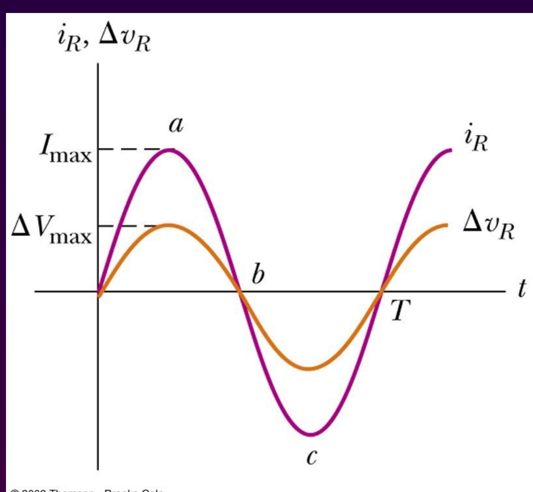


Impedance may be purely resistive :

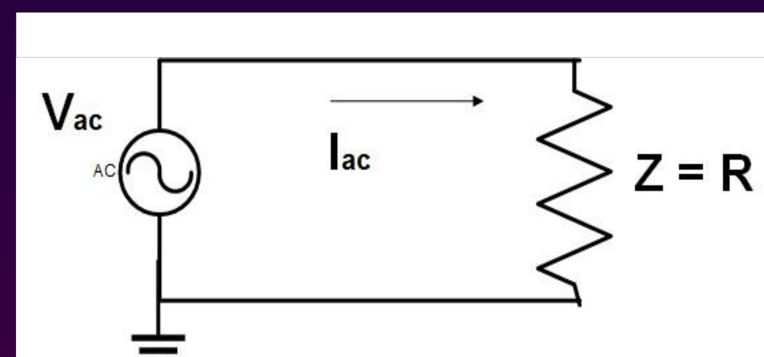
$$I = \frac{V}{Z} = \frac{P}{V}$$



Electrically, incandescent lamps, coffee pots, heaters, 'look' like a simple resistor.

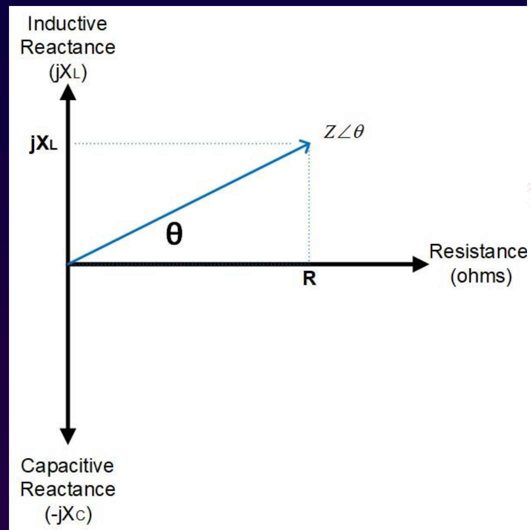


Where current and voltage are in phase

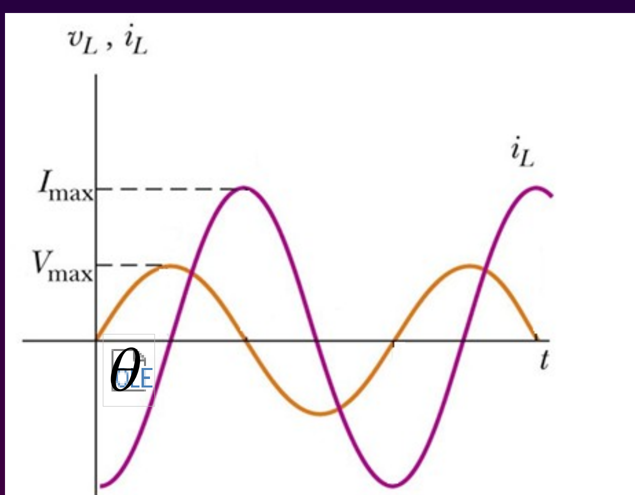


Impedance may be resistive & inductive:

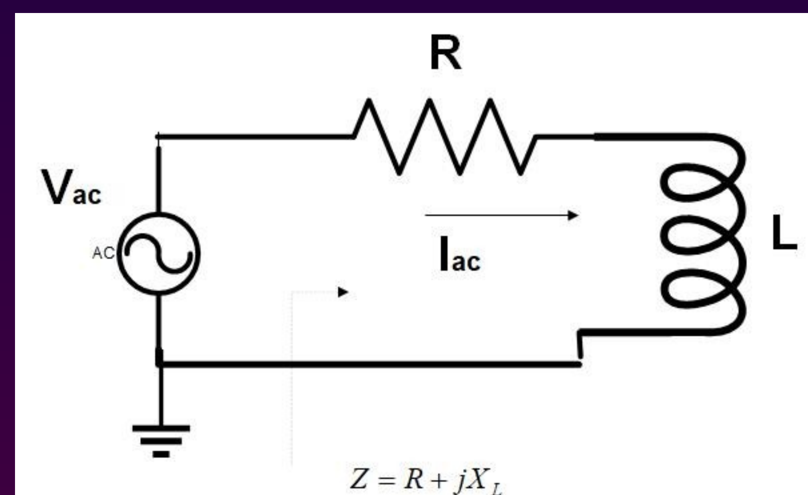
$$I = \frac{V}{Z\angle\theta}$$



Electrically, motors, loud speakers, solenoid valves 'look' like a series R-L circuit.

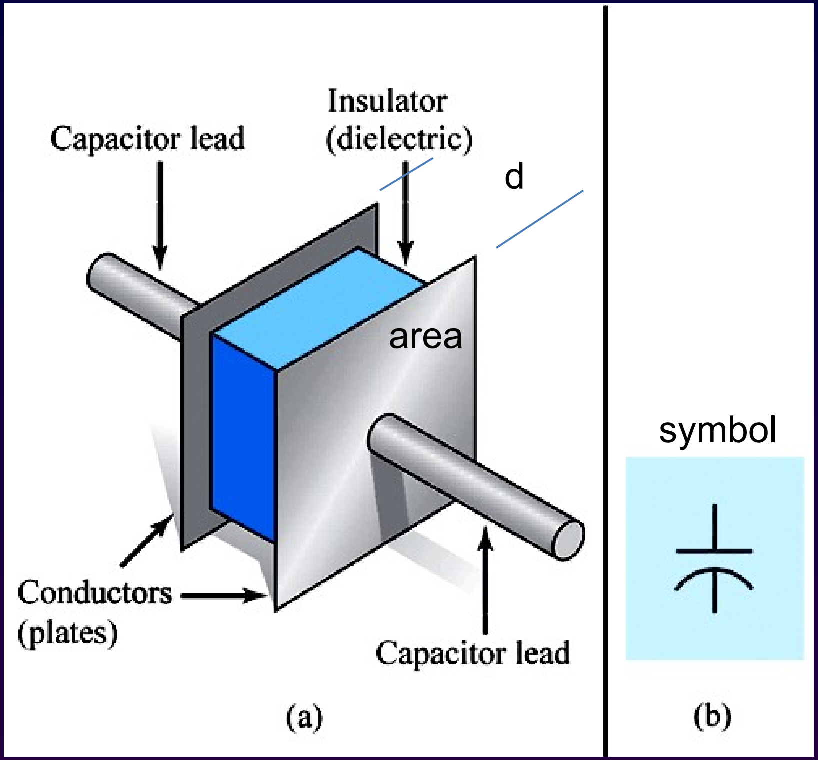


Where current *lags* the voltage

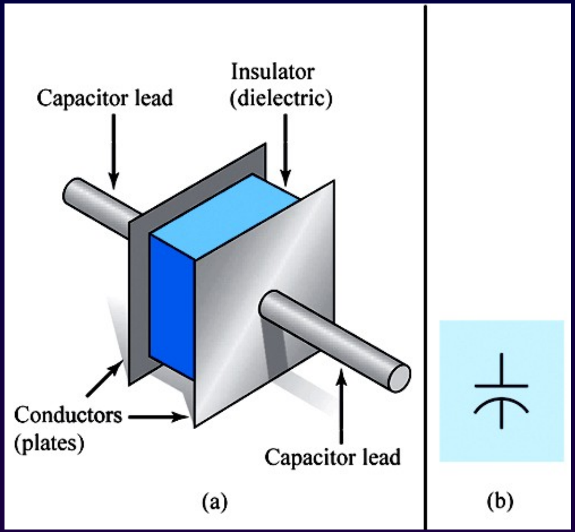


Capacitors & Capacitance:

- A capacitor consists of two conductors (or *plates*) separated by an insulator called the *dielectric*.
- Capacitance exists wherever two conductors are separated by an insulator.
- The amount of capacitance is directly proportional to area of these plates (or length of the conductors) and inversely proportional to the distance between them.
- Circuit capacitance may exist from physical capacitors or virtually from the proximity of conductors.



Capacitors & Capacitance:



- Stray or parasitic capacitance will allow AC currents to flow between these conductors.

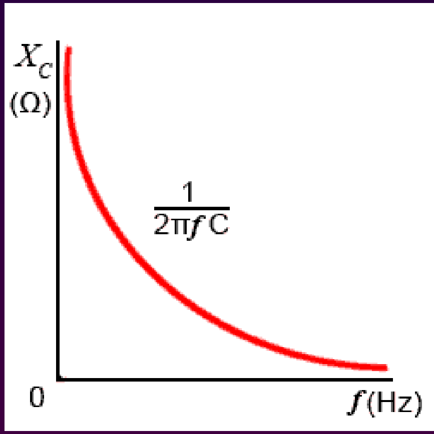
- The magnitude of such currents is determined from:

$$I = \frac{V}{|X_C|}, where\ |X_C| = \frac{1}{2\pi fC}$$

where:

Xc = capacitive reactance in ohms

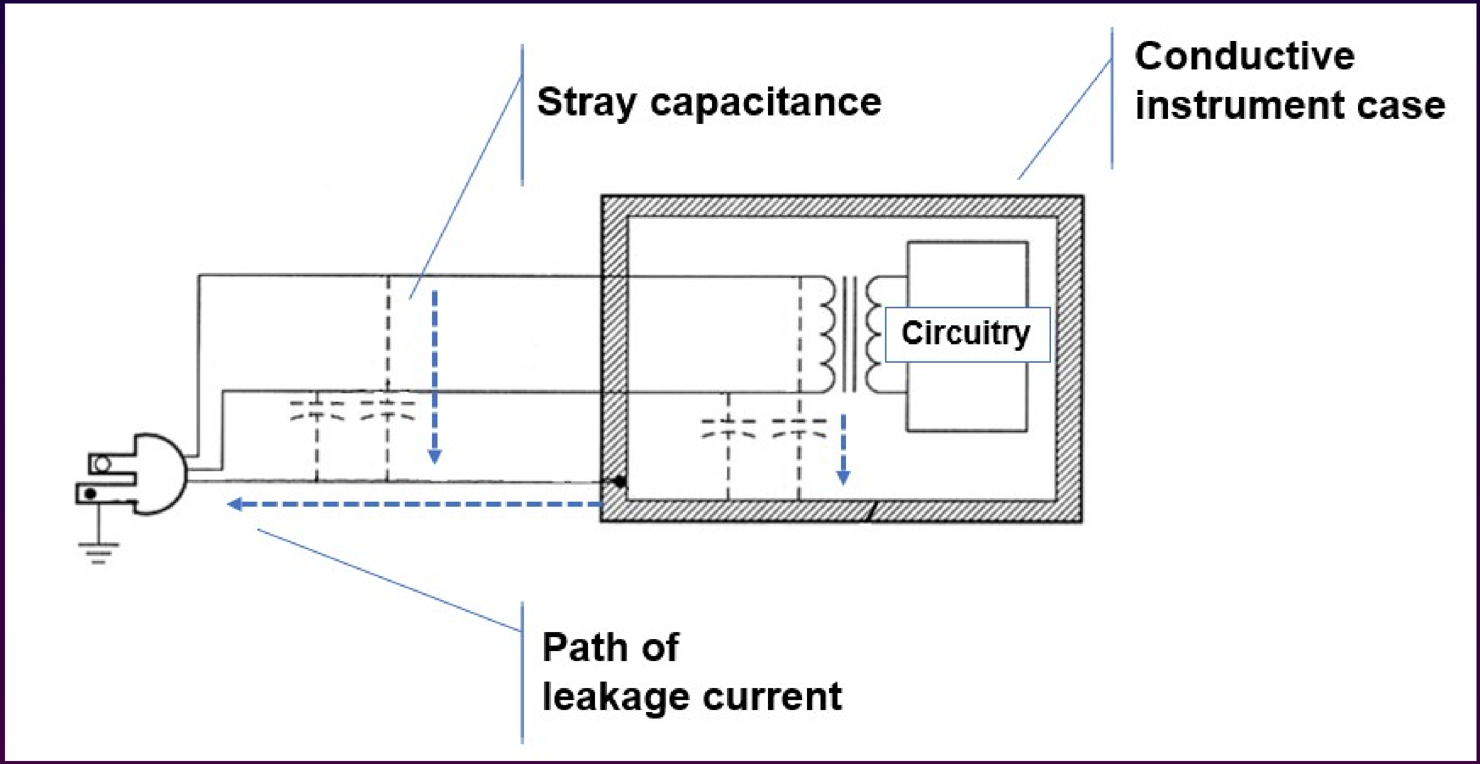
f = frequency in Hz



Stray (parasitic) Capacitance . . .

- is an unavoidable and usually unwanted capacitance that exists in an electric circuit or device due to the simple proximity of conductors separated by insulators.

- ***is the primary cause of leakage current in AC-powered devices.***



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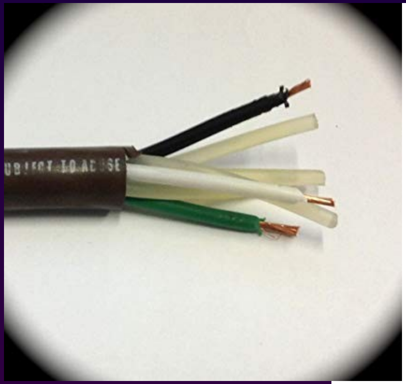
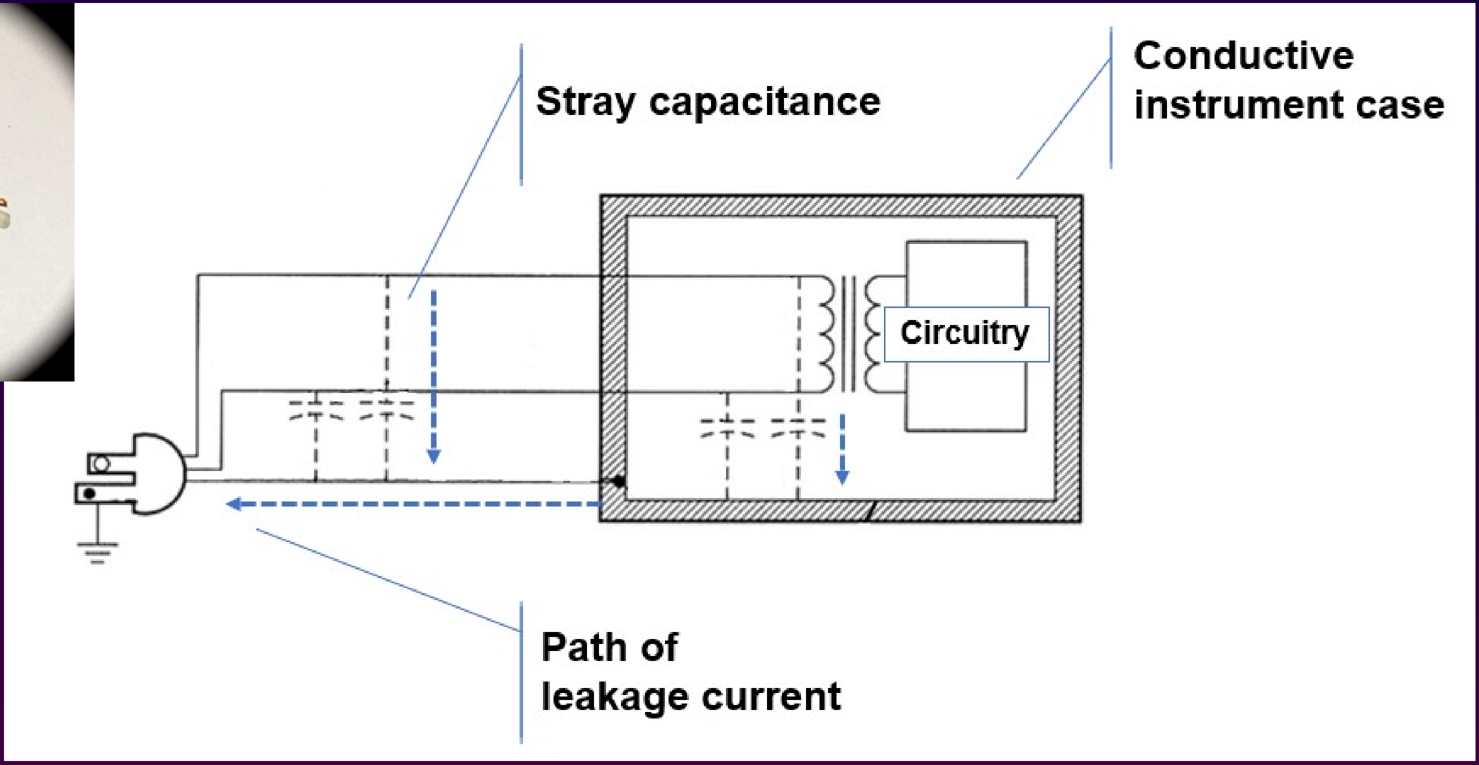


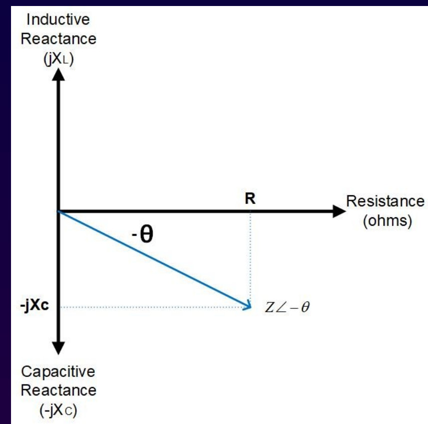
S

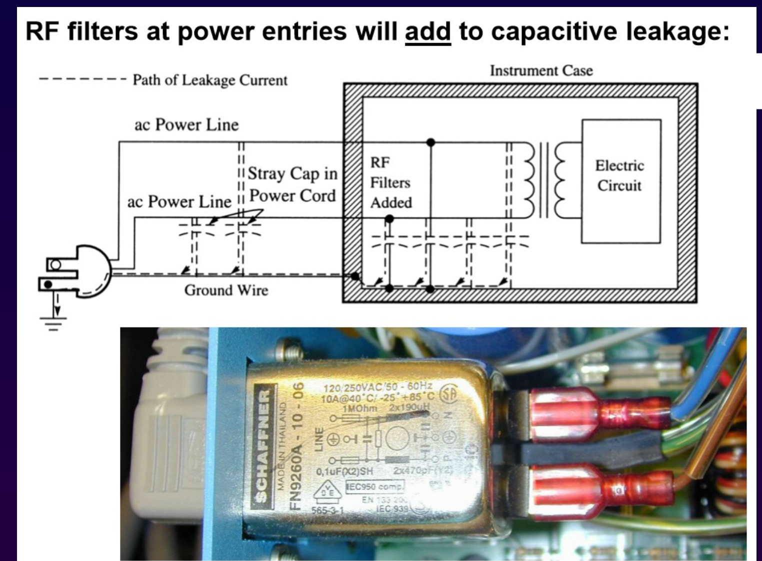
is minimized in low-leakage line cords.

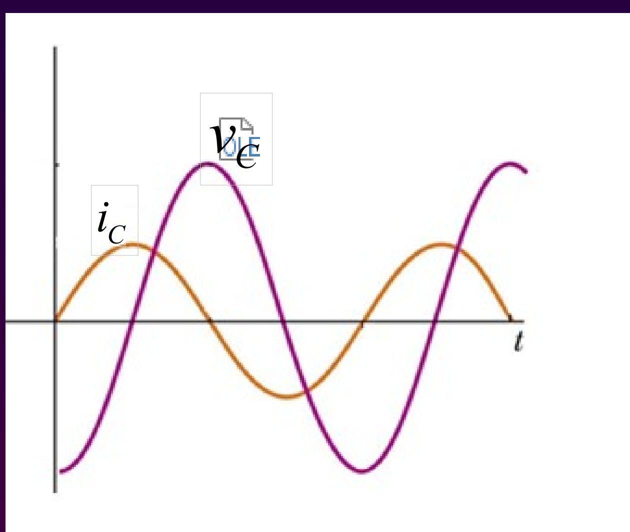


Impedance may be resistive & capacitive:

$$I = \frac{V}{Z\angle -\theta}$$





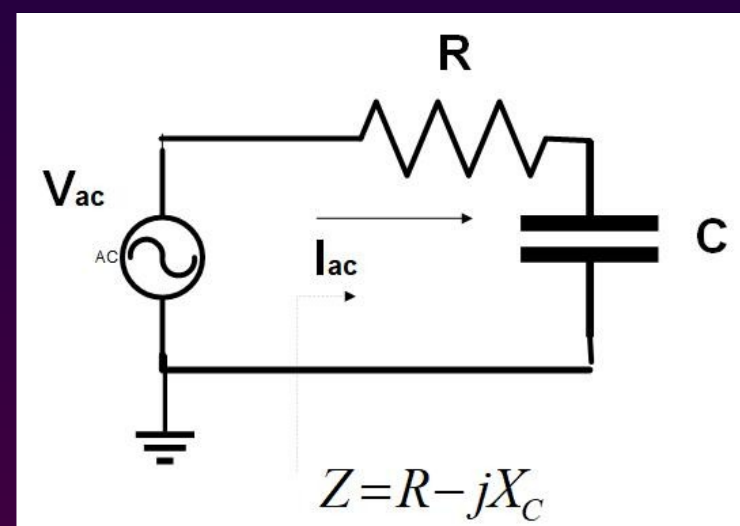


c

Where

leads

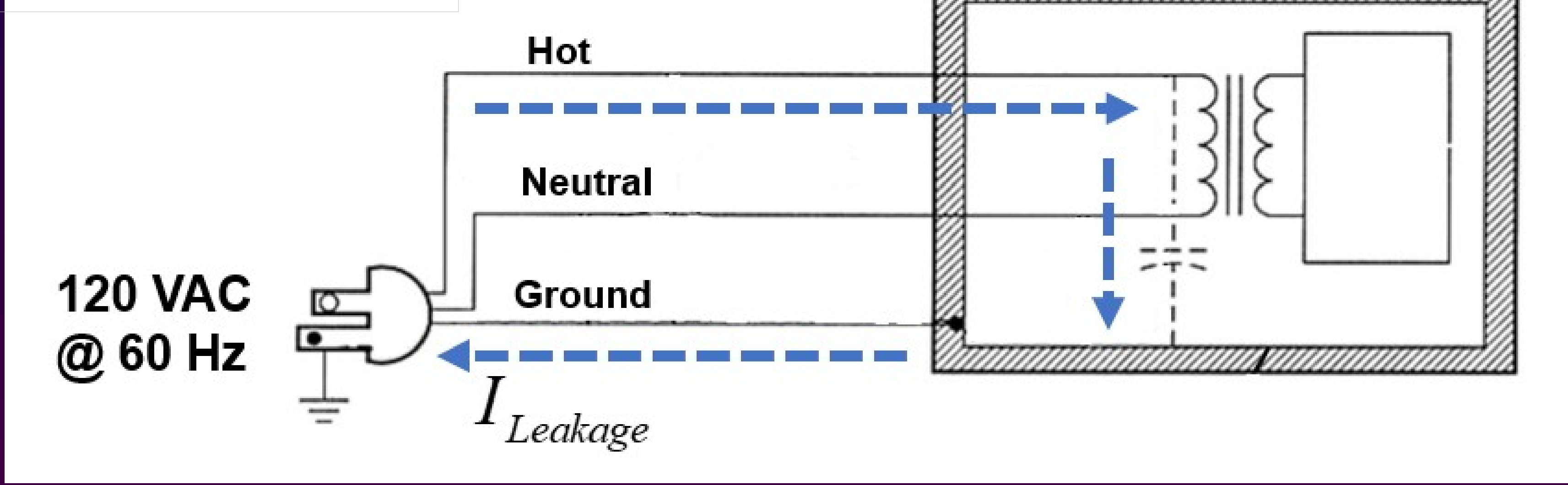
the voltage

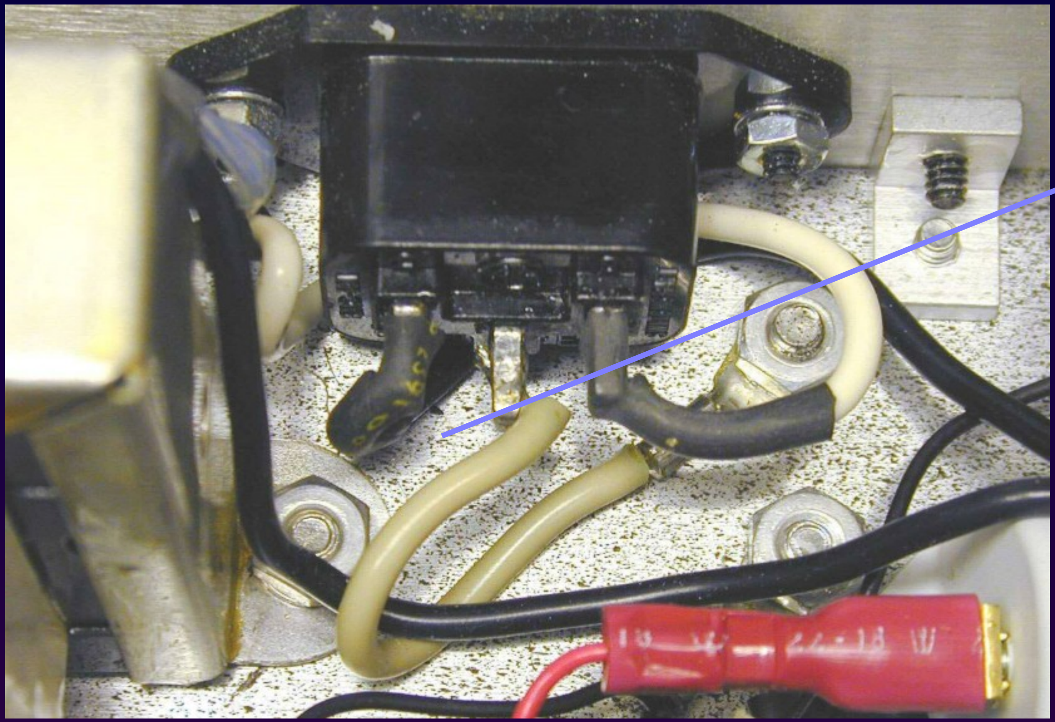


For example, 10 nF of stray (or actual) capacitance between the hot side of the incoming power line and a conductive case would create a leakage current of 452 uA :

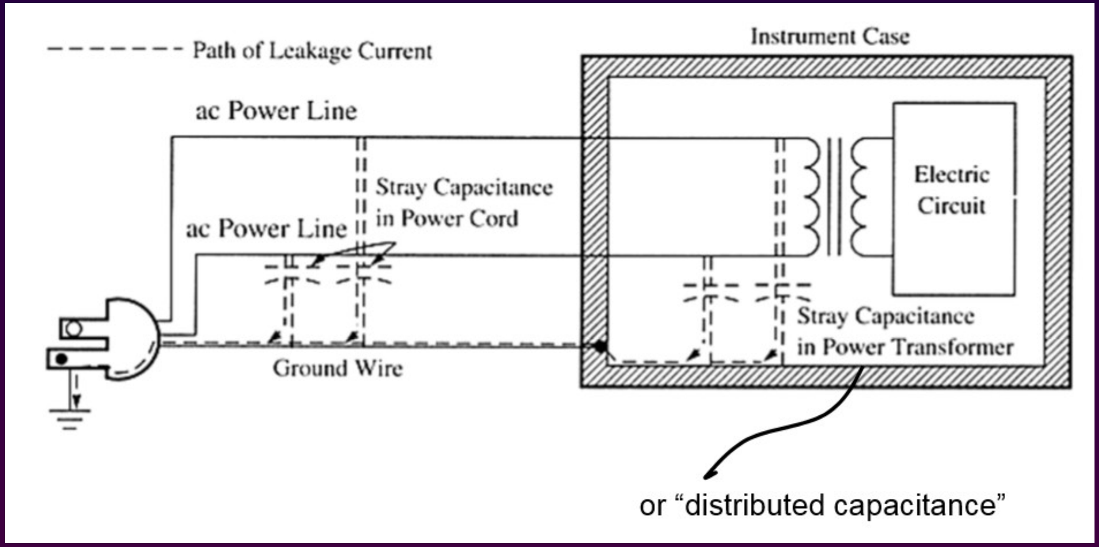
$$|X_C| = \frac{1}{2\pi fC} = \frac{1}{2\pi(60Hz)(10nF)} = 265Kohm$$

$$I_{Leakage} = \frac{120V}{265K} = 452uA$$

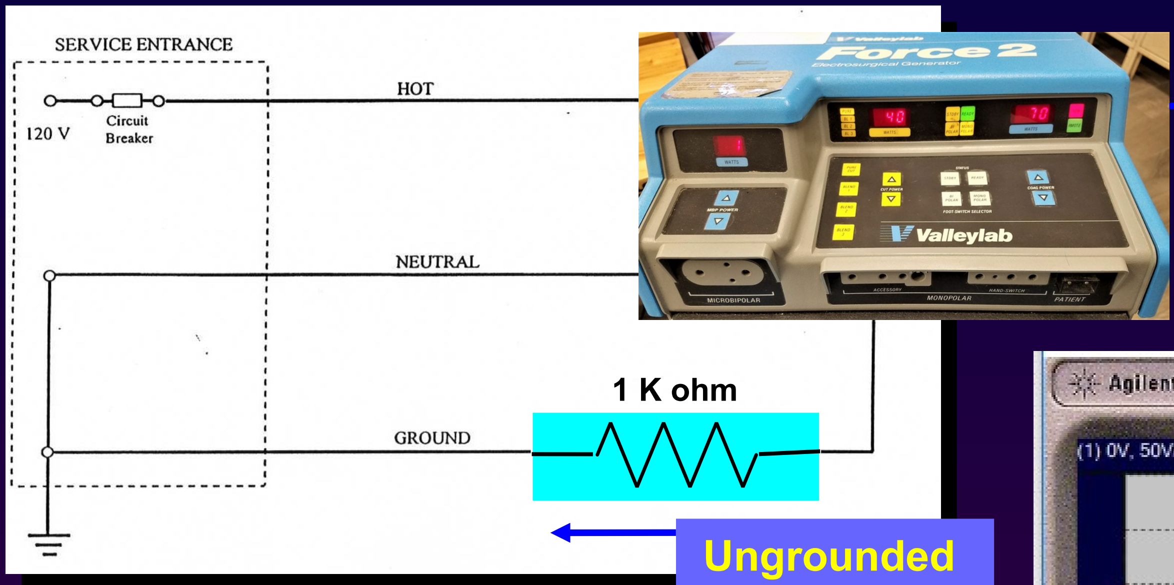




The physical proximity of conductors separated by an insulator creates a capacitance (and a conductive pathway) between these conductors.

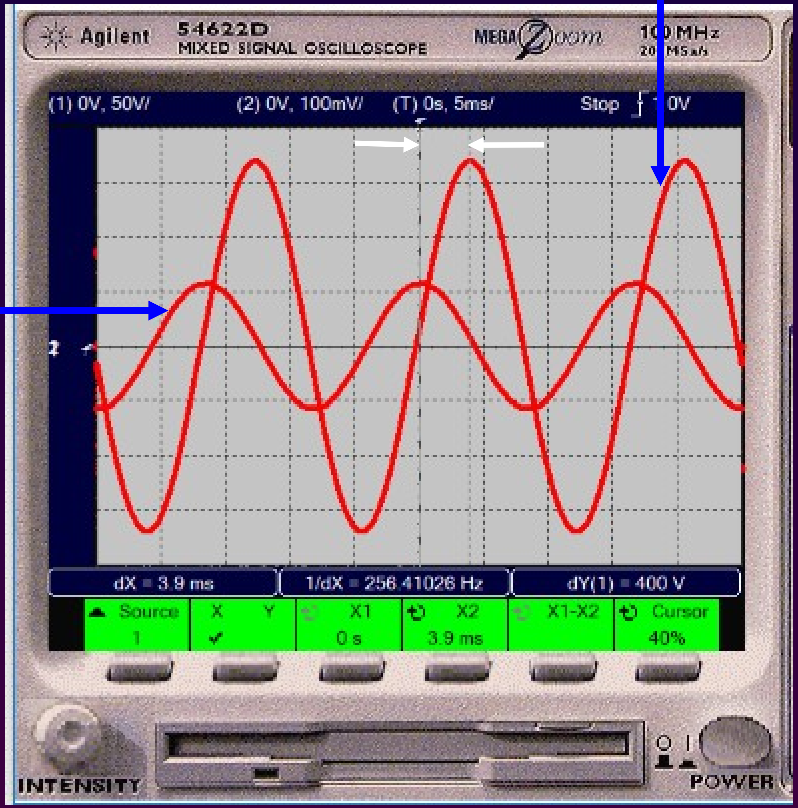


Example: R-C equivalent circuit responsible for leakage current from Valleylab ESU



Line voltage = 120 V_{rms}

Ungrounded leakage current = 81 uA_{rms}



from:

$$\frac{\theta}{360^\circ} = \frac{3.9ms}{16.66ms}$$

$$\theta = 84^\circ$$

$$Z_{Leakage} = \frac{V}{I} = \frac{120\angle 0^\circ V}{81\angle 84^\circ \mu A} = 1.48\angle -84^\circ Megohm$$

$$Z_{Leakage} = 155k - j1.47 Mohm$$

$$from: X_c = \frac{1}{2\pi fC},$$

$$C = 1.8nF$$

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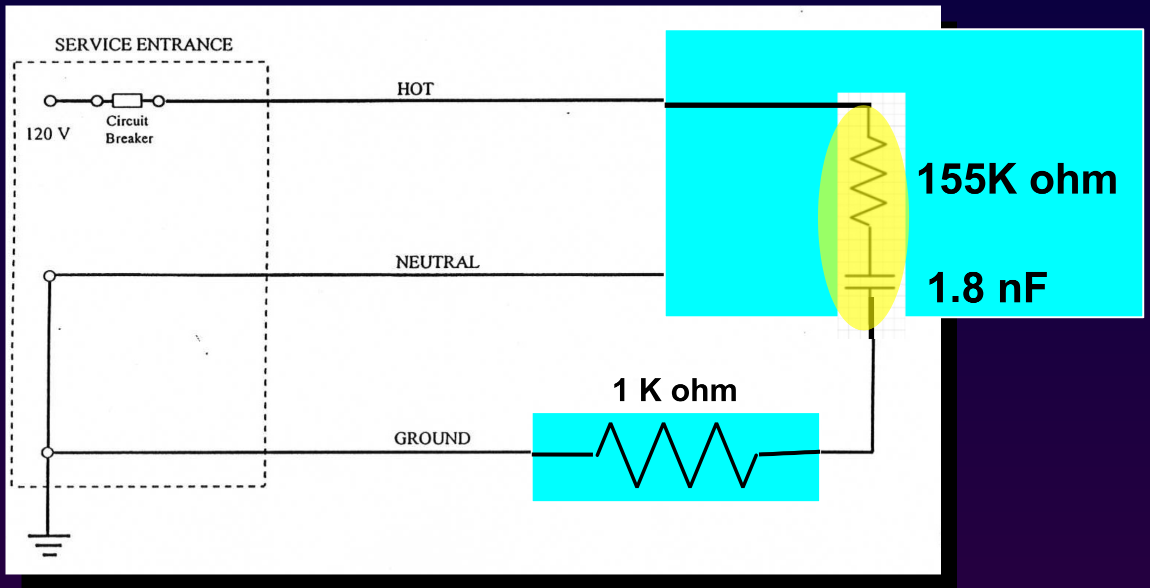

Electrically, this is what the ESU 'looks' like to your safety analyzer.

from:

$$\frac{\theta}{360^\circ} = \frac{3.9ms}{16.66ms}$$

$$\theta = 84^\circ$$

$$Z_{Leakage} = \frac{V}{I} = \frac{120\angle 0^\circ V}{81\angle 84^\circ \mu A} = 1.48\angle -84^\circ Megohm$$

$$Z_{Leakage} = 155k - j1.47Mohm$$

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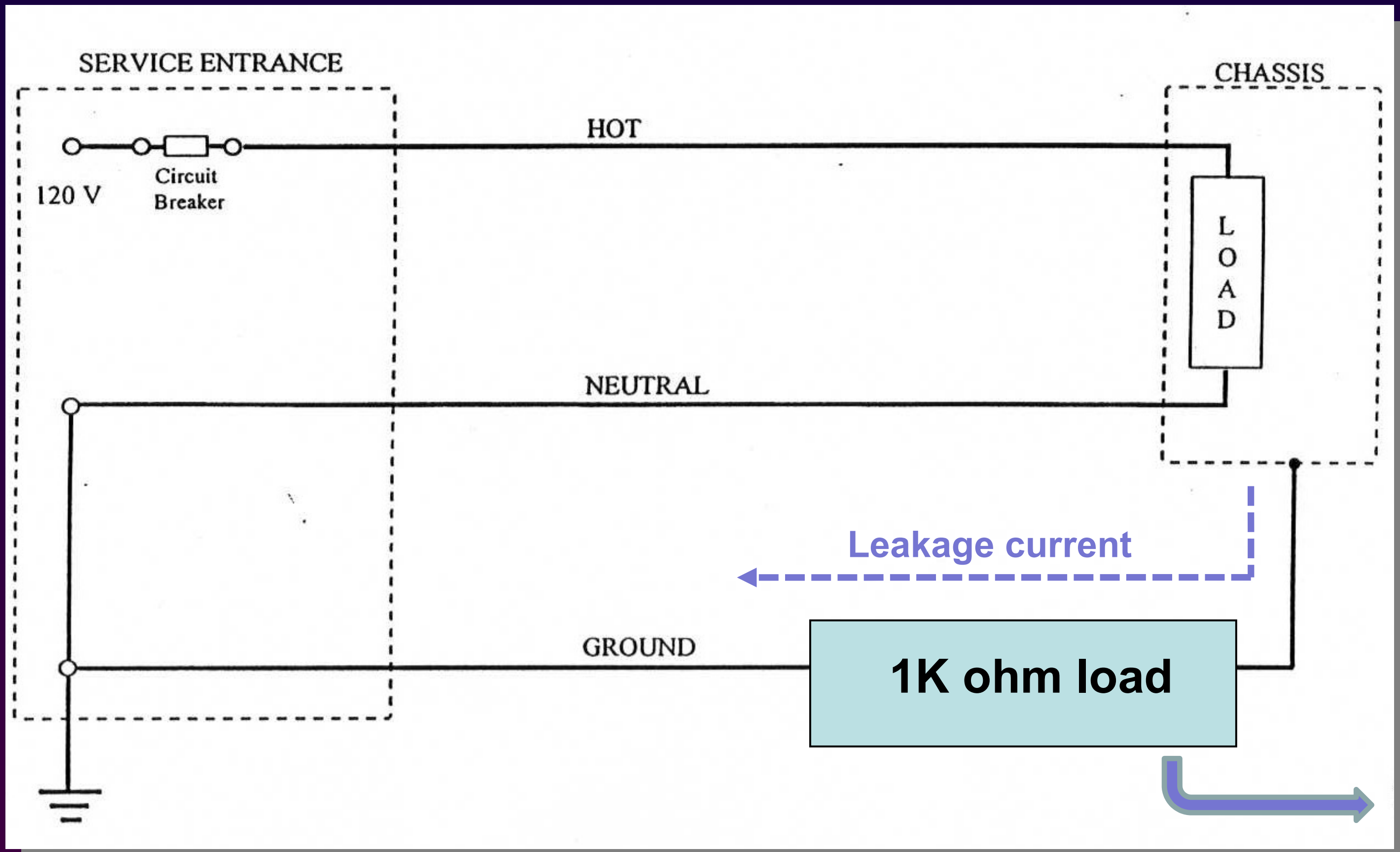
$$C = 1.8nF$$

Chassis Leakage Current Measurements:

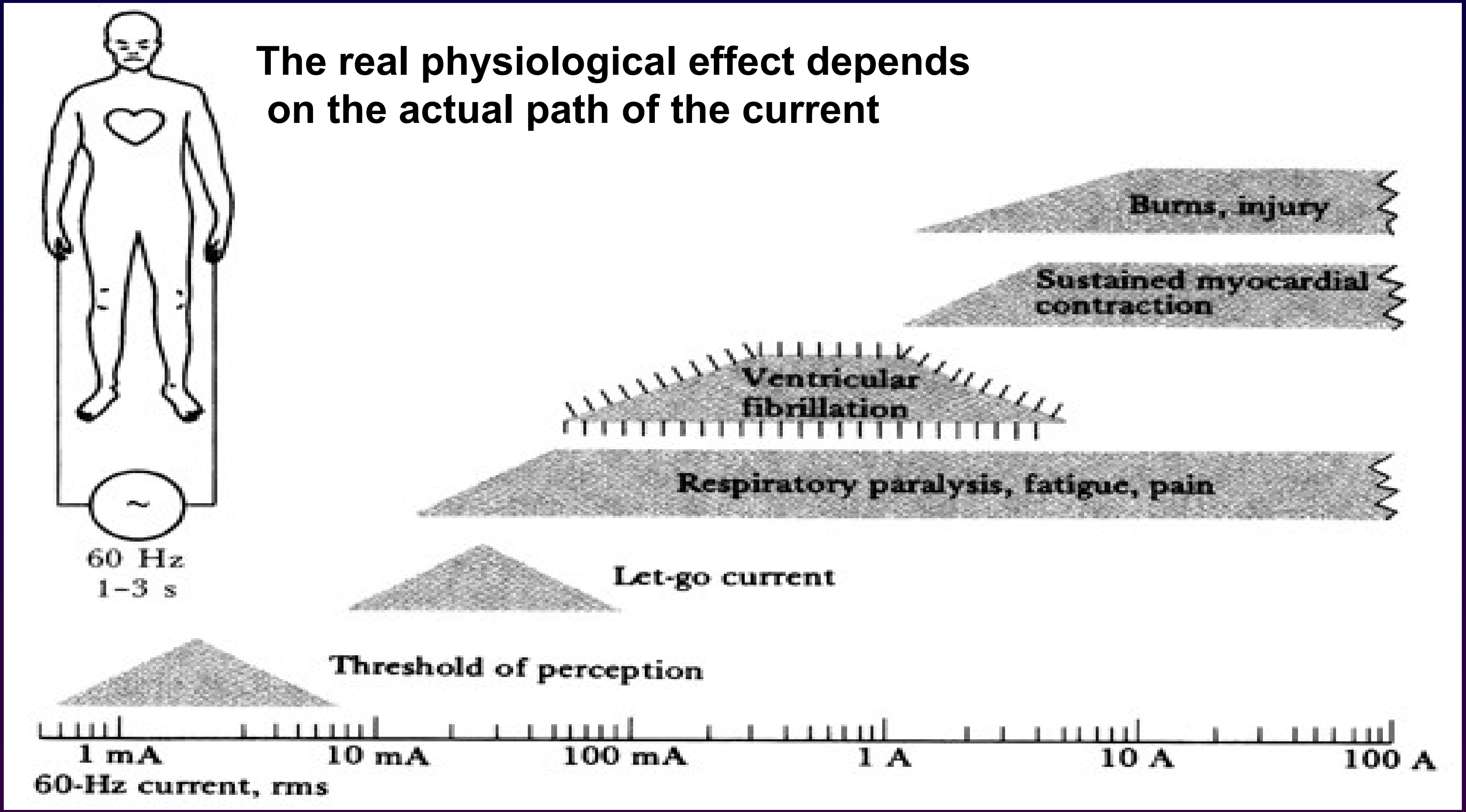
The standard AAMI / ANSI 1K ohm test load is inserted in series with the device's ground conductor. An AC RMS millivoltmeter connected across this load will read chassis leakage current in RMS microamperes.



Physiological Effects of Electricity

- For electricity to have an effect on the human body:
  - An electrical potential difference must be present
  - The individual must be part of the electrical circuit, i.e., a current must enter the body at one point and leave it at another.
- The physiological effects are due to current not voltage:
  - A high voltage applied over a large impedance (rough skin) may not cause much (any) damage
  - A low voltage applied over very small impedances (heart tissue) may produce large currents (and ventricular fibrillation)
- The magnitude of the current is simply the applied voltage divided by the total effective impedance.
- Electricity can have one of three physiological effects:
  - Electrical stimulation of excitable tissue (muscles, nerve)
  - Resistive heating of tissue
  - Electrical burns / tissue damage for direct current and high voltages

Physiological Effects of Electricity



From: W.H. Olson in J.G. Webster (1998). Medical Instrumentation : Application and Design, 3rd. ed.. Wiley. p. 624.

The Electrical Threshold of Perception and Medical Device Leakage Currents

Larry Fennigkoh, Ph.D., P.E., CCE
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Your electrical threshold of perception is the smallest level of electrical current passed between two body parts that you can just barely detect or feel. Below this threshold, electrical current may still be flowing into and out of your body – it is now just too small to be perceived.

Early electrical safety concerns for medical devices were based on such sub-threshold leakage currents being potentially fatal should they accidently be passed directly into a patient's heart via an external cardiac pacing catheter [1].

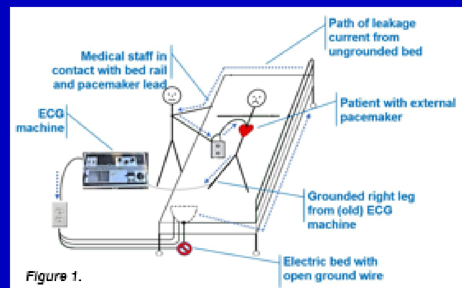


Figure 1.

As illustrated in Figure 1, the source of such currents could be from an ungrounded electric bed > passing unknowingly through the caregiver's hand in contact with the bed rail > through the pacing catheter and the patient's heart > then back to earth via an ECG right-leg ground electrode. In this scenario, the caregiver is completing the electric circuit but not feeling the leakage current from the electric bed because it is below their threshold of perception. With the heart being particularly sensitive to such direct electrical stimulation, fatal cardiac arrhythmias could be the result [2].

While these early and obsessive electrical safety concerns and risks were never shown to exist beyond the hypothetical, they did mobilize healthcare and effectively gave birth to clinical engineering and the healthcare technology management profession.

In getting perspective on what is required before either a patient or caregiver would receive a shock from a medical device, consider the five necessary and sufficient conditions noted in Figure 2 [3]. Since they are all independent events, the elimination of any one of them eliminates any shock risk completely. As such, and with the risk of electric shock to either patients or their caregivers now having been reduced to the near nonexistent, the testing and measurement of medical device leakage currents may be reduced or eliminated completely.

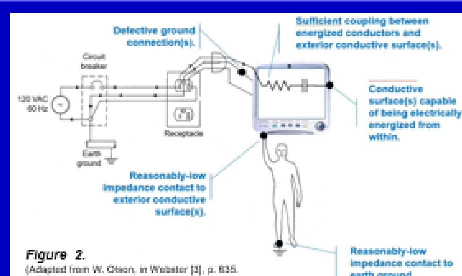
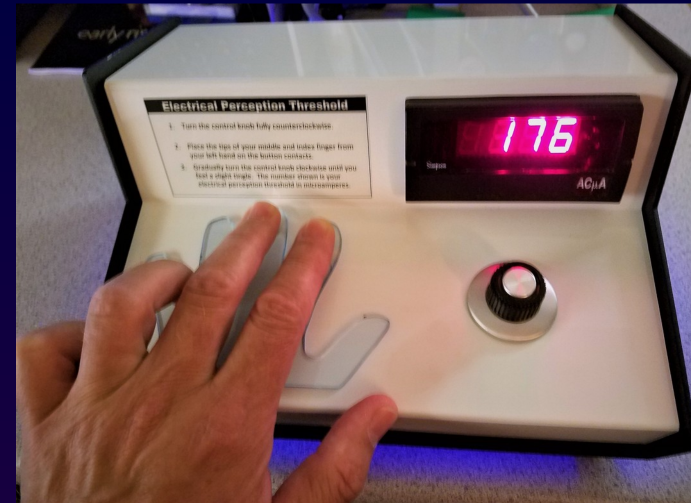


Figure 2.
(Adapted from W. Olson, in Webster [3], p. 635.

Determine your own threshold of perception to 60 Hz AC currents by following the instructions below. See and 'feel' what biomeds have been faithfully measuring for these past 50 years!

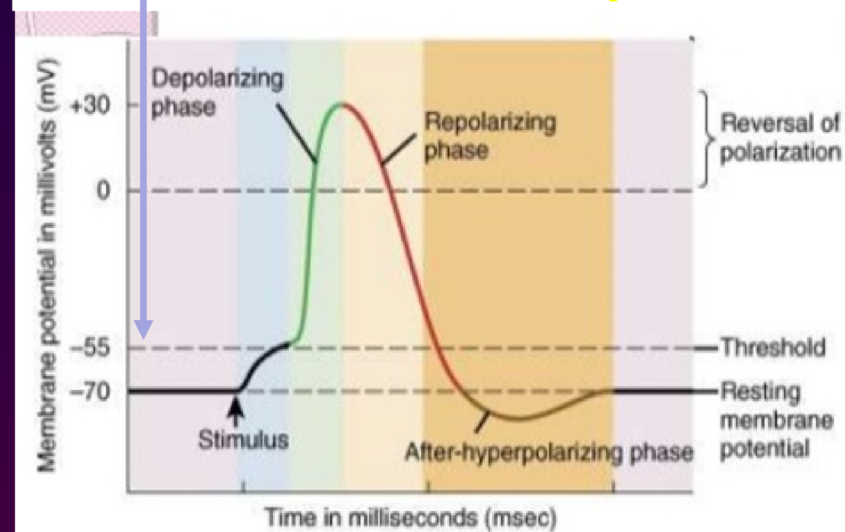
References:

1. G. Friedlander (1971). Electricity in hospitals: elimination of lethal hazards. IEEE Spectrum. September.
2. L. Geddes, L. Baker (1971). Response to passage of electric current through the body. J. of the Association for the Advancement of Medical Instrumentation. Vol 5, No.1, January-February.
3. J.G. Webster (1998). Medical Instrumentation & Design. 3rd ed., Wiley.



Perception occurs when nerve cell membrane potential threshold is

Nerve action potential



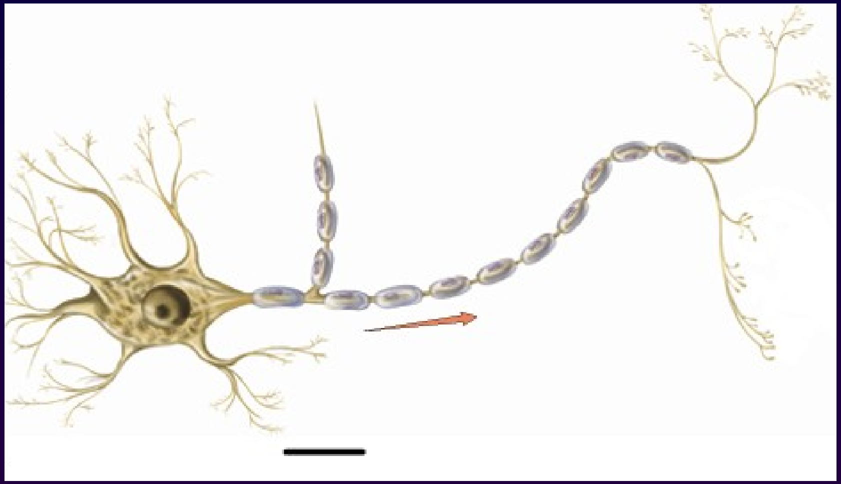
Neurons as electrical pulse generators

(or biological transducers)

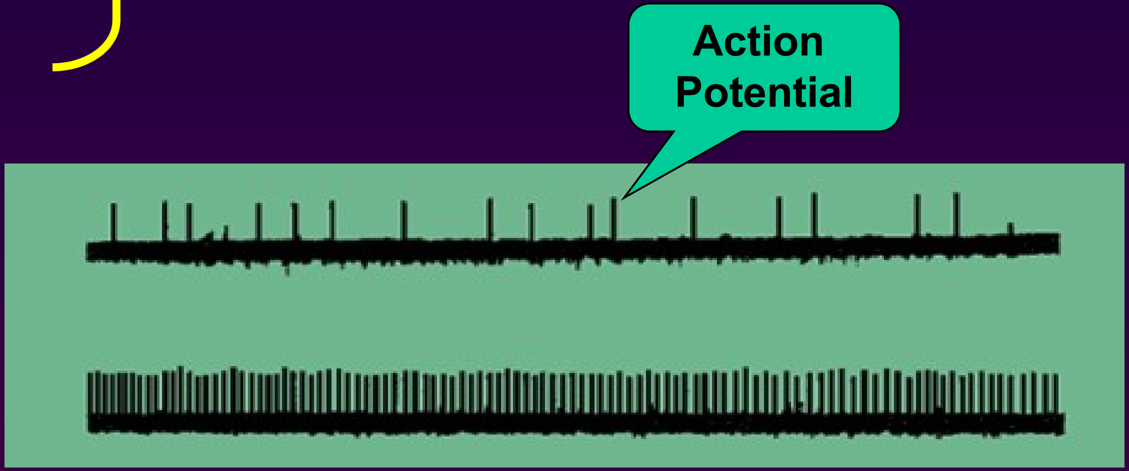
Inputs:

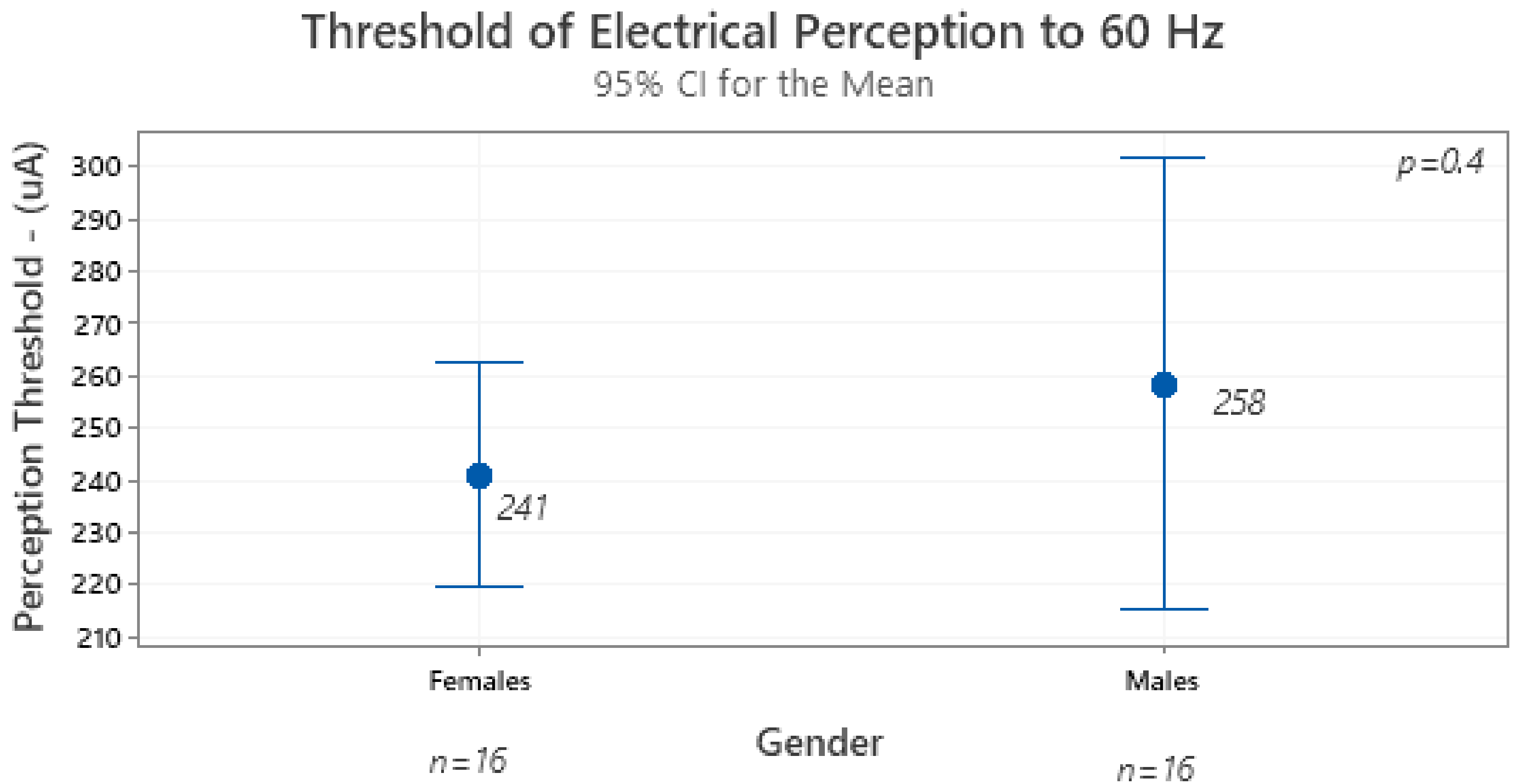
Stimuli:

- light
- pressure
  - stretch
  - force
  - vibration
- temperature
- electrical
- chemical
  - pH
  - O2
  - CO2
  - PaO_2
  - PcO_2



Outputs:

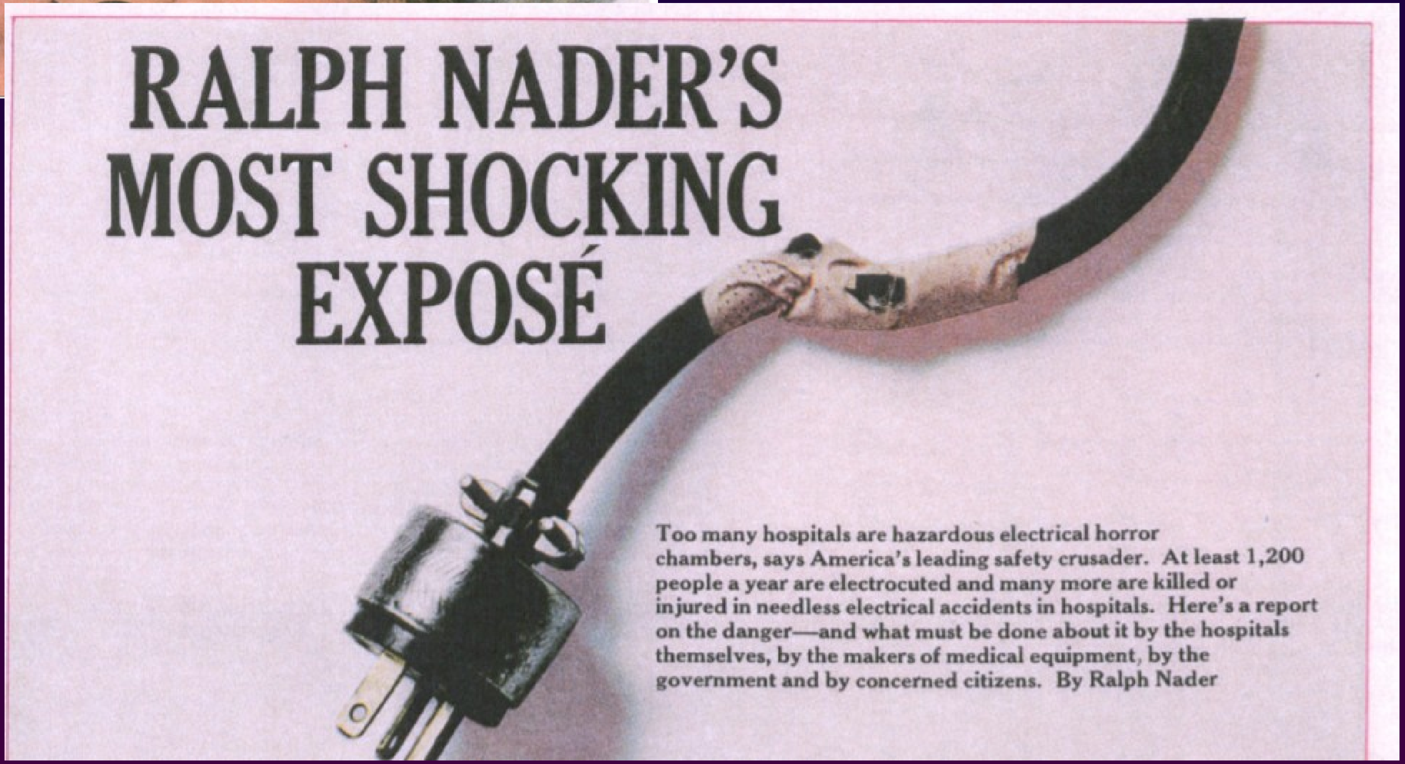



Threshold of Electrical Perception to 60 Hz
95% CI for the Mean
Perception Threshold - (uA)
300
290
280
270
260
250
240
230
220
210
p=0.4
241
258
Females
Males
Gender
n=16
n=16

LF:10/17


Electrical Perception Threshold
176

"... at the very least 1,200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures."



but, Ralph Nader wasn't the first . . .

Carl Walter, MD
1905-1992

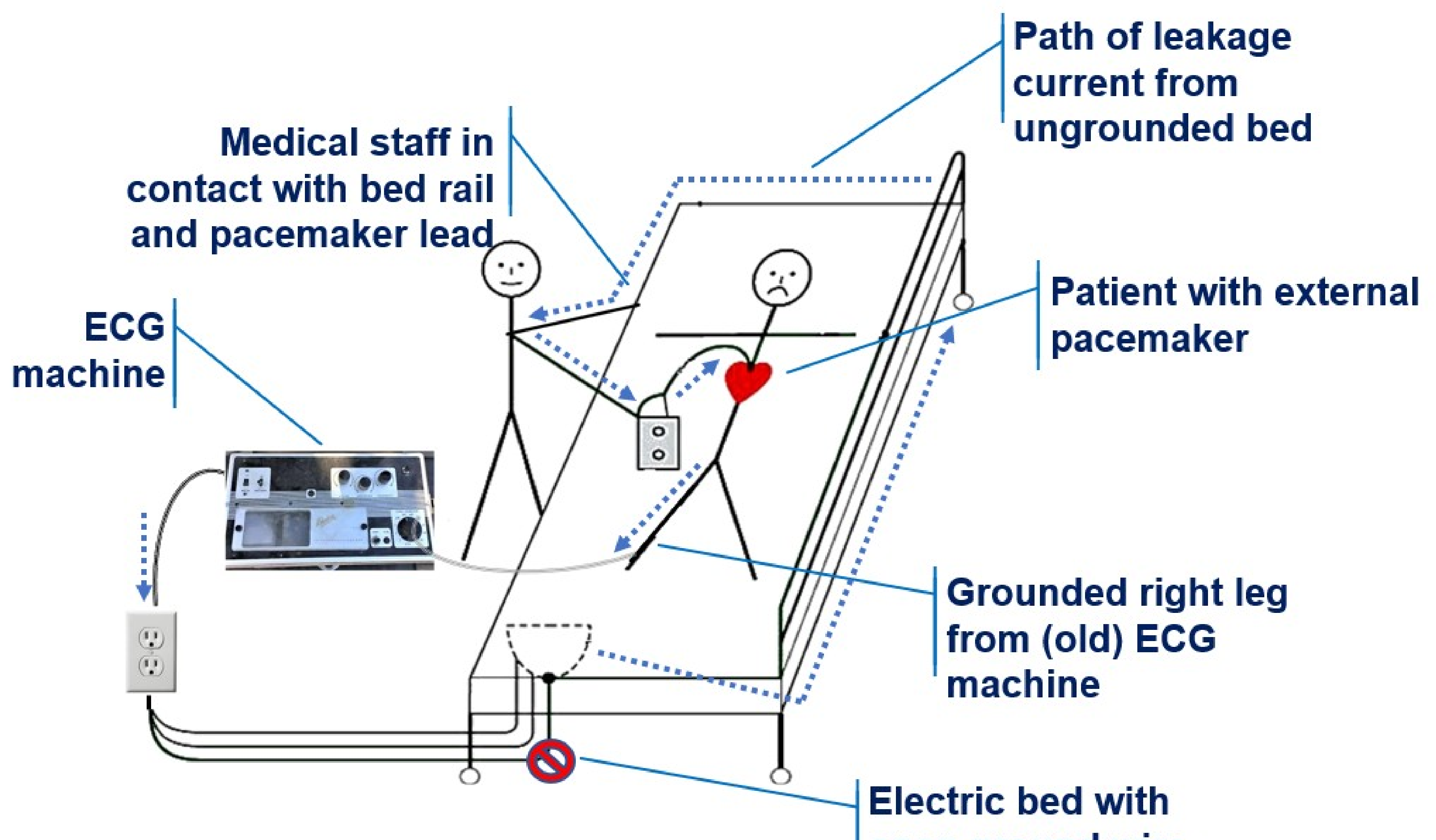
- *First claimed in 1968 that there were 1,200 misdiagnosed electrocutions annually in hospitals;*

- *"The issue of microshock electrocution, . . . its widespread publicity, the enactment of codes and laws to combat it, and the economic fortunes of the electrical transformer industry, are inextricably intertwined. Phony statistics have been used to promote the sales of safety equipment and manipulate the National Electric Code to require the use of specific products." (1973)*

Joel Nobel, MD
1934-2014

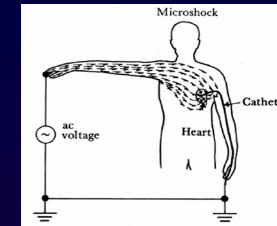
From M.G. Ridgway, The Great Debate on Electrical Safety – In Retrospect. In J. Dyro (ed.) Clinical Engineering Handbook, 1st. ed. pp. 281-283. 2004. Academic Press.

The worst-case scenario that started it all . . .



Adapted from: G. Friedlander (1971). Electricity in Hospitals: elimination of lethal hazards. IEEE Spectrum. September.

Early microshock and ventricular fibrillation threshold studies . . .



JOURNAL OF THE ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION
Vol. 5, No. 1, January-February 1971
Printed in U.S.A.

Response to passage of electric current through the body[1]

L. A. GEDDES AND L. E. BAKER
Baylor College of Medicine, Houston, Texas 77025

50 – 400 uA could fibrillate dog hearts

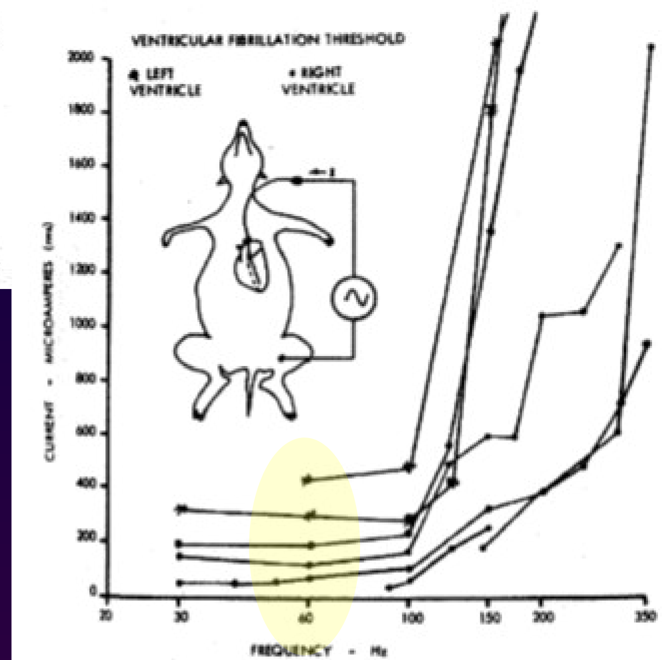


FIG. 5. Threshold for ventricular fibrillation with catheter-borne sinusoidal current applied for 5 sec for each trial.

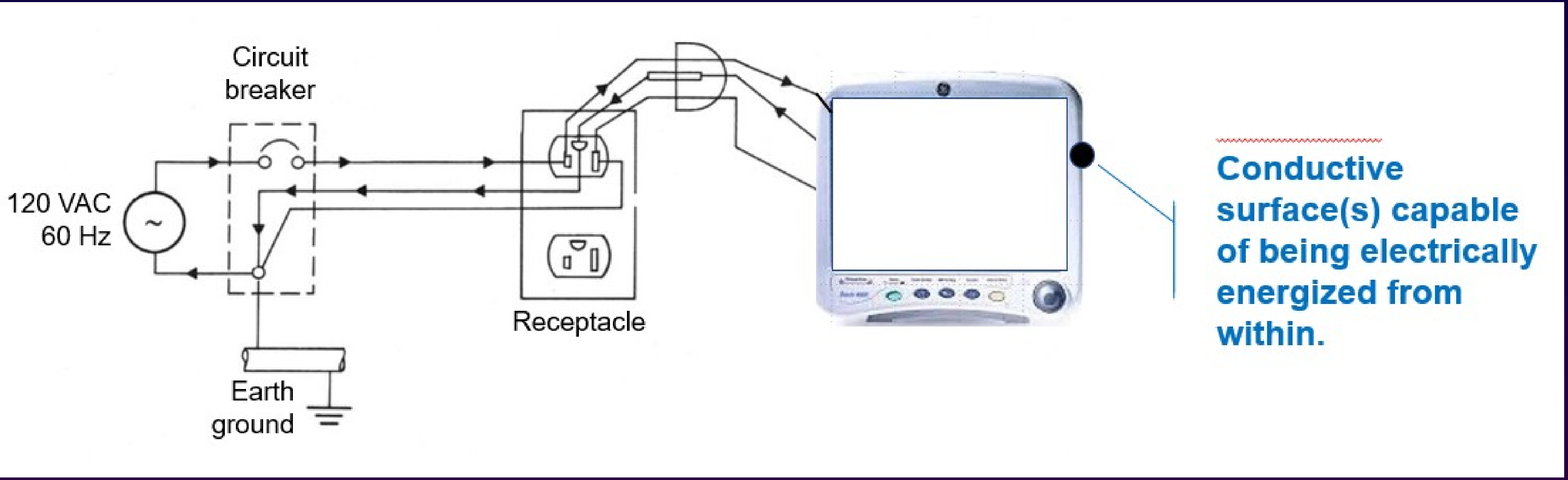
IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. BME-23, NO. 1, JANUARY 1976

60-Hz Ventricular Fibrillation and Pump Failure Thresholds Versus Electrode Area

O. Z. ROY, SENIOR MEMBER, IEEE, JOHN R. SCOTT, STUDENT MEMBER, IEEE, A

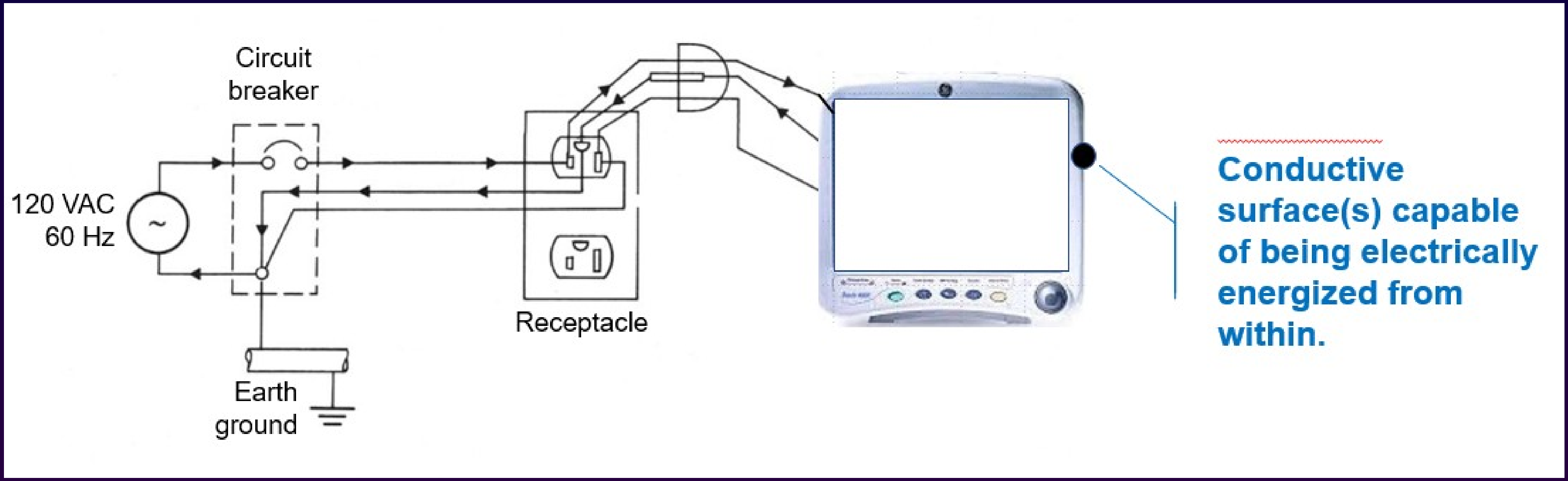
(6) Although the validity of the 10 μA leakage current as a safety standard has been questioned, it should not be discarded without a reasonable substitute. We have not had a rhythm disruption or fibrillation at currents of 10 μA or less. However, our results show that 200 to 300 μA is much too high and that levels of 50 to 60 μA can produce a significant number of fatalities.

Necessary events before a device can deliver a shock



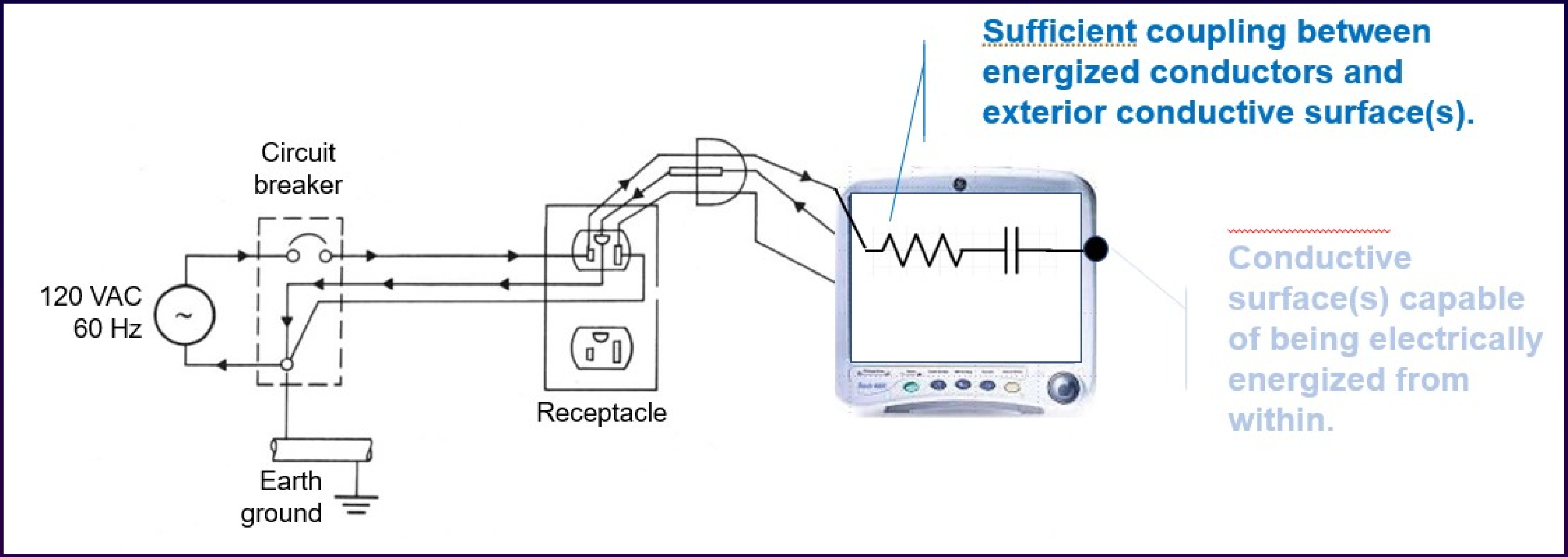
Adapted from W. Olson in Webster's Medical Instrumentation & Design (1998), 3ed., p. 635.

Necessary events before a device can deliver a shock

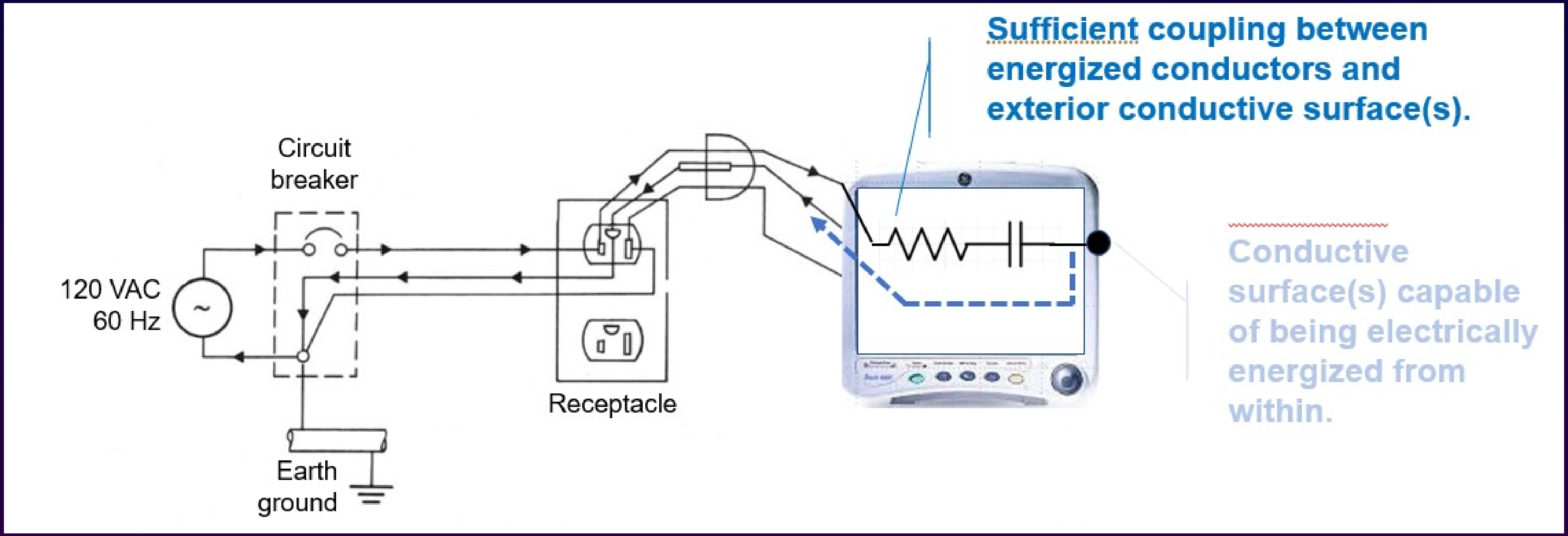


Where are the conductive surfaces on these devices ??

Necessary events before a device can deliver a shock

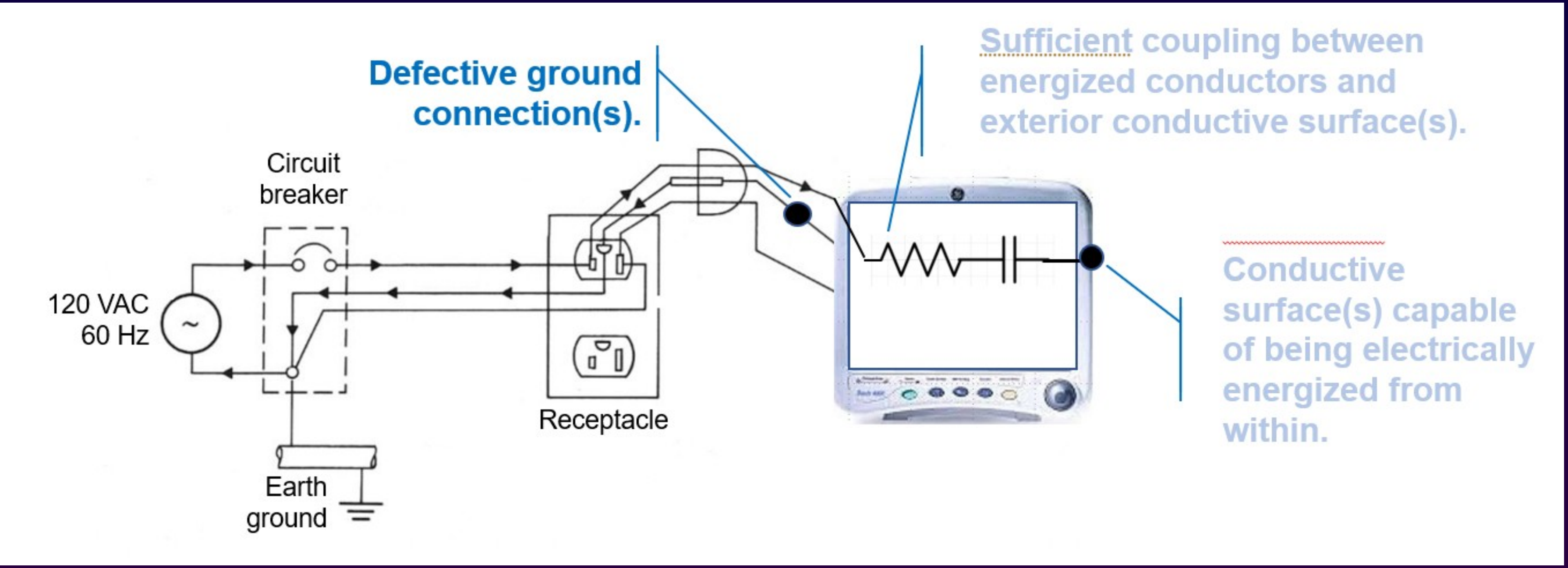


Necessary events before a device can deliver a shock

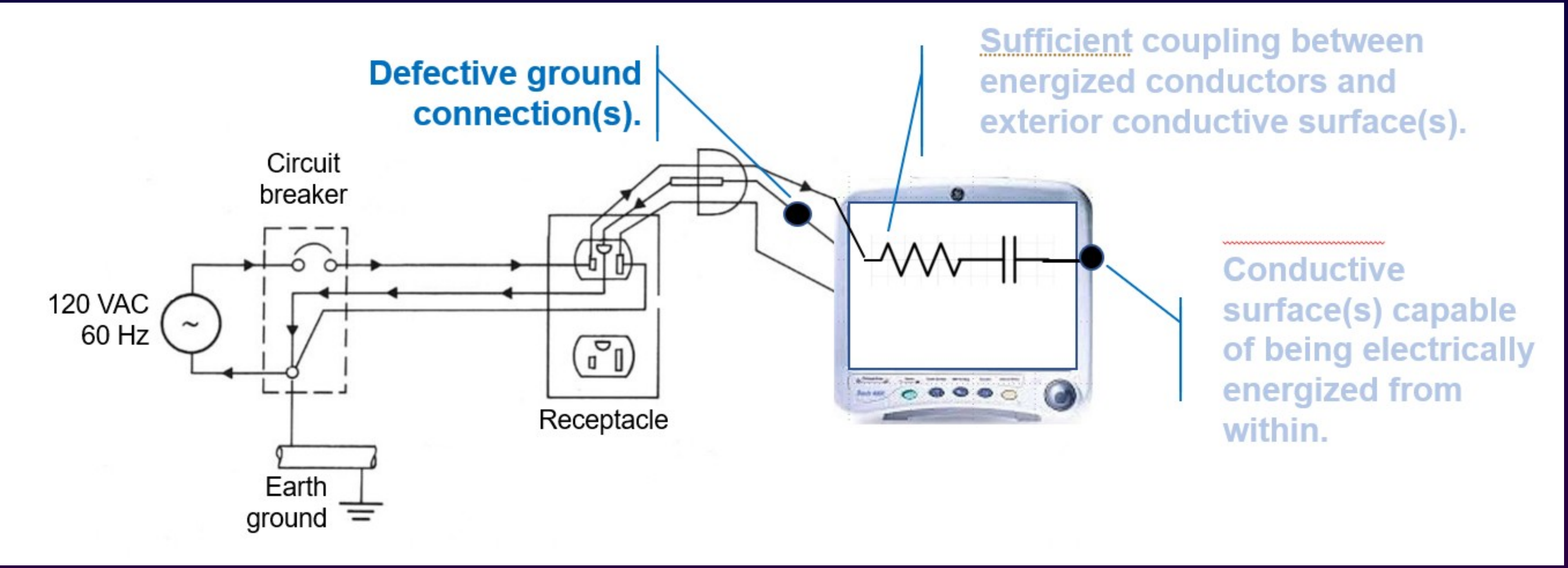


The magnitude of the device's leakage current is determined by the impedance between the hot side of the power line and any conductive pathways to earth ground.

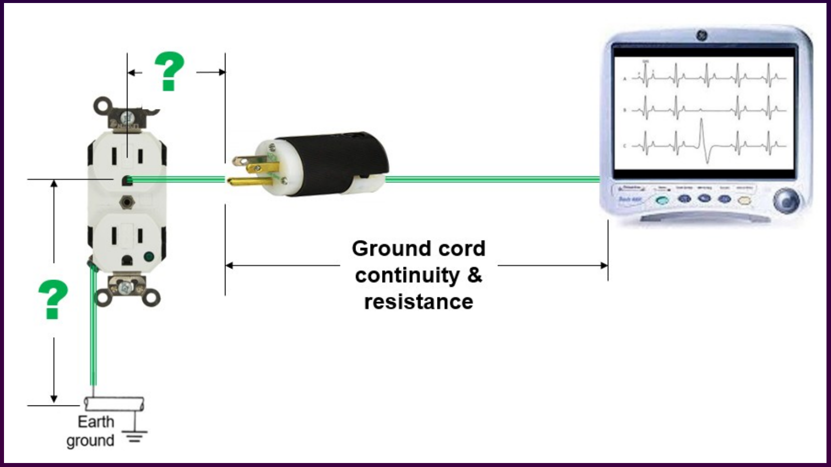
Necessary events before a device can deliver a shock



Necessary events before a device can deliver a shock



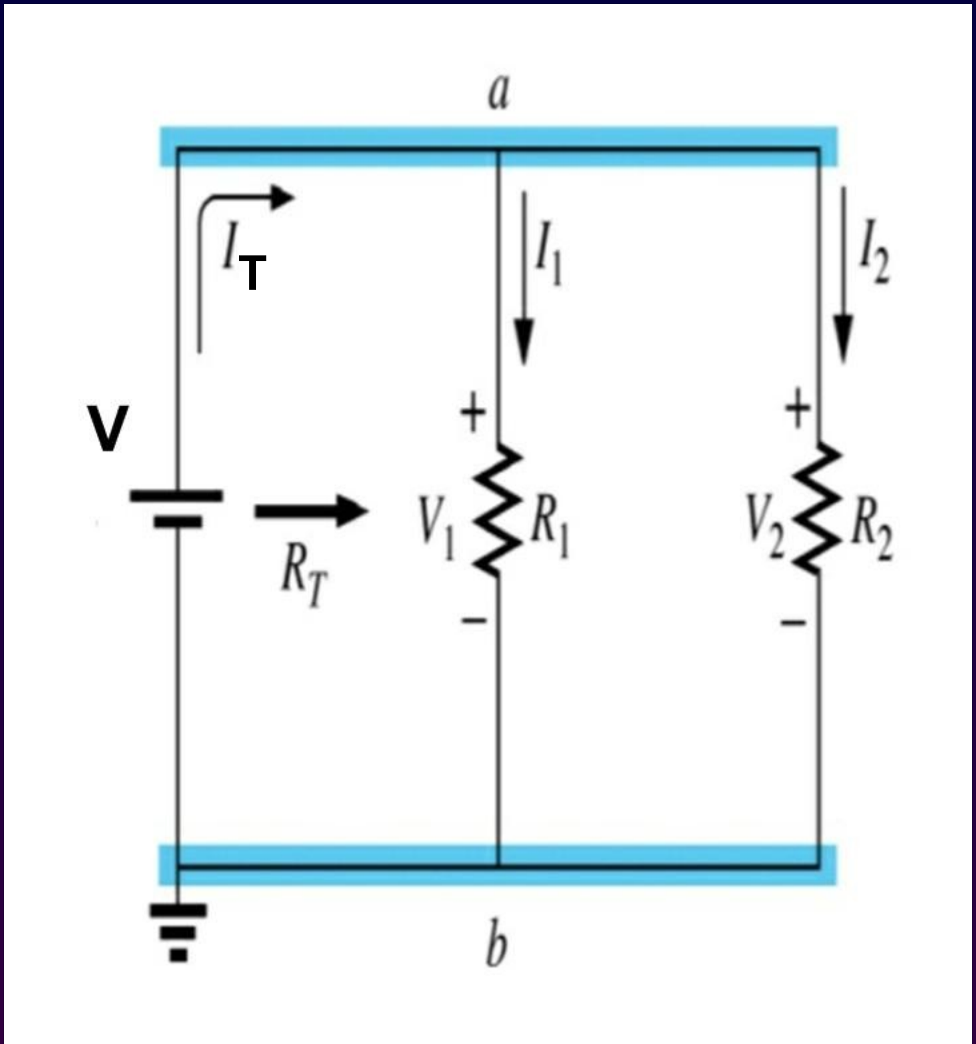
Verifying and ensuring the integrity of a device's ground connections are more important than knowing its leakage current.



Why low-resistance ground connections offer protection from device leakage currents:

Kirchhoff's Current Law:

- The algebraic sum of all of the currents entering and leaving a node must equal zero; or
- $I_T = I_1 + I_2$; or
- $I_T - I_1 - I_2 = 0$

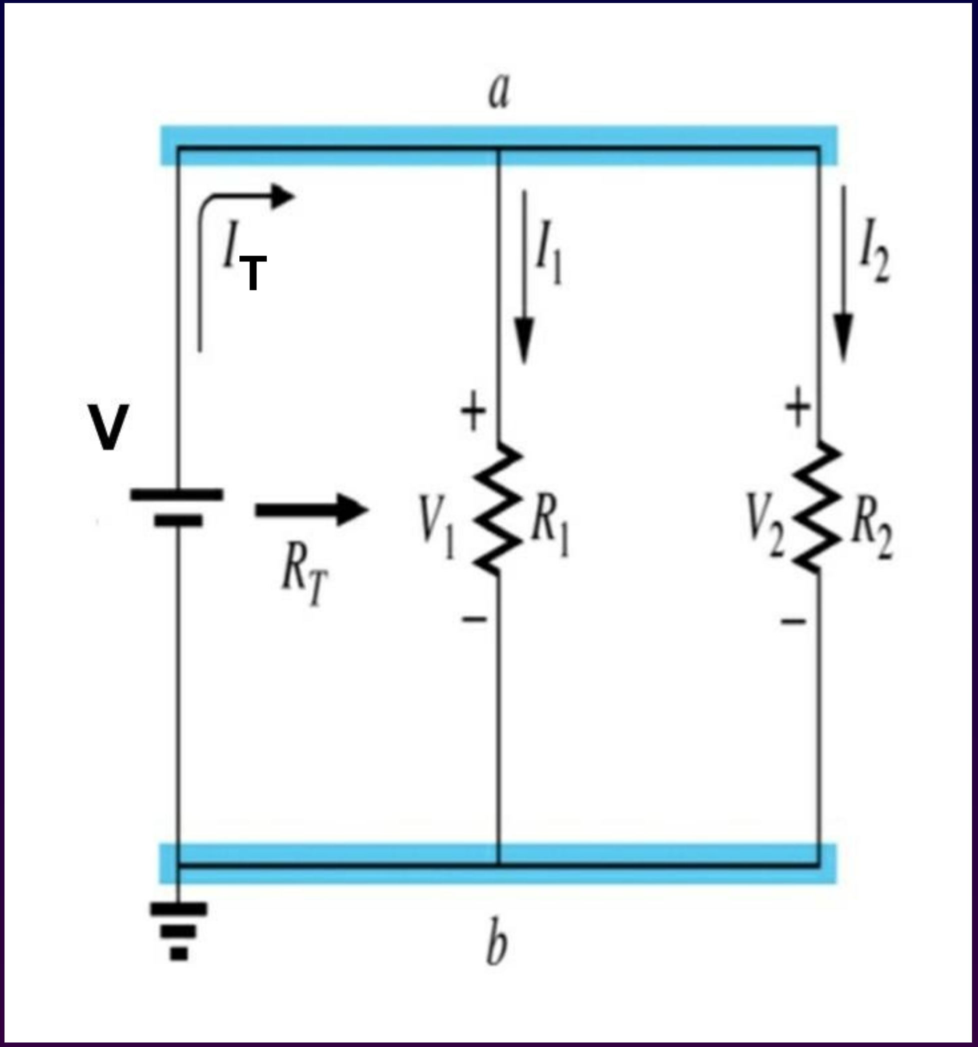


Current Divider Rule:

- Because the voltage stays the same in parallel circuits:

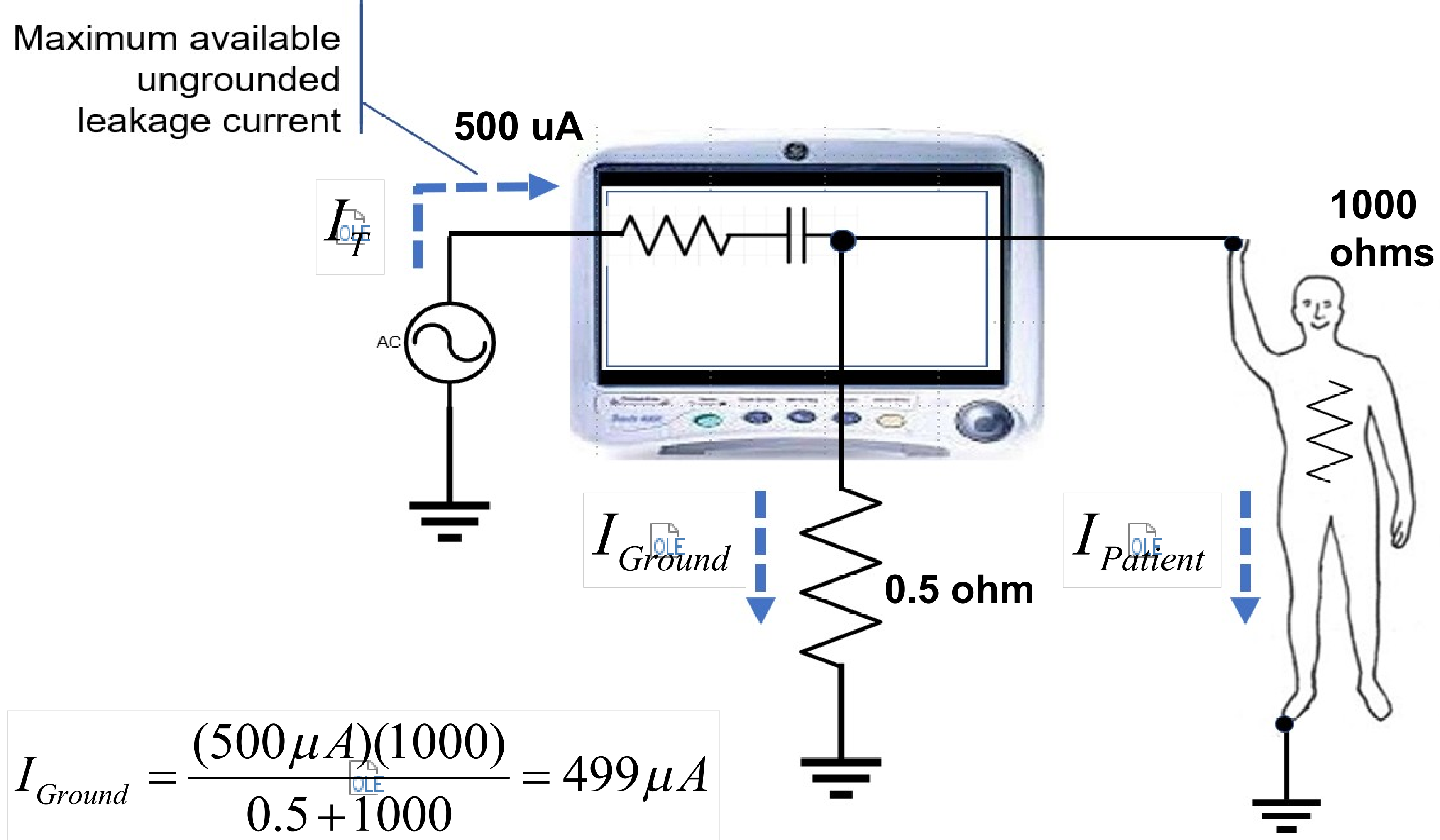
$$I_1 = \frac{I_T \cdot R_2}{R_1 + R_2}$$

$$I_2 = \frac{I_T \cdot R_1}{R_1 + R_2}$$



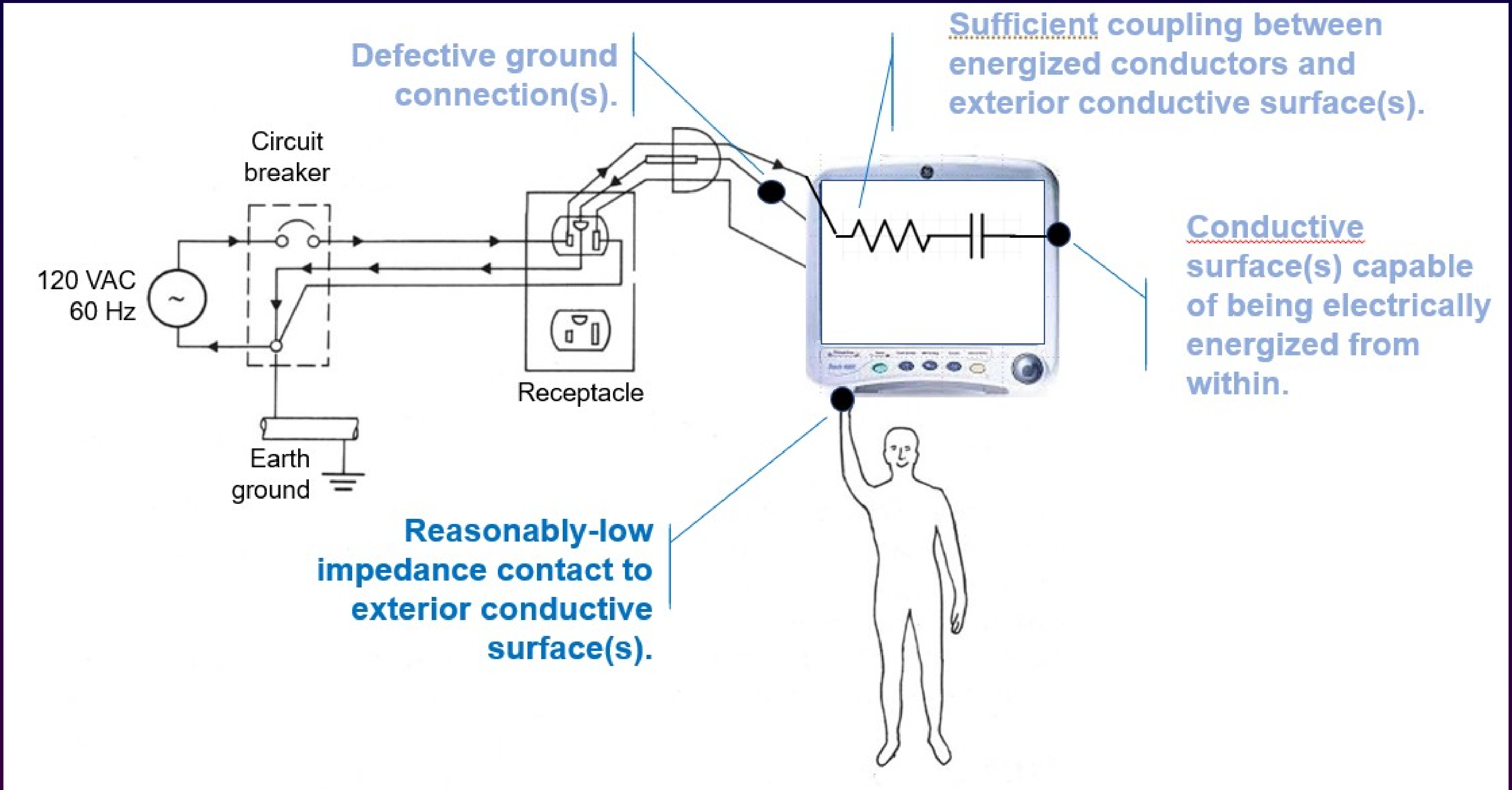
Which is why a very low resistance ground path is protective against either micro- or macroshock from leakage current . . .

for example:

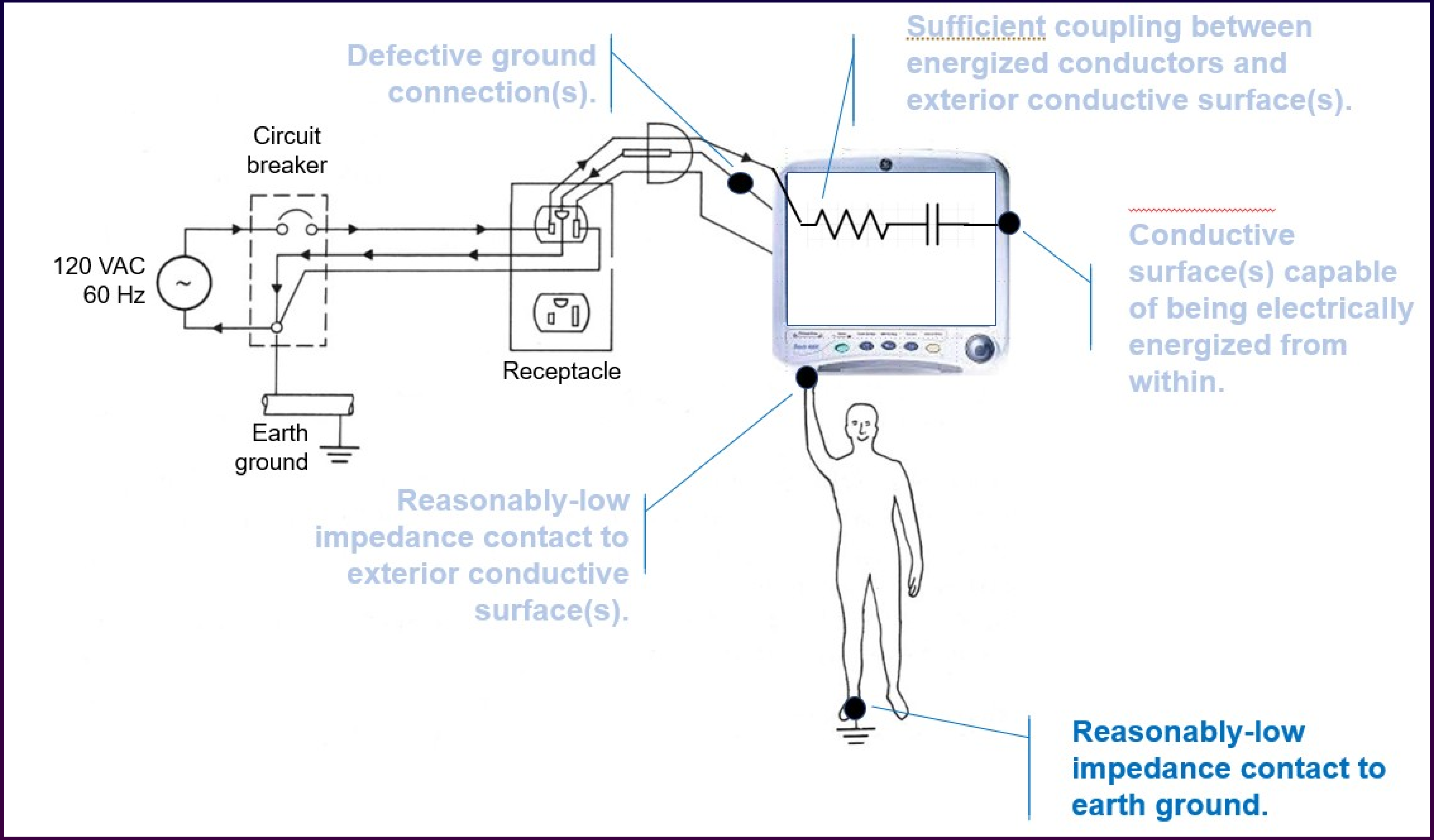


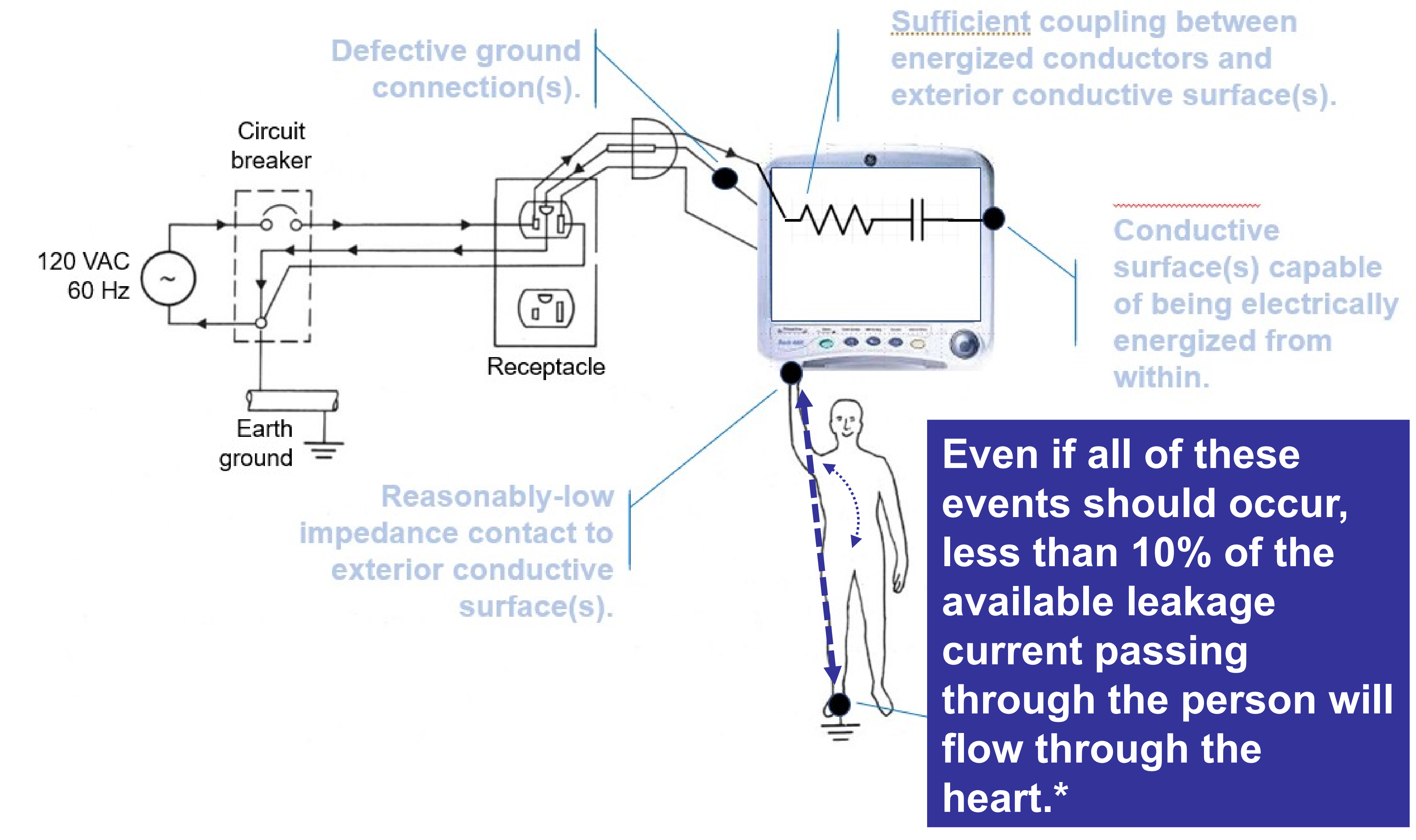
$$I_{Ground} = \frac{(500\mu A)(1000)}{0.5 + 1000} = 499\mu A$$

Necessary events before a device can deliver a shock



Necessary events before a device can deliver a shock





* From Freiberger, in J.P. Reilly (1998). Applied Bioelectricity: From electrical stimulation to electropathology. Springer. P. 41.

Necessary events before a device can deliver a shock

1. Exterior conductive surface

The
surfa
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2. Electrical coupling to conductive surface

The
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3. Defective ground connection

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4. Patient / user contact with device

Th
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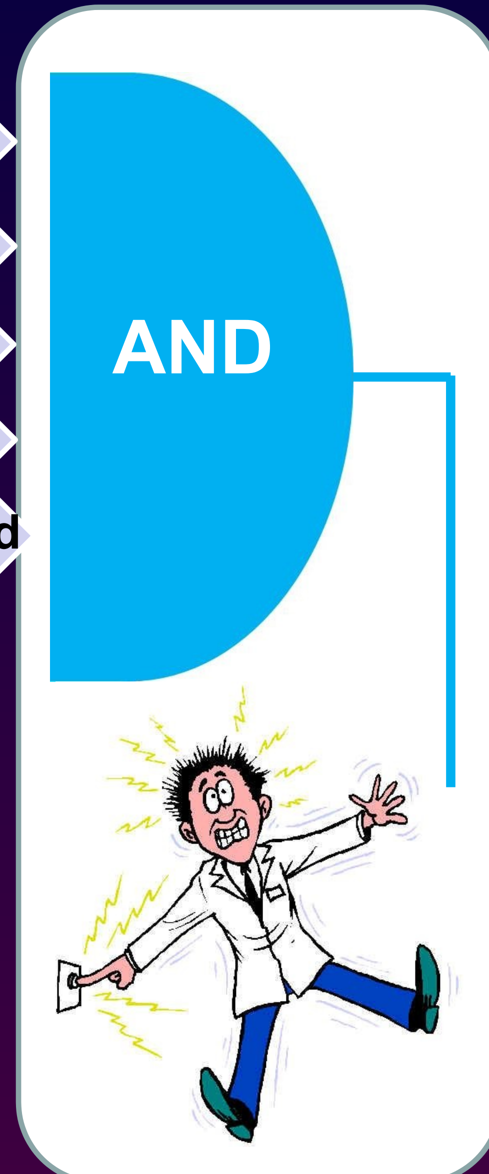
5. Patient / user contact with ground

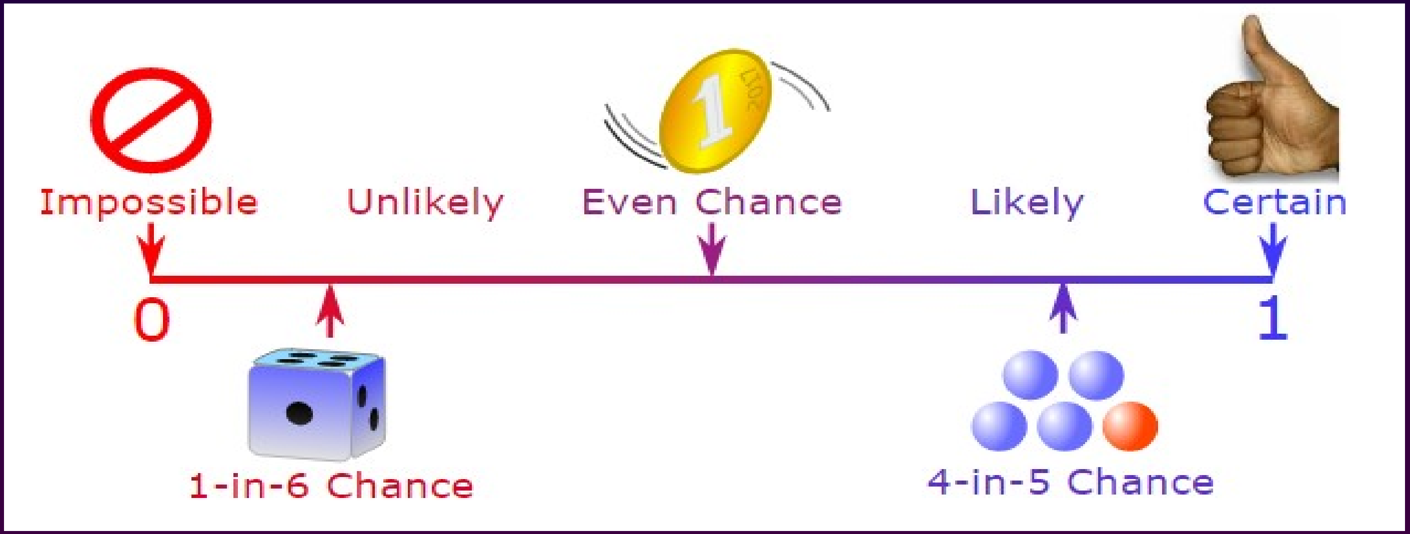
The patient or device user makes simultaneous and reasonably good (i.e., low impedance) contact with an electrical return path or ground.



Remember:

Probability . . . is a measure of the likelihood or chance that an event will occur. Numerically, it ranges from 0 to 1:

P = 0 **P = 0.5** **P = 1**



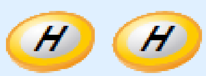
And,

the total or *compound probability* of independent events, e.g., a coin toss, is the product of their individual probabilities:

Example: Probability of 3 Heads in a Row

For each toss of a coin a "Head" has a probability of 0.5:

0.5



$0.5 \times 0.5 = 0.25$ $\left(\text{or } \frac{1}{2} \times \frac{1}{2} = \frac{1}{4}\right)$

$0.5 \times 0.5 \times 0.5 = 0.125$ $\left(\text{or } \frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} = \frac{1}{8}\right)$

And so the chance of getting 3 Heads in a row is **0.125**

The compound probability (chance) of all five of these independent events occurring and delivering either a micro- or macro shock is:

$$= p(1) \times p(2) \times p(3) \times p(4) \times p(5)$$

$$= \longrightarrow 0 \text{ !!}$$

And / or, eliminating the chance of any one of these five events from occurring also reduces the total probability of shock to zero.

Conclusions & Recommendations:

Continue to:

- **inspect AC line cords, strain reliefs, plug caps;**

Conclusions & Recommendations:

Continue to:

- inspect AC line cords, strain reliefs, plug caps;
- **measure and verify ground cord resistance.**

Conclusions & Recommendations:

Continue to:

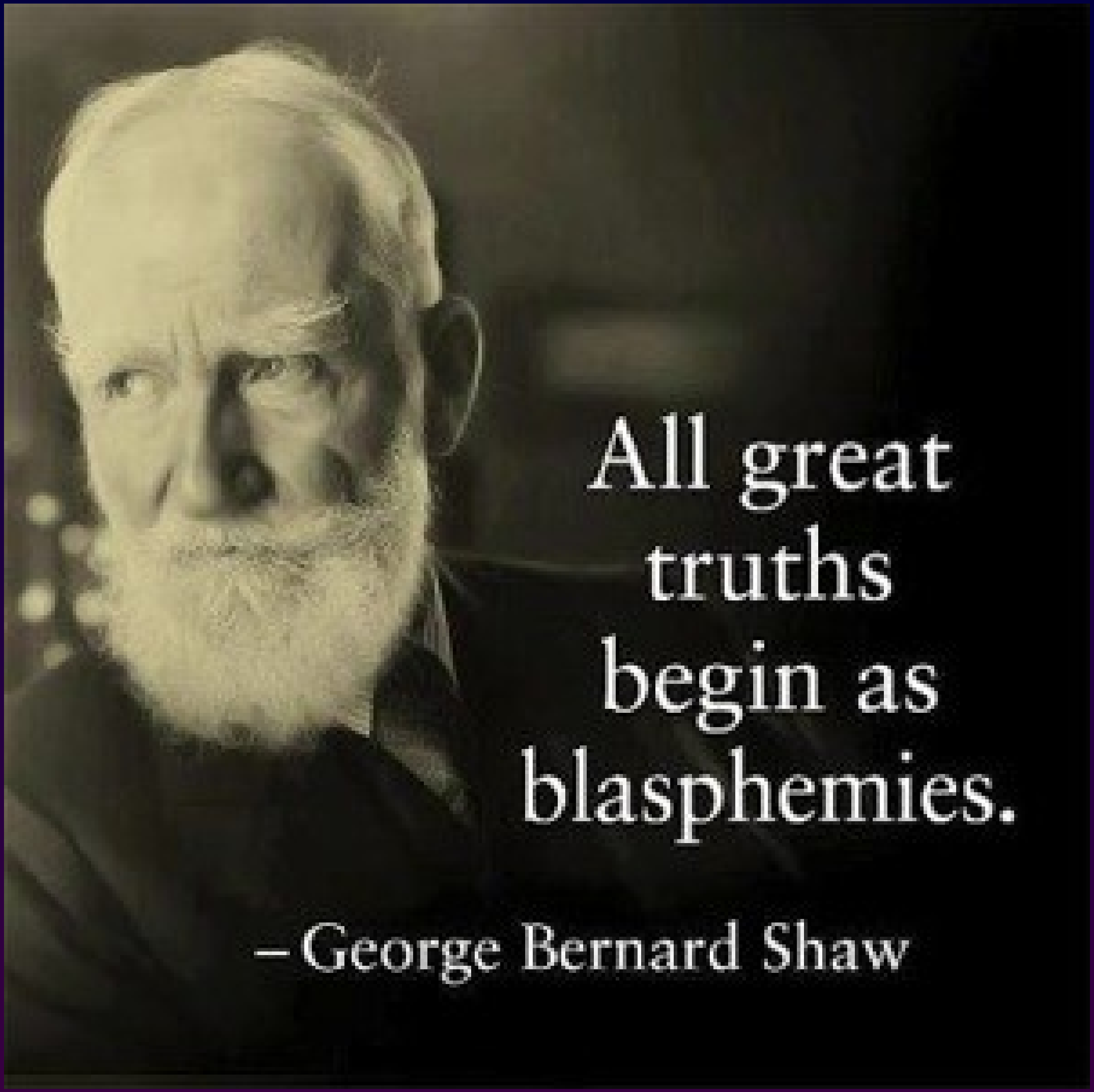
- inspect AC line cords, strain reliefs, plug caps;
- measure and verify ground cord resistance;
- **don’t forget outlet contact tension.**

Conclusions & Recommendations:

Continue to:

- inspect AC line cords, strain reliefs, plug caps;
- measure and verify ground cord resistance;
- don't forget outlet contact tension.

Other than during incoming inspections and after major repairs, eliminate the routine measurement and testing of device leakage currents.



Thanks & questions ?