

Pulppen[®] Pulp Vitality Tester

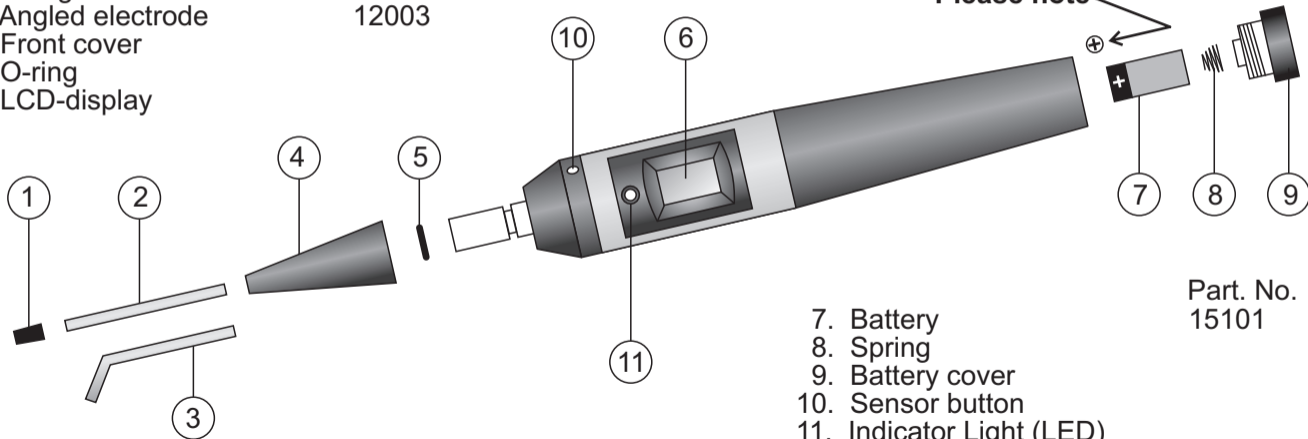


CE-marked according to
EC-Directive 93/42 (EEC)

FIG.1

- 1. Conductive rubber tip
- 2. Straight electrode
- 3. Angled electrode
- 4. Front cover
- 5. O-ring
- 6. LCD-display

Part. No.
15105
12002
12003



DP2000

Please note

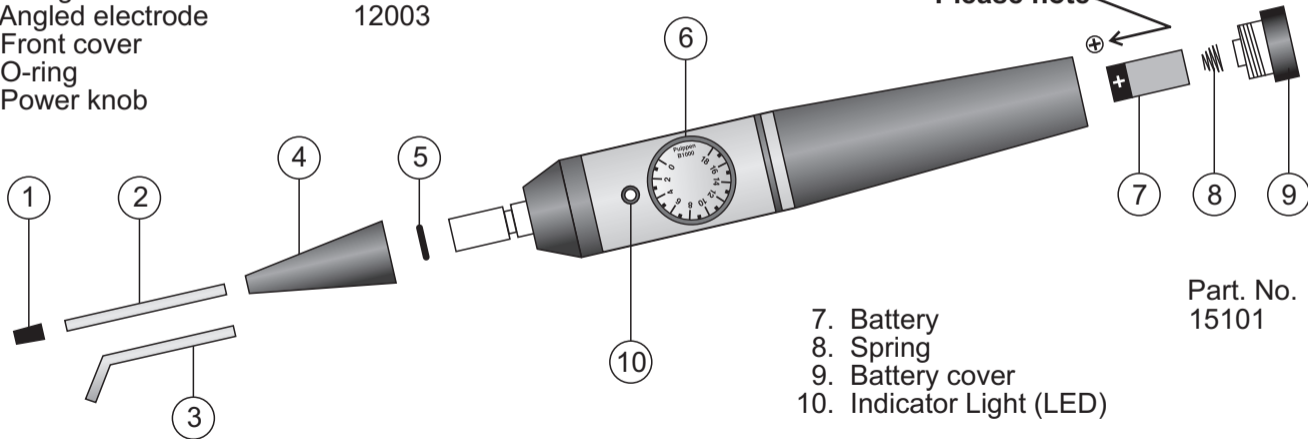
- 7. Battery
- 8. Spring
- 9. Battery cover
- 10. Sensor button
- 11. Indicator Light (LED)

Part. No.
15101

FIG. 2

- 1. Conductive rubber tip
- 2. Straight electrode
- 3. Angled electrode
- 4. Front cover
- 5. O-ring
- 6. Power knob

Part. No.
15105
12002
12003



B1000

- 7. Battery
- 8. Spring
- 9. Battery cover
- 10. Indicator Light (LED)

Part. No.
15101

INTRODUCTION

The Pulppen DP2000 & B1000 are highly accurate instruments destined for daily clinical use. With a long experience in electronics and engineering, Denlux has successfully incorporated the latest available technology in the PULPPEN, to provide you with a compact, lightweight, handheld instrument, capable of providing accurate, scientific readings.

After carefully reading these Instructions, you may want to refer to the Theory of operation section at the back of this booklet for additional information on the theory behind the function of the PULPPEN and other pulp vitality testers.

**WARNING!! NOT to be used by or on persons using a pacemaker
(concerns user and patient)**

INSTRUCTIONS FOR USE

Before first using the PULPPEN:

Unscrew the battery cover (9) at the rear end of the PULPPEN (see FIG. 1-9 & 2-9). Insert the battery as shown with the positive (+) end first. Remount the battery cover.

Next, insert a straight or angled electrode (FIG. 1- 2/ 3 & FIG. 2-2/3). Push the electrode into place until it can go no further. Make sure a conductive rubber tip (FIG. 1-1 & 2-1) is placed over the tip of the electrode.

USING THE PULPPEN

1. PULPPEN DP2000 - To switch ON the Pulppen DP2000 pulp vitality tester, place your index finger on the sensor button while holding the metal body at the same time. The LCD display will light up. The PULPPEN will stay on for as long as you maintain this grip. When you remove your index finger, the LCD will store the last reading taken for approximately 30 seconds and then switch OFF automatically.

PULPPEN B1000 - To switch ON the PULPPEN B1000 pulp vitality tester, grip the metal body of the instrument, making sure that your thumb, or a finger of the hand holding the PULPPEN, be placed across the black sensor/isolation band at the rear end of the metal body.

Once contact is made, the yellow LED (light emitting diode) will start flashing, indicating that the PULPPEN is ON. It will stay ON for as long as you maintain your grip on the instrument. Approximately 30 seconds after you release your grip, the PULPPEN will switch OFF automatically.

While using Pulppen B1000 always make sure to reset the power knob back to zero (Fig. 2-6) opposite the LED before taking another reading.

2. Before taking a reading, dry the tooth that is to be diagnosed. The tooth should always be kept dry so as to avoid leakage current which could give false readings!

3. A circuit must be established from the PULPPEN's tip, through the patient, your hand, and back to the metal body of the PULPPEN. There must be a contact between your hand and the metal body of the PULPPEN at all times. Likewise, make sure that there is a contact between your other hand and the patient in order to complete the circuit. To do so, place a moistened finger on the patient's lower lip.

If wearing latex examination gloves, an electrical circuit must be established between the patient and the PULPPEN. This can be done by using the Contact Kit (not shown here; Denlux part no. 15110): one end, a handle, is given to the patient to hold; the other, a metal ring, is fixed to the metal body of the PULPPEN. When using the Contact Kit, always moisten the examination gloves!

PULPPEN DP2000 - Place the PULPPEN tip on the dried target tooth's surface. While maintaining contact with the tooth, touch the sensor button (Fig. 1-10) with your index finger. The PULPPEN will emit electronic pulses through the tooth at a regularly increasing amplitude, as indicated by the pulsating yellow LED (light emitting diode).

PULPPEN B1000 - place the PULPPEN tip on the dried target tooth's surface. While maintaining contact with the tooth, using your index finger, turn the power knob (Fig. 2-6). The PULPPEN will emit electronic pulses sending them through the tooth. The power (amplitude) of the emission will increase as you turn the knob clockwise.

4. As soon as the patient feels a tingling sensation from the target tooth, and reacts according to an agreed hand signal, remove the PULPPEN tip from the tooth and read the tooth stimulus level indicator:

PULPPEN DP2000 - The LCD will display the stimulus level and will automatically reset itself at zero before taking a new measurement.

PULPPEN B1000 - The stimulus level can be read from the graduated face of the power knob, opposite the LED. Always reset this to zero before taking a new reading!

RESPONSE LEVELS

Normal tooth sensitivity levels are:

	DP2000	B1000
Incisors:	5-10	2-4
Bicuspid:	10-15	3-5
Molars:	15-20	4-6

PLEASE NOTE THAT response levels outside these ranges do not systematically indicate an abnormal condition. Individual cases can vary greatly. Readings correspond to current levels mentioned in the Theory of Operation section of this booklet. (Users of PULPPEN B1000 should use the above table to compare DP2000 values to B1000 ones).

5. Should the patient show no reaction to the stimuli, first check the following:

That the yellow LED is flashing, indicating that the PULPPEN is functioning correctly. Should there be a problem, then check your grip on the PULPPEN. Check that the tooth's surface is dry. To improve conductivity you can dip the tip of the electrode and the rubber cap into either hypochlority or saline solution.

PULPPEN B1000 - When you switch ON the PULPPEN, please make sure that your thumb, or a finger on the hand gripping the PULPPEN, is placed across the black sensor/isolation band at the rear end of the metal body.

PULPPEN B1000 - If the yellow LED is not flashing, then the battery is dead. If there is still no improvement after changing the battery, the PULPPEN must be sent for servicing.

PULPPEN DP2000 - The LCD acts as battery power indicator. If the numbers displayed flashes, then the battery must be changed. If there is no improvement after changing the battery, the PULPPEN needs servicing.

PLEASE NOTE It is not possible to make a reading while wearing examination gloves unless using the PULPPEN with a Contact Kit.

IMPORTANT NOTICE

The PULPPEN is a practical aid for the dentist. Should a patient NOT react to the stimuli, an X-ray image can support the diagnosis.

Healthy teeth have been known not to react to stimuli because of the interference due to moisture on the tooth's surface, the presence of the metal filling or calcification of pulpal tissue.

A patient may also feel stimulus although it is likely the pulpal nerve of the tooth is dead. It is **IMPORTANT TO DRY THE TARGET TOOTH PROPERLY!** In such a case, the stimulus can be felt in a neighbouring tooth, (the stimuli being emitted from the PULPPEN having been transmitted to another tooth by moisture).

IMPORTANT NOTICE

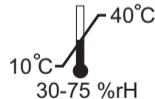
The Pulppen DP2000 and B1000 fulfils requirements in IEC/EN 60601-1-2 (EMC) concerning electromagnetic compatibility, however do not use the device in nearby presence of mobilphones, micro wave equipment etc.



The device and battery should not be disposed of as ordinary waste. Worn out device or battery may be returned to the distributor/manufacturer.

IPX3

BF



See last page

CARE & MAINTENANCE

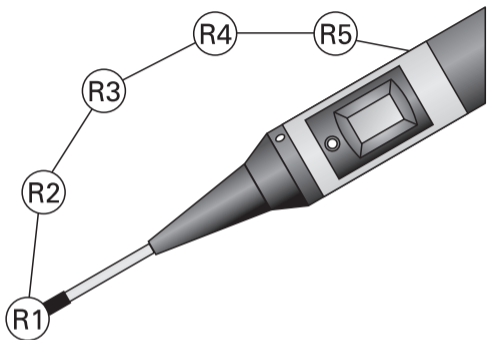
Hygiene: The PULPPEN handpiece may be disinfected using disinfectant wipes or sprays. Electrodes and rubber tips shall be sterilized prior to use. Electrodes and conductive rubber tips can be steam autoclaved 134 degree C for 5 minutes. Rubber tips will withstand 3-5 times autoclaving after which they shall be disposed of.

Battery life span: DO NOT place the PULPPEN on either a metal surface or on surface containing carbon (e.g., carbon paper). The PULPPEN could switch itself on resulting in a battery power loss. Always remove the battery if the PULPPEN is not to be used for extended periods of time; this improves the battery life span.

IMPORTANT: Always use the same type of battery (Denlux part no. 15101) as supplied with the PULPPEN. Use of other types of batteries can cause malfunction and/or incorrect readings.

Normal battery life span is 1-2 years by regular use (8 hours constant).

Servicing/Repair: In case of a malfunction, the PULPPEN should be returned to the distributor for repair by a qualified service engineer. DO NOT attempt to repair the PULPPEN yourself!



- R1 Resistance between tip and tooth
- R2 Body resistance of the patient (primarily the tooth)
- R3 Resistance between dentist and patient
- R4 Body resistance of dentist
- R5 Resistance between dentist and PULPPEN

THEORY OF OPERATION

The magnitude of the nervous system's reaction to an electrical stimulus depends on the current and not the voltage applied. This is no surprise, considering that a current is the number of electrons passed through a media per second, and that nerve pulses are bunches of electrons transmitted between nerve cells.

Pulp testers based on the voltage sources:

Ohm's law confirm the relationship between voltage, current and resistance: $\text{Voltage} = \text{Current} \times \text{Resistance}$. Most available pulptesters are based on the principle of the "ideal voltage source". Such a source has no zero internal resistance. This ensures that no matter how large the current being drawn from the source, the voltage remains constant, giving rise to a current defined by the resistance of the media to which the voltage is applied (the load).

However, since the current is the significant factor in nerve stimuli applications, it follows that it is necessary to know the resistance of the load, in order to establish the magnitude of the current. The load resistance when using the pulp tester comprises of several resistances in series, but the resistance of the tooth itself is by far the greatest.

Unfortunately this resistance is very poorly defined, and may vary over several orders of magnitude from patient to patient and from minute to minute, even with the same patient. And without knowledge of the resistance of the load, it is impossible to control the voltage in a way that implies the current of a certain magnitude through the load. Consequently, it is impossible to determine which level of stimuli the tooth responds to using a pulp tester based on voltage source, as the only thing that can be determined is whether a response occurs or not.

Pulptesters based on current sources:

All these difficulties are overcome with the PULPEN DP2000 or B1000, which are based on the principle of ideal current source. The ideal current source has an infinite internal resistance, ensuring that the voltage at the output of the current can vary freely depending on the resistance of the load connected, while the current being transferred remains constant.

Some manufacturers try to approach the concept of a true current source by using a high-voltage source, with a large resistance in series with the source. In most uncritical applications, this will give sufficiently accurate results, but with larger resistance loads, such as a very dry tooth, it will introduce the possibility of gross error.

MODE OF OPERATION

The current pulses emanating from the tip of the DP2000 and B1000 are 10 milli seconds long rectangular signals of negative polarity, repeated at 170 milli seconds intervals (i.e. 6 times per second). This gives the highest possible stimulus level and ensures that the patient feels no pain or electric shock, but only a light tingling sensation.

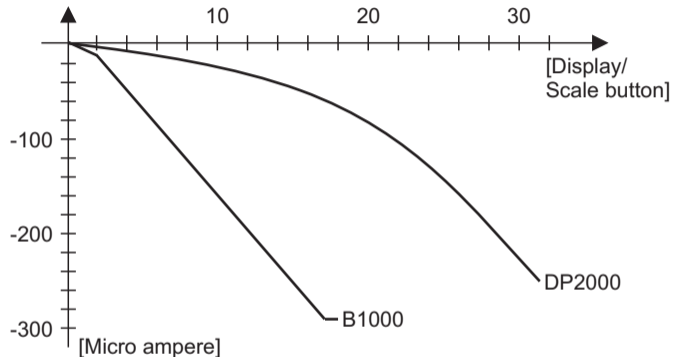
The amplitude of the pulses is increased automatically in an exponential fashion. The negative polarity corresponds to the natural polarity of nerve signals, and stimulates the pulp 2½ times as powerfull as an equivalent signal of positive polarity.

The PULPEN DP2000 and B1000 have a nearly ideal current source with, an internal resistance of the order

of hundreds of mega ohms. (It is almost impossible to make a current source better than this). This makes it possible to accurately register the exact stimulus level. The only problem is, that large load resistances require a very high driving voltage.

In the DP2000 and B1000 the driving voltage is 270 volts, which is sufficiently high. This enables the DP2000 and B1000 to supply up to 250 micro ampere per one mega ohm load. If the load has a resistance of more than a mega ohm, the maximum current delivered to the load will decrease and the ranges will be correct. In extreme cases molars may have a resistance of ten mega ohm, but as a living pulp will respond to a current of 20 micro ampere, the current level will remain accurate, and sufficiently high, to carry out the test.

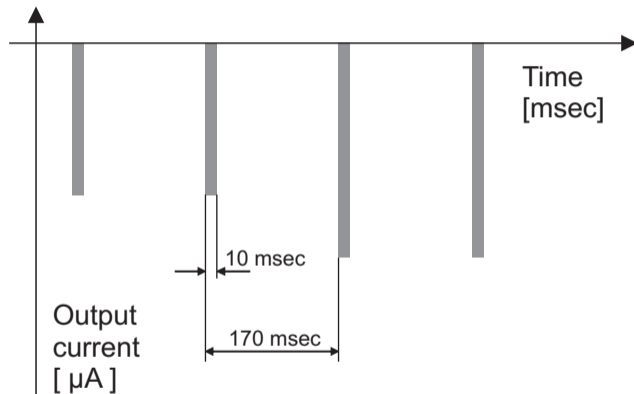
Output current vs. Pulppen reading



The graph and table show the relationship between the display readings and the output current level from the DP2000 and B1000. The figures are nominal values (tolerance +/- 2,5%).

Reading DP2000	Output current	Reading DP2000	Output current	Reading B1000	Output current
00	1.6	19	83.3	1	(0.4)
01	3.3	20	91.5	2	12
02	4.9	21	99.7	3	32
03	6.5	22	109.7	4	50
04	8.2	23	120.2	5	66
05	9.8	24	133.0	6	88
06	13.1	25	148.7	7	109
07	16.3	26	165.0	8	125
08	19.6	27	181.4	9	144
09	22.9	28	197.7	10	162
10	26.1	29	214.0	11	181
11	31.0	30	230.4	12	202
12	35.9	31	250.0	13	218
13	40.8	32	0.0	14	240
14	45.8			15	258
15	52.8			16	277
16	58.8			17	290
17	67.0			18	290
18	75.2				
	[μA]		[μA]		[μA]

Output current vs. Time



TECHNICAL DATA

Output current : 0-250 micro ampere
Driving voltage: 270 Volt
Pulse frequency: 6 Hz
Pulse shape: 10 milli second
Pulse polarity: Negative

DIMENSIONS

Length: 182 mm
Diameter: 25 mm
Weight : 120 g

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