

Modifié le

Reference: _____ Serial No.: _____
 Company name: _____ Product: _____

APPLICATION DOMAIN

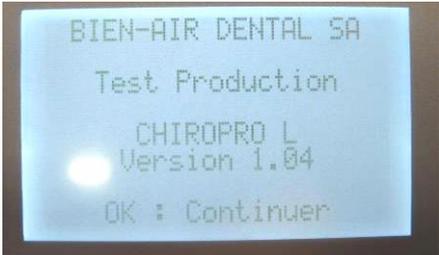
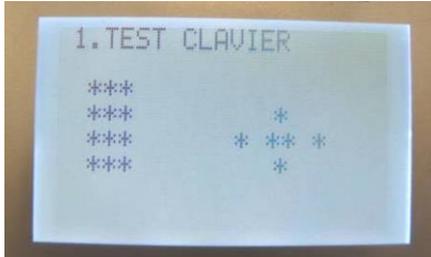
Checking protocol applies to the following devices:

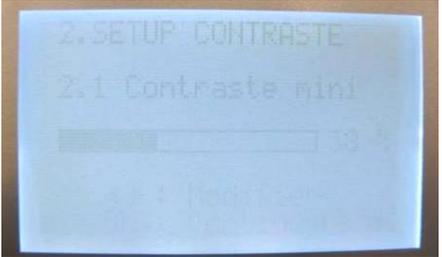
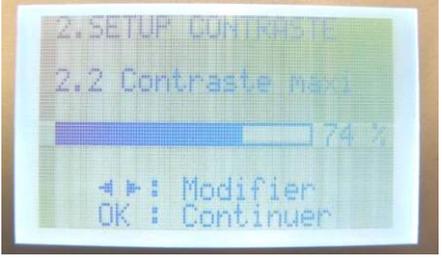
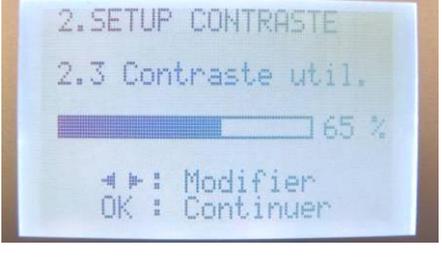
Chiropro L, reference 1600613
 Chiropro L, USA, reference 1600679
 Osseocare, référence 1600871

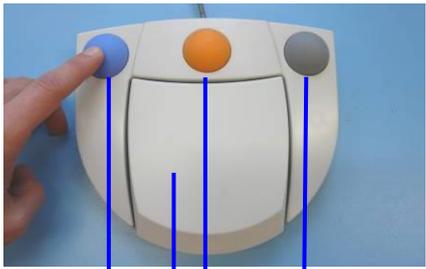
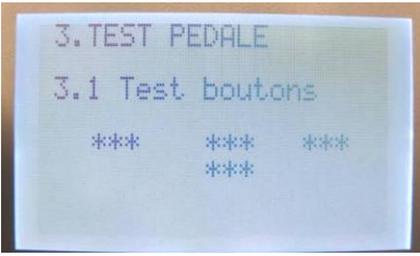
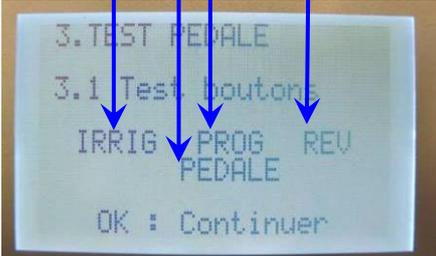
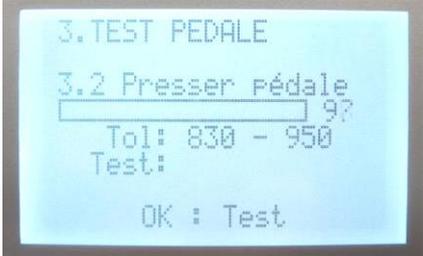
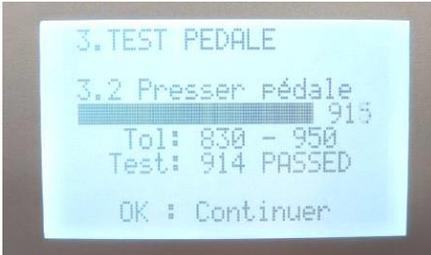
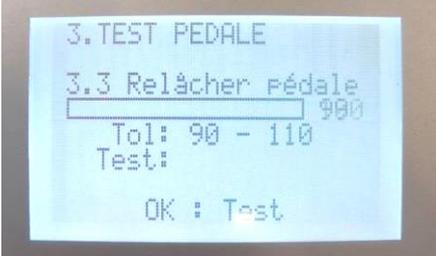
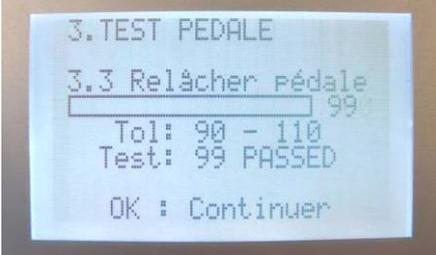
Chiropro, reference 1600724
 ProImplant, USA, reference 1600730
 Osseocare US, référence 1600872

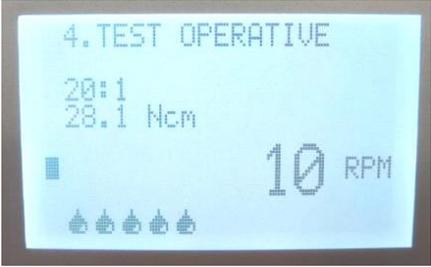
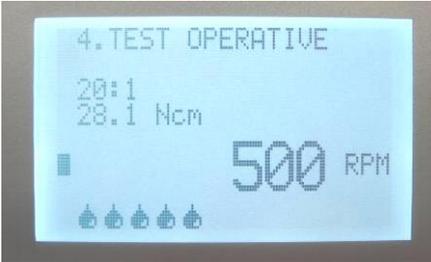
CHECKING CRITERIA

Y = Yes N = No

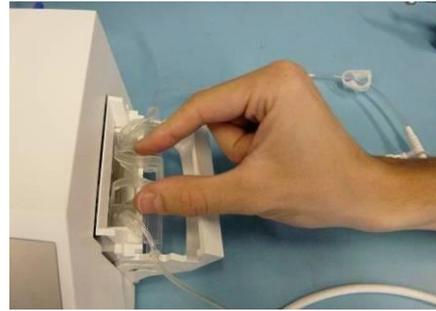
POS	PROCEDURE	Y	N
1.	<p>Connect the peripherals for the set to be tested to the control unit: The pedal, the cable and its motor and the CA20:1 L contra-angle. When the device is not accompanied by the peripherals, these must be replaced with new parts or parts in perfect condition for the duration of the test.</p> <p>Connect the Bien-Air device to the electricity supply using the appropriate cable.</p>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<p>Simultaneously:</p> <p>Press the 3 buttons    and switch on the device (switch to position - I -)</p> 	<input type="checkbox"/>	<input type="checkbox"/>
3.	<p>The screen shows:</p>  <p>CHIROPRO L, reference 1600613 Check the software version: must be 1.03 or above.</p> 	<input type="checkbox"/>	<input type="checkbox"/>
4.	<p>Press the Ok button to continue.</p> 	<input type="checkbox"/>	<input type="checkbox"/>
5.	<p>The screen should appear as follows:</p> 	<input type="checkbox"/>	<input type="checkbox"/>

6.	<p>Press the 4 buttons shown opposite in turn. Check the correspondence between the display on the screen and the button activated.</p>		<input type="checkbox"/>	<input type="checkbox"/>
7.	<p>As soon as all the buttons have been tested, the message "Ok: Continue" will appear.</p>		<input type="checkbox"/>	<input type="checkbox"/>
8.	<p>Press the Ok button to continue.</p>		<input type="checkbox"/>	<input type="checkbox"/>
9.	<p>Adjust the screen contrast using the following buttons:  . Set the contrast to the minimum that still allows the information displayed to be read. Confirm with Ok to continue.</p>		<input type="checkbox"/>	<input type="checkbox"/>
10.	<p>Now set the contrast to the maximum using the following buttons:  . Confirm with Ok to continue.</p>		<input type="checkbox"/>	<input type="checkbox"/>
11.	<p>Set the optimum contrast using the following buttons:  . Confirm with Ok to continue</p>		<input type="checkbox"/>	<input type="checkbox"/>

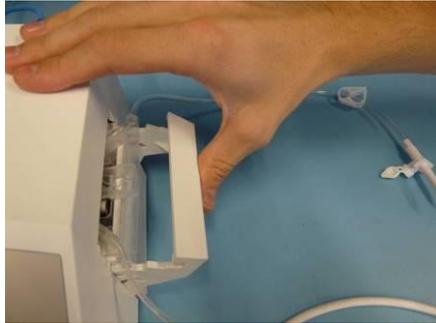
12.	Test the pedal by following the steps below:		<input type="checkbox"/>	<input type="checkbox"/>	
	<ol style="list-style-type: none"> 1. Blue button: press and check the correspondence with the screen (IRRIG) 2. Orange button, press and check correspondence (PROGR) 3. Grey button, press and check correspondence (REV) 4. Pedal rocker, press and check correspondence (PEDALE) 				
13.	Confirm with Ok to continue.		<input type="checkbox"/>	<input type="checkbox"/>	
14.	Depress the pedal fully.		<input type="checkbox"/>	<input type="checkbox"/>	
15.	<p>Press the Ok button, and hold until "OK : continue" is displayed. Release the pedal and then press the Ok button.</p>		<input type="checkbox"/>	<input type="checkbox"/>	
					
					
16.	Test with the pedal released: Press the Ok button.		<input type="checkbox"/>	<input type="checkbox"/>	
					
17.	As soon as the test is completed, press the Ok button.		<input type="checkbox"/>	<input type="checkbox"/>	
					

<p>18.</p>	<p>The screen must show the same image as the photo opposite. If necessary, use the arrows to set the different parameters.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>19.</p>	<p>Checking the direction of rotation and the light. See various models to proceed.</p>			
<p>20.</p> 	<p>Checking the direction of rotation: Depress the pedal to check the default direction of rotation as indicated beside.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>21.</p>	<p>CHIROPRO L models with light, reference 1600613 and USA reference 1600679 : Check there is a bright white light.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>22.</p>	<p>Increase the speed to 500 rpm.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>23.</p>	<p>Check that the direction of rotation is reversed. Press the grey button on the pedal, start the motor and check to hear "beep" and to see the "R ←" symbol on the screen. Check that the bur's direction of rotation is reversed in relation to point 21.1.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>24.</p>	<p>Press the grey button on the pedal to revert to the default direction of rotation.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p>25.</p> 	<p>Practice on a material test block. Check the bur's speed decline in relation with force. No error messages should appear on the device during the test.</p>		<input type="checkbox"/>	<input type="checkbox"/>

26. Insert an irrigation line into the pump.



27. Close the cover.



28. Check the operation of the peristaltic pump with an irrigation line.
Adjust the pump to maximum.

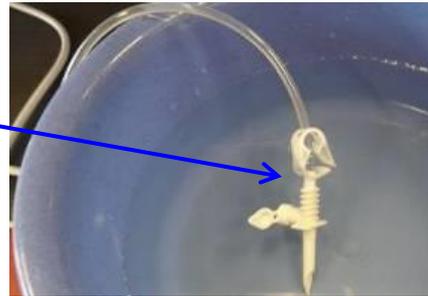
29. Fill the container with fresh water and place the line's white end piece in it.



Important: the hose must not be pinched.
The end piece must be completely submerged.

Verification:

To start with, place the other end of the hose in the recipient. Depress the pedal until water is regularly expelled without any air, then stop.



30. Now place this end in the measuring beaker.

Recommendation:

Use a high narrow beaker with a capacity which allows **5 to 50 ml** to be accurately measured, in increments of one ml.
See the example in the photo opposite.



31.	Time 15 seconds of operation, with the pedal depressed.		<input type="checkbox"/>	<input type="checkbox"/>
32.	Measure the quantity of water ejected into the measuring beaker. The required quantity is 35 ml ± 5 ml in 15 seconds.		<input type="checkbox"/>	<input type="checkbox"/>
33.	Once the test is done, make the pump turn during three minutes at maximum flow with an irrigation line placed in the pump.	<input type="checkbox"/>	<input type="checkbox"/>	
34.	Check manually that each roller turns freely. If one roller does not turn freely, replace the roller support REF 1501112-001.		<input type="checkbox"/>	<input type="checkbox"/>
35.	Press the Ok button.		<input type="checkbox"/>	<input type="checkbox"/>
36.	The screen CHIROPRO L, ref 1600613 indicate Until software version 1.04 → Version 1.05 or above → Then press Ok again.	Skip to 39. 5. TEST ENDO	<input type="checkbox"/>	<input type="checkbox"/>
37.	End of the tests.	<input type="checkbox"/>	<input type="checkbox"/>	
38.	The screen shows: CHIROPRO L, reference 1600613.		<input type="checkbox"/>	<input type="checkbox"/>
39.	Switch off the device (switch in position -O-).		<input type="checkbox"/>	<input type="checkbox"/>

40.	<p>Finally proceed to Electrical test according to EN60601-1 (EARTH connection, LEAK-AGE CURRENTS, AUXILIARY, CURRENT TO THE PATIENT as per IEC 60'601-§19). The link between the inspection report and repair form is the responsibility of the repairer.</p> <p>Bien-Air Subsidiaries: Please refer to checking instruction IC 751-005-EN</p>	<input type="checkbox"/>	<input type="checkbox"/>
41.	<p>Traceability : Complete and archive the documents SU 824-xxx and IC 751-015_xx in either electronic or paper format. Any returns to Bien-Air Switzerland must include a copy of completed form.</p>	<input type="checkbox"/>	<input type="checkbox"/>

CERTIFICATE OF CONFORMITY

Name and visum: _____ Date : _____

Remarks: _____

DOCUMENT APPROVED BY :	NAME:	DATE :	SIGNATURE :
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