Evaluation of safety for Varios Combi Pro

1 Introduction

1.1 The safety evaluation of ME Equipment or ME Systems should be performed by persons skilled in electrical testing (as defined in IEC 61140) who have been appropriately trained in the testing of the relevant equipment.

1.2 The procedure in this document is based on IEC 62353.

1.3 Test results must be recorded.

1.4 The order of inspection procedure should be kept.

1.5 This procedure should be performed:

- Periodically, refer to section 2.5
- After any repair and/or modification or upgrade of the medical device.

2 Inspection

2.1 Visual inspection

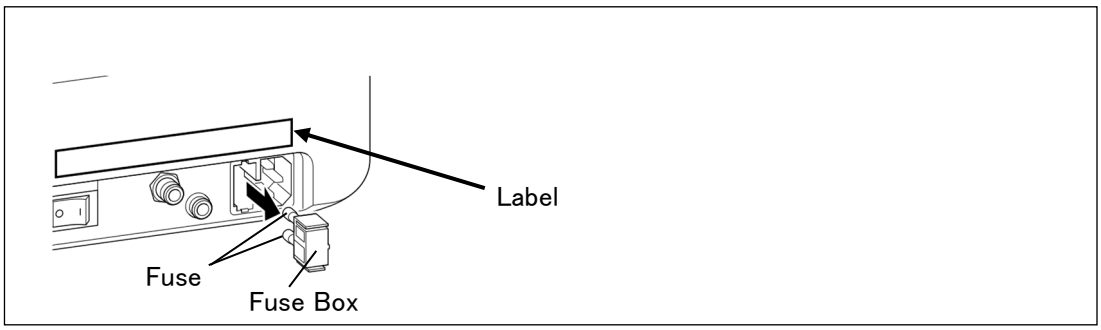
This procedure shall be done before any measurement.

2.1.1 Special attention shall be paid to the following;

1) any damage such as deformation or crack on the Control Unit and Foot Control.
2) the rating plate is legible and complete.
3) the Operation Panel display can be read correctly.
4) the LCD Panel can be read correctly.
5) any damage such as deformation or crack on the accessories, e.g. Handpiece, Handpiece Cord, Handpiece Hose and AC Power Cord.



2.1.2 The markings on fuses shall match to specification shown on the label on the back of the Control Unit.

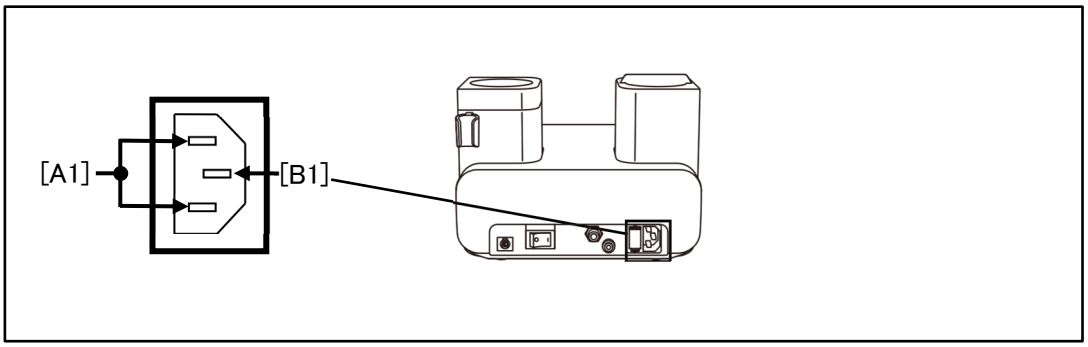


2.2 Insulation resistance

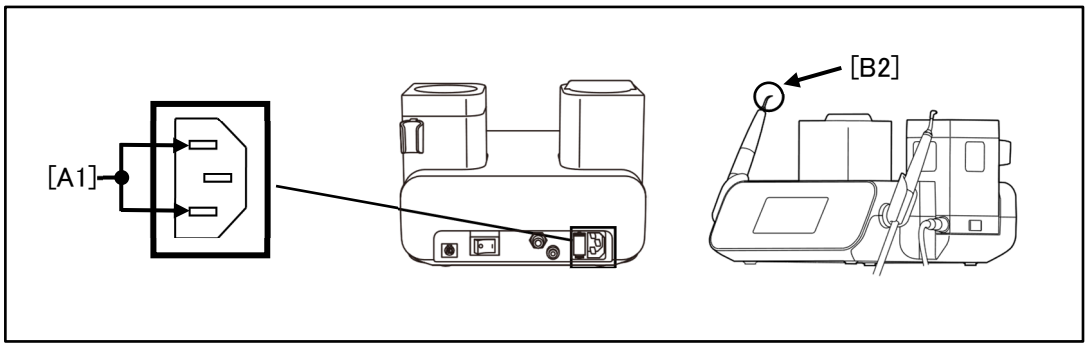
The lowest value and measured point should be recorded.

Turn the power switch ON.

2.2.1 Measure resistance between MAINS PART [A1] and protective earth [B1] with a test voltage of 500 V DC.



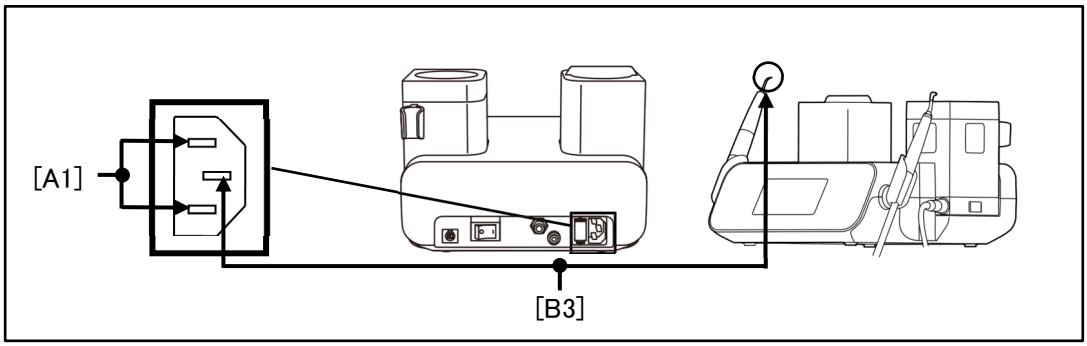
2.2.2 Measure resistance between MAINS PART [A1] and APPLIED PART [B2] with a test voltage of 500 V DC.



2.3 Equipment leakage current

Turn the power switch ON.

2.3.1 Measure leakage current between MAINS PART [A1] and APPLIED PART and all connected parts [B3] .



2.4 Functional test

Perform the operation check based on the OM-E0841E "Check before treatment" included with the product.

2.5 Interval

2.5.1 This procedure should be performed at least every 2 years.

TEST RECORD

Responsible organization	Test before putting into service ☐ Recurrent test ☐ Test after repair ☐

Equipment		
Model		Varios Combi Pro
Manufacturer		NAKANISHI INC.
Applied part type		B
Class of protection		I
Mains connection		Detachable power supply cord
Serial number	Control unit	
	Handpiece	

Test						
Procedure No	Item	Acceptance criteria	Measured point	Measured value	PASS	FAIL
2.1	Visual inspection				☐	☐
2.2.1	Insulation resistance	> 2MΩ		MΩ	☐	☐
2.2.2	Insulation resistance	> 2MΩ		MΩ	☐	☐
2.3.1	Equipment leakage current	< 1000μA		μA	☐	☐
2.4	Functional test				☐	☐

Measurement equipment

Note
Next recurrent test necessary in ☐6/ ☐12/ ☐18/ ☐24 months.

Overall Assessment

☐ No safety or functional deficiencies were detected.

☐ Deficiencies detected but no direct risk to continue clinical use. Correction required.

☐ Equipment shall be taken out of operation until deficiencies are corrected.

☐ Equipment does not comply - Modification / Exchange of components / Taking out of service is required.

Operator	Date	Signature