NOTICE

Much care and attention has been given to the design and manufacture of this equipment. Biometrics trusts that you find the system simple to use and effective for monitoring limb movements. In the event that you have any queries regarding the application of the equipment, please do not hesitate to contact us. You are assured of our best attention.

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1.0 INTRODUCTION

1.1 Biometrics’ range of goniometers and torsiometers (both referred to as sensors) are designed for the measurement of limb angular movement. The sensors are attached across the joint employing double-sided medical adhesive tape and connected to the range of Biometrics’ instrumentation. The sensors and instruments are lightweight and unobtrusive allowing data of human activity to be displayed or recorded while leaving the subject to move freely in the normal environment.

1.2 Various display and recording instrumentation has been carefully developed for both routine clinical measurements and specific research applications.

1.3 All sensors have been independently certified to EN60601-1 (IEC601-1) and conform to the Medical Devices Directive 93/42/EEC.

2.0 WARNINGS

2.1 WHEN CONNECTING TO BIOMETRICS INSTRUMENTATION THE USER MUST COMPLY WITH ALL APPROPRIATE MEDICAL AND ELECTRICAL REGULATIONS.

2.2 WHEN USING GONIOMETERS AND TORSIOMETERS, CARE SHOULD BE TAKEN SO THE SENSORS ARE ONLY HANDLED AND MANIPULATED AS INSTRUCTED. MISHANDLING MAY RESULT IN INACCURATE DATA, REDUCED LIFE OR FAILURE.

2.3 WHEN USING ALL GONIOMETERS AND TORSIOMETERS THE MINIMUM PERMISSIBLE VALUE OF BEND RADIUS MUST BE OBSERVED AT ALL TIMES, PARTICULARLY WHEN ATTACHING AND REMOVING THE SENSORS FROM THE SUBJECT. FAILURE TO DO THIS WILL RESULT IN REDUCED LIFE.

2.4 UNDER NO CIRCUMSTANCES SHOULD THE SENSOR BE REMOVED FROM THE SUBJECT BY PULLING ON THE MEASURING ELEMENT AND PROTECTIVE SPRING. THE ENDBLOCKS MUST BE REMOVED INDIVIDUALLY AND CAREFULLY MAKING SURE THAT THE MINIMUM PERMISSIBLE BEND RADIUS IS OBSERVED, PARTICULARLY WHERE THE MEASURING ELEMENT ENTERS THE ENDBLOCKS.

2.5 WHEN USING SG AND Q SERIES SENSORS CARE SHOULD BE TAKEN DURING MOUNTING SO THAT THE MEASURING ELEMENT ALWAYS FORMS A “SIMPLE” BEND SHAPE. IF AN “OXBOW” SHAPE (REFER TO FIGURE 8, PAGE 18) OCCURS IN THE ELEMENT THIS WILL REDUCE ACCURACY.

2.6 WHEN USING F SERIES GONIOMETERS THE UNIT SHOULD NOT BE BENT MORE THAN ± 20° IN THE Y-Y PLANE (FIGURE 1, PAGE 15) OTHERWISE REDUCED LIFE OR FAILURE WILL RESULT.

2.7 WHEN CLEANING OR DISINFECTING GONIOMETERS AND TORSIOMETERS THE POWER SOURCE SHOULD BE SWITCHED OFF AND THE SENSORS SHOULD BE DISCONNECTED.

2.8 BIOMETRICS ACCEPTS NO LIABILITY, OR CONSEQUENTIAL LIABILITIES FOR THE LOSS, OR EFFECTS OF LOSS OR CORRUPTION OF DATA CAUSED WHEN USING THESE INSTRUMENTS.

2.9 IN ORDER TO GUARANTEE THE ACCURACY OF THE GONIOMETER MEASURING SYSTEM OVER TIME, IT IS RECOMMENDED THAT A TWO POINT CHECK IS PERFORMED PRIOR TO PERFORMING ANGULAR MEASUREMENTS.

THIS CAN BE ACHIEVED BY ZEROING THE GONIOMETER AGAINST A KNOWN STRAIGHT EDGE E.G. 12” RULE AND DISPLACING IT BY A KNOWN ANGLE (USUALLY 90°), IF THE MEASUREMENT IS NOT WITHIN THE REQUIRED ACCURACY THEN THE SENSORS PLUS ASSOCIATED INSTRUMENTATION SHOULD BE RETURNED TO THE MANUFACTURER FOR INVESTIGATION. PRIOR TO RETURNING TO THE MANUFACTURER CHECK THAT ANY BATTERIES USED CONTAIN SUFFICIENT CHARGE.
3.0 GENERAL DESCRIPTION

Biometrics Ltd manufactures three types of sensors:

SINGLE AXIS GONIOMETER F35 (Figure 1)

3.1 Biometrics’ goniometer F35 permits the measurement of angles in one plane. Referring to figure 1, angles are measured when rotating one endblock relative to the other about axis X-X. The goniometer is not designed to measure rotations about Y-Y. Any attempt to bend the unit in this way more than ± 20° from the neutral position will result in a reduction of the life of the unit. The goniometer does not measure rotations about axis Z-Z though this movement is permitted without reduced life occurring. This goniometer is designed for the measurement of finger and toe flexion/extension.

TWIN AXIS GONIOMETERS SG65, SG110, SG110/A, SG150, SG150/B (Figures 2, 3)

3.2 Biometrics’ “SG” series twin axis goniometers permit the simultaneous measurement of angles in two planes, e.g. wrist flexion/extension and radial/ulnar deviation. Referring to figures 2 & 3, rotation of one endblock relative to the other about axis X-X is measured using the grey plug. Similarly, rotation of one endblock relative to the other about axis Y-Y is measured using the green plug (figure 2). Assuming the goniometer is mounted correctly as outlined below, the outputs of the two channels are independent of linear displacements along axis Z-Z. It should be noted that rotation of one endblock relative to the other around axis Z-Z cannot be measured. All twin axis SG series goniometers function the same way, the difference being physical size.

SINGLE AXIS TORSIOMETERS Q110 and Q150 (Figure 4, 5)

3.3 Biometrics “Q” series single axis torsiometers permit the measurement of rotations in one plane, e.g. forearm pronation/supination. Referring to figures 4 & 5, axial rotation of one endblock relative to the other along axis Z-Z is measured from the grey plug. If the torsiometer is bent in planes X-X or Y-Y the output remains constant. All torsiometers function in the same way, the difference being physical size.
3.4 The working mechanism is the same for all three types of sensor. Between the two endblocks inside the protective spring there is a composite wire that has a series of strain gauges mounted around the circumference. As the angle between the two ends changes (figure 3) the change in strain along the length of the wire is measured and this is equated to angle. The design is such that only angular displacements are measured. If the two ends move linear relative to each other (figure 2), within the limits of the sliding endblock, without changing the relative angles between them, then the outputs remain constant.

3.5 The amount of strain induced in the gauges is inversely proportional to the bend radius that the beam is bent around (figure 6). If the stated minimum permissible bend radius is exceeded then the life will be reduced or in severe cases failure may result.

3.6 WHEN USING ALL GONIOMETERS AND TORSIOMETERS THE MINIMUM PERMISSIBLE VALUE OF BEND RADIUS MUST BE OBSERVED AT ALL TIMES, PARTICULARLY WHEN ATTACHING AND REMOVING THE SENSORS FROM THE SUBJECT. FAILURE TO DO THIS WILL RESULT IN REDUCED LIFE.

3.7 The sensors have been designed to be as light as possible and the operating force to be a minimum. This permits free movement of the joint without external influence.

3.8 The sensors measure the angle subtended between the 2 endblocks. Using all Biometrics instrumentation the datum position is set by simply pressing an auto set key. Readings will be measured from this position until the zero position is reset or in some cases the instrumentation is switched off.
4.0 OPERATION

4.1 Due to the wide range of applications, one method of attachment cannot be recommended. However, experience has proven double-sided medical adhesive tape (Biometrics Part Number T10) to be a good method in the majority of cases.

4.2 For accurate results, during long periods of testing, it is recommended that double-sided adhesive tape is employed between the endblocks and skin, and single sided adhesive tape is placed over the top of the endblocks. No tape should come into contact with the spring. The interconnect lead should also be taped down near the goniometer.

4.3 For applications where quick or rapid movements of the joint are involved, it is recommended to fit a “sock” bandage over the whole sensor and interconnect lead. This does not apply to goniometer F35 that has a different working mechanism. The operation of the F35 is described in sections 4.12 to 4.15.

4.4 In certain applications, when mounting the goniometer across the joint, (for example when measuring flexion/extension of the wrist as shown in figure 12), the centre of rotation of the sensor measuring element does not coincide with the centre of rotation of the joint. As the joint moves through a determined angle the relative linear distance between the two mounting positions will change. To compensate for this, all sensors are fitted with a sliding endblock that permits changes in linear displacement between the two endblocks along axis ZZ without the measuring element becoming overstretched or buckled (refer to figure 7). In the free or unstretched position the distance between the two endblocks is L1. If a light force is applied pushing the endblocks away from each other this length will increase to a maximum of L2. When the light force is removed the distance between the two endblocks will automatically return to L1.

This has several advantages:

- Improved accuracy
- Enables the sensors to be worn comfortably and undetected under normal clothing.
- Reduces the tendency for the position of the sensors to move relative to the underlying skeletal structure.

4.5 If a light force is now applied pushing the two endblocks linearly towards each other the only way the distance L1 can decrease in length is by the measuring element buckling as shown in figure 8. This buckling is detrimental to the accuracy of the “SG” series and “Q” series sensors (this does not apply to the F35 goniometer) and the following attachment instructions are provided for the most commonly measured joints, to ensure that it does not occur in practice.
4.6 In general, there are no fixed rules governing which size of sensor is most suitable for a particular joint; this depends on the size of the subject. The sensor must be capable of reaching across the joint so that the two endblocks can be mounted where least movement occurs between the skin and underlying skeletal structure. In certain circumstances more than one size of sensor will be appropriate. The following table is given for guidance only and refers to an adult population.

<table>
<thead>
<tr>
<th>JOINT</th>
<th>SENSOR</th>
<th>MEASURED OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>wrist</td>
<td>SG65</td>
<td>flexion/extension, radial/ulnar deviation</td>
</tr>
<tr>
<td>forearm</td>
<td>Q110 or Q150</td>
<td>pronation/supination</td>
</tr>
<tr>
<td>elbow</td>
<td>SG110</td>
<td>flexion/extension</td>
</tr>
<tr>
<td>ankle</td>
<td>SG110 or SG110/A</td>
<td>dorsiflexion/plantarflexion, inversion/eversion</td>
</tr>
<tr>
<td>knee</td>
<td>SG150</td>
<td>flexion/extension</td>
</tr>
<tr>
<td>hip</td>
<td>SG150</td>
<td>flexion/extension, abduction/adduction</td>
</tr>
<tr>
<td>back</td>
<td>SG150/B</td>
<td>flexion/extension/lateral flexion</td>
</tr>
<tr>
<td>neck</td>
<td>Q150</td>
<td>axial rotation</td>
</tr>
<tr>
<td>back</td>
<td>Q110</td>
<td>axial rotation</td>
</tr>
<tr>
<td>neck</td>
<td>SG110</td>
<td>flexion/extension, lateral flexion</td>
</tr>
<tr>
<td>finger DIP, PIP, MCP</td>
<td>F35</td>
<td>flexion/extension</td>
</tr>
<tr>
<td>toe</td>
<td>F35</td>
<td>flexion/extension</td>
</tr>
</tbody>
</table>

4.7 To minimise the effects of crosstalk when measuring 2 axes of wrist and hip joints, it is recommended that the size of goniometer used is as shown in the above chart. Please refer to the following paragraph on crosstalk and the notes on wrist and hip application for further information.

CROSSTALK

4.8 Crosstalk is defined as a measure of the ability of the goniometer to measure independently the simultaneous angular movements of a joint in 2 degrees of freedom. It should be noted that with the commonly measured joints as discussed in this manual, crosstalk is primarily only of relevance when dealing with the wrist and hip. Refer to the appropriate sections for further information on monitoring these joints. Provided the guidelines on the size selection and mounting position are followed, crosstalk between the 2 channels will be minimised to an acceptable level.

4.9 Specification of crosstalk for all Biometrics twin axis SG series goniometers is less than $\pm 5\%$ measured over an angular range of $\pm 60^\circ$ i.e. if a joint is moved through $60^\circ$ from the neutral position in one plane without movement in the orthogonal plane, then the sensor output in the orthogonal plane may change by a maximum of $\pm 3^\circ$.

USEFUL INFORMATION

4.10 As with all measuring equipment the user should understand the working principles (i.e. what the sensor actually measures) before use so that correct interpretation of the data is made.

4.11 The sign convention for certain joints will differ depending which side of the body the sensor is attached to. Sign conventions for the most common joints are shown in figures 20, 21, and 22.
4.12 The F35 goniometer is a single axis goniometer intended for use on fingers and toes. Referring to figure 1, angles are measured by rotating one endblock relative to the other about axis X-X. The goniometer is not designed to measure rotations about Y-Y. ANY ATTEMPT TO BEND THE UNIT IN THIS WAY MORE THAN $\pm 20^\circ$ FROM THE NEUTRAL POSITION WILL RESULT IN REDUCED LIFE OR FAILURE. The goniometer does not measure rotations about the axis Z-Z.

4.13 The unit is designed to be fitted over the joint to be measured (figure 9) and has high flexibility and low operating force to ensure the instrument does not interfere with normal joint movement. One endblock is attached either side of the joint. Unlike the “SG” series and “Q” series sensors an “oxbow” shape is permitted in the measuring element (figure 10). This is not detrimental to the results and does not reduce the life of the sensor.

CARE SHOULD BE TAKEN SO THAT THE MINIMUM BEND RADIUS IS NOT EXCEEDED.

4.14 When attaching the goniometer with tape, two kinds will be required for best results:-

- Single sided medical tape
- Double sided medical tape

4.15 Firstly, pieces of double sided tape are attached to the underside of the goniometer endblocks. These should then be stuck to the subject, ensuring allowance is made for the sliding of the goniometer. The goniometer should be fully extended when the joint is fully flexed. The two endblocks should then be pressed firmly onto the subject, ensuring that the goniometer is lying over the top of the joint. When the joint is extended the goniometer may present an “oxbow” as shown in figure 10. For additional security, a single wrap of single sided medical tape should now be passed around each endblock. The cable and connector leaving the goniometer should be secured with tape to ensure that this does not cause the goniometer to become detached.

THE WRIST

4.16 Start with the subject’s shoulder in abduction at 90 degrees and elbow flexed at 90 degrees, such that the forearm is close to full pronation. As shown in figure 11, attach the distal endblock to the dorsal surface over the third metacarpal with the centre axis of the hand and endblock coincident. While fully flexing the wrist (figure 12) extend the goniometer to position 2 (figure 7) and attach the proximal endblock to the forearm so that when viewed from the dorsal plane the axes of the forearm and endblock are coincident. The wrist may now be flexed or extended, radial or ulnar deviated with the goniometer freely sliding between positions 1 and 2. Measurement of flexion/extension is obtained from the grey plug and radial and ulnar deviation from the green plug.

4.17 If monitoring both movements of flexion/extension and radial/ulnar deviation with a varying position of pronation and supination, the 2 endblocks of the goniometer should be mounted close to the wrist joint to minimise crosstalk. To do this the goniometer type no. SG65 must be used.

THE ELBOW
4.18 Start with the subject’s shoulder in abduction at 90 degrees and elbow and forearm at neutral. Attach the distal endblock to the forearm with the centre axis of the endblock coincident with the centre axis of the forearm (figure 13). With the elbow at neutral, move the goniometer to position 2 (maximum length) and attach the proximal endblock to the upper arm with the centre of the endblock and the centre axis of the upper arm coincident. The elbow may be fully flexed and extended with the distal endblock freely sliding between positions 1 and 2. Measurement of flexion/extension is obtained from the green plug, the grey plug being redundant. The distal endblock should be mounted in close proximity to the elbow joint. Movements of pronation and supination may be made and will affect the measurement of flexion/extension minimally.

THE ANKLE

4.19 Start with the subject standing in the neutral position with the foot on a flat surface. When using the SG 110/A, attach the fixed endblock of the SG110/A to the side of the foot as shown in figure 14. Invert the ankle to the maximum anticipated during measurement and with the goniometer in position 2 attach the sliding endblock to the lateral aspect of the lower leg so that the axis of the leg and endblock are coincident. Dorsi flexion/plantar flexion of the ankle may now be monitored using the green plug and inversion/eversion using the grey plug.

4.20 When using the SG 110, attach the distal endblock of the SG110 to the back of the heel as shown in figure 15. Dorsiflex the ankle to the maximum anticipated during measurement and attach the proximal endblock to the posterior of the leg with the goniometer in position 1 so that the axis of the leg and endblock are coincident. Dorsiflexion/plantar flexion of the ankle may now be monitored using the grey plug and inversion/eversion using the green plug.

THE KNEE

4.21 Start with the subject standing in the neutral position with the foot on a flat surface. Mount the distal endblock laterally on the leg so the axes of the leg and endblock coincide, when viewed in the sagittal plane (figure 16), with the leg fully extended in the position of reference extend the goniometer to position 2 (maximum length) and attach the proximal endblock to the thigh so the axes of the thigh and endblock coincide. The knee may now be flexed or extended with the goniometer freely sliding between positions 1 and 2. Measurements of flexion/extension may be monitored using the green plug, the grey plug being redundant.
THE HIP

4.22 Start with the subject standing in the neutral position with the foot on a flat surface. Attach the proximal endblock to the side of the trunk in the pelvic region as shown in figure 17. With the limb in the position of reference, extend the goniometer to position 2 (maximum length) and attach the distal endblock to the thigh so that axes of the thigh and endblock coincide (when viewed in the sagittal plane as shown). The hip may now be flexed or extended, abducted or adducted with the goniometer sliding freely between positions 1 and 2. Measurement of flexion/extension is obtained from the green plug, abduction/adduction from the grey plug.

4.23 During normal gait the amount of hip rotation is small, therefore accurate measurements of flexion/extension and abduction/adduction may be obtained. If flexion/extension and abduction/adduction are to be monitored with a significant amount of hip rotation, then crosstalk will effect the absolute readings and this should be considered when interpreting the results.

THE BACK

4.24 Attach the proximal endblock to the sacral area at S1 as shown in figure 18. With the patient upright and the goniometer near minimum length, attach the sliding endblock to the back at T12-L1 (this will vary depending upon patient height). Zero the goniometer with the patient in this upright position. The SG150/B measures relative change in lumbar curvature through flexion/extension and lateral flexion to both sides. Measurement of flexion/extension is obtained from the grey plug and lateral flexion from the green plug.

4.25 The SG150/B is most effective for standing measurements with isolated X-X or Y-Y planar movements. Crosstalk between the channels may be experienced with rotational movements. (See also sections 4.8 and 4.9). Seated tasks and tight clothing may adversely effect the accuracy of the readings.

FOREARM PRONATION/SUPINATION

4.26 Attach the two endblocks of the torsiometer to the forearm as shown in figure 19 with the slider mechanism approximately midway between the two extremes. Measurements of pronation/supination may now be made from the grey plug. Movements of wrist flexion/extension or radial ulnar deviation will not effect the output.
CONNECTION TO BIOMETRICS INSTRUMENTATION

4.27 All sensors are connected to the instrumentation by means of the J type interconnect leads. These are available in three different sizes:-

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<td>J1000</td>
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<tr>
<td>J1500</td>
<td>1500</td>
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</tbody>
</table>

4.28 Connect the black connector of the J type lead to the appropriate connector of the goniometer or torsimeter. Ensure that the locking mechanism is correctly aligned before insertion. The other end of the J type lead may be connected to the appropriate instrumentation.
5.0 MAINTENANCE

5.1 The sensors contain no user serviceable components. In the event of malfunction the sensor should be returned to the supplier, accompanied by a description of what has been observed and what instrumentation was in use.

5.2 No periodic maintenance is required to ensure the correct functioning of the sensors.

6.0 CLEANING AND DISINFECTION

6.1 IMPORTANT - WHEN CLEANING OR DISINFECTION, THE SENSORS MUST BE DISCONNECTED FROM ALL INSTRUMENTATION.

6.2 NO SOLVENTS, ACIDIC OR STRONG ALKALINE MATERIALS SHOULD BE USED TO CLEAN THE SENSORS OR DAMAGE WILL RESULT.

6.3 Cleaning may be carried out by wiping the sensors with a damp cloth or a cloth moistened with soapy water.

6.4 Disinfection of the sensors should be carried out as for cleaning though disinfectant should be employed instead of soapy water.
7.0 SPECIFICATION

(Refer to figure above).

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<td>Crosstalk¹</td>
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<td>≤±5%</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
</tbody>
</table>

Transducer type: strain gauge
Life²: 600,000 cycles minimum
Accuracy: ±2° measured over 90° from neutral position
Repeatability: better than ±1°
Analogue resolution: infinite
Operating temperature range: +0°C to +40°C
Storage temperature range: -20°C to +50°C
Operating humidity range: 30% to 75%
Storage humidity range: 30% to 75%
Atmospheric pressure range: operation: 700hPa to 1060hPa, storage: 500hPa to 1060hPa

¹ Specification of crosstalk for all Biometrics twin axis SG series goniometers is measured over ±60°. i.e. if a joint is moved through 60° from the neutral position in one plane without movement in the orthogonal plane, then the sensor output in the orthogonal plane may change by a maximum ±3°.

² Life test results have been collected by cycling the sensors through movements that would happen during everyday use. For example, placing a sensor on an adult elbow and moving from the neutral position to maximum flexion and back, the unit will function for a minimum of 600,000 cycles.

FIGURE 1

Single Axis Goniometer F35
FIGURE 3

Twin Axis Goniometer
SG Series

FIGURE 4

Single Axis Torsiometer
Q Series
FIGURE 5

Single Axis Torsiomater
Q Series

FIGURE 6
This over compression of the sensor may damage it.

Do NOT mount sensor in this way.

Minimum and maximum distances between the endblocks.

Exceeding these parameters (Over compression or over stretching of the sensor) may damage it.

“Oxbow Shape”
This over compression of the sensor may damage it.
Do NOT mount sensor in this way.