Clinical Movement Analysis Society
– UK and Ireland

Clinical Gait Analysis Standards
Document approved by membership:

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Contents

Introduction

CMAS aims to promote quality in the provision of movement analysis services by the development of standards relating to clinical gait analysis services. The implementation of these standards will be monitored by auditing and accrediting clinical gait analysis laboratories.

This document details the standards developed by the Standards Working Group of CMAS. The initial work was carried out from March 2002 up to February 2004. During 2004-7 the implementation of audit was explored, revealing the need for further changes to the standards. This work was started in late 2007 and completed during 2008, when a complete revision of the standards was launched. Standards will continue to be reviewed at regular intervals with revisions being made where needed.

Conformity to a standard allows accuracy or quality to be judged by auditing the processes against a checklist of key points stated in the agreed audit checklists. Details of the procedures carried out locally will be detailed in a protocol. The protocols should be sufficiently detailed to act as a guideline for all staff performing the stated task. Examples of protocols will be shared within the community of laboratories seeking accreditation.

A clinical gait analysis laboratory will be required to maintain its own set of written protocols conforming to the associated standards for the procedures relevant to that laboratory, or as stand alone protocols where indicated in the list in the clinical gait analysis procedure document. Standards contain references to protocols where appropriate.

The scope of the standards deliberately excludes areas where local or national policies apply. These areas include:-

- Health and Safety
- Infection Control
- Patient Confidentiality
- Financial Issues
- Waiting time targets
- Patient consent procedures
- Communication/correspondence policies and record access
- Human resources
- Professional body requirements
- Local statutory training

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STANDARD: Resources and Facilities	
1. Staffing	
Mandatory Requirements	1. Each laboratory should have a list of current staff employed.
	2. Staff should have current registration with the Health Professions Council / General Medical Council; or alternatively will be under the supervision of a named practitioner with current registration.
	3. The laboratory must keep a log for each staff member containing, a. The identity of any professional registration body, along with the registration number b. Evidence of gait laboratory induction training for new staff. This should be signed by the trainer, who should be competent (see e) c. Annual update of repeatability measures (where applicable). Some repeatability issues should be examined each year, however it is not necessary to cover all areas in a single year. This should be signed by the lab manager. d. Evidence of participation in on-going in-service training activities. This should be signed by the trainer, who should be competent (see e) e. List of individual competences in patient history taking, clinical examination, data collection, data interpretation, scope of clinical recommendations. This should be signed by the lab manager.
	4. Gait laboratory induction training should include, a. Training on all local protocols (signed record) b. Shadowing of established staff until local staff are satisfied (signed record) c. Repeat data collection on unimpaired subjects, checked against laboratory's normal database.
	5. It is necessary to have a skill mix within the staff team, including clinical, technical and scientific expertise. This should include at least one member of staff with a clinical and one with a technical background.
Recommendations	6. All staff should have attended a recognized gait course eg ESMAC, GCMAS, SIAMOC etc 7. A minimum of two staff should be employed to run a laboratory. 8. Co-operation between laboratories is encouraged for senior staff for peer supervision. 9. New staff are encouraged to visit other laboratories as part of their induction training.

2. Equipment	
Mandatory	1. Each piece of equipment should have a separate log, including a. record of equipment manufacturer, make and model. b. software and version numbers c. manufacturer's contact details. d. storage location of manufacturer's operational guidelines. e. list of all the relevant data collection procedures 2. All equipment classed as a medical device and manufactured after 1998 should be CE marked.
	3. Each laboratory should have access simple calibration equipment eg a set of calibrated weights for up to a minimum of 25kg and one metal pole with markers attached.
	4. Simple measurement tools eg tapes, scales etc should be inspected annually of accuracy and, where appropriate, safety.

CMAS recommends that more rigorous checks are also performed on a less frequent basis, or for trouble shooting, examining, for example:-

5. Force plate tests	absolute force values in all measured directions centre of pressure
6. 3D position	absolute marker position in capture volume - static and dynamic relative marker position in capture volume - static and dynamic
7. EMG	timing delay frequency response
8. Video vector	centre of pressure relative value of force – vector proportional to load on all settings
9. Pedobarograph	linearity of pressure measurement equality of cell response
10. System	synchronisation of all data sources relative spatial positions of relevant equipment (e.g. force plates and 3D)

CMAS recognises that the current mandatory requirements (1-4) are the minimum required. It is envisaged that more detailed mandatory requirements, based on recommendations 5-10, will be added in future versions.

3. Environment	
Mandatory	1. Facilities to have access for disabled patients, in line with the statement of purpose. 2. Facilities to have controlled access for security purposes during patient assessment. 3. The examination couch to have a firm surface and adjustable height to allow access for examiner. 4. A minimum 7 metre walking space is necessary for gait data collection. 5. Room temperature should be between 21 and 28°C to be suitable for the partially dressed patient. (Laboratories should have a thermometer to monitor this) 6. The environment should be quiet and non-distracting. 7. A designated area should be provided where the patient can both change and be examined in privacy. 8. Patient toilet facilities, including toilet for the disabled, to be available. 9. Adequate seating facilities available for patient and families. 10. Staff hand washing facilities to be provided. 11. Floor surface to be clean, be non-slip and level, free from obstacles 12. Examination couch and covers should be clean.
Recommendations	13. CMAS strongly recommends 10 metre walkways for new facilities

STANDARD: Referral Management	
Mandatory	1. Each laboratory should have a clear, current statement of purpose, including a. Test facilities available (equipment) b. Clinical expertise c. Level of reporting (ie gait description only, clinical opinion, treatment recommendations) d. Any exclusions (patients)
	2. Referrals should only be accepted if they are in line with the statement of purpose.
	3. Each laboratory should have an information sheet to send to patients referred for gait analysis. This should include the CMAS web address to allow patients to read the statement of purpose.
	4. Laboratories should have a written protocol defining the patient journey including referral, appointment and reporting.

STANDARD: Data Collection	
Mandatory	1. For each type of test performed there should be a written protocol including, a. laboratory preparation (including calibration spot check, see below) b. patient preparation (including clothing) c. placement of any markers or electrodes d. minimum data set e. data checks to be performed before the patient leaves f. standard file names and formats g. storage location for patient data (electronic and paper records)
	2. For each type of test performed there should be a standard recording method. Information should include, a. results of any calibration spot checks b. results of any verification tests involving patient c. comments on compliance/co-operation d. indication of whether gait pattern is typical e. conditions recorded under (eg barefoot, shoes, splints, walking aids) f. staff involved in data collection g. problems encountered during data collection
	3. For clinical examination a. protocol should specify patient posture and measurement method (photographs/pictures are recommended)
	4. For video/video vector analysis a. Simple pole test should be used to check the alignment of the video in a video/vector analysis
	5. For force plates a. The written protocol should state how patients are patients are aligned to avoid targeting of the plates. b. Circumstances when this does not apply should be identified in the protocol. c. Calibrated weights should be used to test the force plate at the start of each session (unless more rigorous/alternative approach is employed)
	6. For 3D movement analysis systems a. A simple pole test (including markers) should be performed at the start of each session unless more rigorous/alternative approach is employed) b. The protocol should define how to deal with known artefacts (see Appendix 1). c. Sample video should be collected with all data collection

	7. For EMG a. Standard electrode placement guidelines must be followed (CMAS recommends SENIAM) b. The protocol should define how to deal with known artifacts (see list below). c. Foot switch placement should be defined in the protocol. d. Sample video should be collected with all data collection
	8. For Energy consumption
	9. For plantar pressure measurement
	10. For functional tests/questionnaires a. -Appropriate validated tests should be used wherever possible.
	11. For dynamometry

STANDARD: Data and Report Management	
1. Data Processing	
Mandatory	1. A clear written protocol is required describing the processing method for each type of test performed. The protocol should specify, a. The software required and version number. b. Signal processing requirements (eg filtering) c. Other processing parameters d. Definition of an acceptable data trial (including reasons for excluding data trials at the processing stage) e. Artefact correction techniques (see Appendix 1) f. Any secondary processing tools
	2. A standard recording method should be used to record processing a. The method should have space to report any problems/artefacts b. A signature box/approval method should be provided to confirm completeness of data before reviewing and reporting. c. The software version number should be recorded.
	3. For 3D gait data a. Interpolation parameters should be stated in the protocol. b. Protocol should state method for identifying gait cycle events (eg initial contact, toe off) c. Details should be given of any post-collection corrections (eg varus wave correction)
	4. For force plates
	5. For EMG
	6. For Energy testing
	7. For Plantar pressure measurement
	8. For Dynamometry

2. Normal Data	
Mandatory	1. A normal database is required for all the measurements being taken within the scope of practice of the laboratory. (This should include relevant aspects of the clinical examination such as range of motion, bony torsion)
	2. Data should be collected in conditions according to the written protocols of the laboratory.
	3. The normal database should include at least 10 subjects.
	4. The should be a written policy for including subjects within the normal database (eg excluding those with certain pathologies, obesity, outliers)
	5. Averaged data for kinematic and kinetic curves for normal reference range to be displayed +/- 1SD (Any other preferred method of showing variation, which must clearly labeled.)
	6. Normal data to be checked for validity against published results. This process should be documented.*
	7. Normal database to be checked after minor changes to protocols or equipment (data from one unimpaired subject should be checked against previous database). A new normal database is required where marker placements/processing models are changed.
	8. Details of each normal database should be kept in a file containing, a. details of all subjects including: age, sex, date & assessors. b. Storage location of raw data files c. Published normal datasets for comparison d. The protocol used e. A printout of the collated data, indicating variability
Recommendation	9. Separate databases should be compiled for different ages and genders. (see Sutherland/Ranchos Los Amigos)

*References:
DH Sutherland et al (1988) "The Development of Mature Walking", *Mac Keith Press, Oxford*
J Perry (1992) "Gait Analysis – Normal and Pathological Function", *SLACK Incorporated, NJ USA*.
Ranchos Los Amigos book

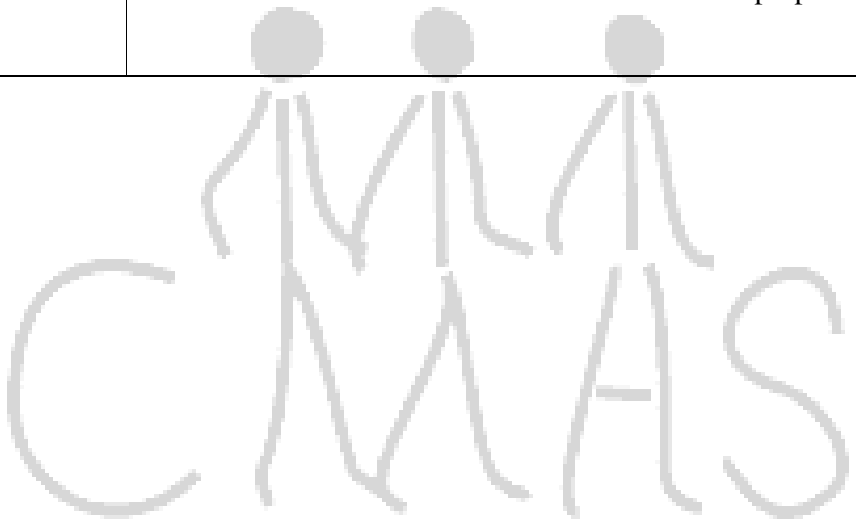
3. Interpretation of Data and Reporting	
Mandatory	1. A written protocol is required to define reporting practice. This should specify the standard content of a report and circulation lists.
	2. Reports should include a. relevant clinical history b. data on consistency c. conditions under which data were collected (eg barefoot) d. patient compliance/cooperation e. comments on whether data are typical for the patient f. any problems or artefact identified (see Appendix 1) g. any corrections applied during data collection and processing (see Appendix 1)
	3. Report to be signed and dated by those taking responsibility for content of report.
	4. The report should be consistent with the statement of scope for the laboratory.
	5. The report should present clear evidence from the data collected for any treatment recommendations.
	6. Values quoted should be compared with reference normal data
	7. Graphs should be plotted against a normal database
	8. The normal comparison group used should be identified.
	9. When the results from validated functional tests or questionnaires are stated references should be included.
	10. Graphs labelled with trial number, date, units and walking condition.
	11. Copy of the full report (electronic, film or paper) to be kept in the laboratory (including all raw data, forms and graphs).
Recommendations	12. Local jargon and terminology should be avoided.

Standard: Document Control	
Mandatory	1. Laboratory must have ready access to the latest version of the CMAS standards.
	2. The laboratory should have a list of all current protocols, clearly stating the issue date, author and version number. 3. The list should be signed by the head of department/service at each reissue of a protocol. The signature is then valid for two years, or until the protocol is replaced.
	4. Protocols should be readily available to all staff.
	5. The laboratory should have a list of all current recording forms/records, clearly stating the issue date, author and version number. 6. Blank forms should be readily available to all staff trained in their use.
	7. All protocols and recording forms should be reviewed every two years and the issue date updated accordingly.
	8. The laboratory should have a list of all the controlled storage locations, where current versions of any documentation can be found. Locations should be specified for, a. Local protocols b. Blank recording forms c. Completed recording forms eg patient notes, equipment/software logs, calibration results. d. Internal audit checklists. e. Internal and external audit reports 9. Controlled documents may be kept in paper or electronic format.
	10. All current documentation should be kept securely, with electronic documents kept under password and edit control and subject to backup procedures. 11. Copies must be kept of previous versions of all protocols and forms for at least 5 years after they are replaced.
	12. All completed patient records should have a. Name, date, date of birth b. Patient reference number on all pages of printed documents and paper forms c. Paper forms should include a signature of the member of staff responsible on each page d. No gaps should be left on standards forms. 'N/A' or equivalent should be used where data are not collected for a genuine reason.
	13. All electronic patient data should be stored in a location which is supported by regular back up.

STANDARD: Auditing the CMAS standards	
1. Management	a. The auditing of the CMAS standards will be overseen by the CMAS Standards and Accreditation Committee (SAC). b. The membership CMAS SAC will be decided by ballot of the CMAS membership. c. The activities of the CMAS SAC will be overseen by the main CMAS committee.
2. Auditors	d. Each laboratory should have at least 2 internal auditors. e. External auditors will be appointed by the CMAS SAC from another accredited gait laboratory. f. An internal auditor(s) will be appointed by the laboratory itself from within its own organisation. This person should be a health professional but need not have experience of gait analysis. g. If internal auditors come from the gait laboratory staff then more than one will be required. h. All auditors will have received guidance/training in audit from the CMAS SAC or another body where appropriate. i. All external auditors will be required to sign a confidentiality agreement before accessing patient records.
3. Audit method	a. External audits will be conducted using the checklists produced by CMAS. b. External audits will include an assessment of internal audit procedures. c. All boxes on the audit checklists should be completed. 'N/A' can be used at the discretion of the auditor. All areas of doubt should be referred to the CMAS SAC. d. The laboratories may use the same check lists for their internal audits, however they are encouraged to expand the audit to cover local protocols in more detail.
4. Audit frequency	a. External auditors will visit the laboratory twice in 2 years, as arranged by CMAS SAC. b. All the audit checklists will be subject to external audit at least once every two years. c. The CMAS SAC can request additional external audits if there is any cause for concern. d. Internal audit will be performed at least 4 times in two years on a timetable drawn up by the laboratory. e. Internal auditors will cover all aspects of the laboratory's work over the 2 year cycle. (This means that a single audit need not cover everything. A laboratory could produce 4 checklists covering the whole process which are then used in rotation).

5. Audit Reporting	a. The results of any audit will be recorded and reported by the auditor. They will also be signed by the laboratory manager. b. All audit records will be kept for at least 5 years. c. Copies of internal audit reports will be held by the laboratory. d. Copies of external audit reports will be sent to the CMAS SAC in order that accreditation can be renewed.
6. Dealing with problems	a. Both internal and external auditors will have direct access to the CMAS SAC if problems arise. b. If issues cannot be resolved by the CMAS SAC, the main CMAS committee may be contacted. c. Problems raised at an internal audit will be documented and reported to laboratory staff by the auditor. The laboratory is then required to put a plan in place to deal with the problem. The internal auditor will then monitor progress at the next audit. d. Major problems raised at an external audit must be reported to the CMAS SAC. The laboratory is then required to put a plan in place to correct the problem within 6 months. A follow up external audit will be arranged for that time. Minor problems can be passed to the internal auditor for follow up.

STANDARD: Accreditation to the CMAS standards ***Draft only – to be finalised AGM 2010***	
1. Management	Accreditation will be overseen by the CMAS Standards and Accreditation committee.
2. Accreditation	Laboratories will be considered for accreditation after a. A Statement of purpose form has been completed and approved b. Internal auditors have been appointed and trained c. Two successful external audits have been completed, covering all the checklists.
3. Dissemination	Accredited labs will receive a certificate from CMAS A list of accredited labs will be made available through the CMAS website, along with the information contained in the Statement of purpose form



Appendix 1: Known artefacts and their correction

- **3D movement analysis**

1. Varus wave produced by knee axis mal-alignment causing flexion/extension motion to be recorded in the coronal plane.

- **EMG**

1.

Subsequent versions of the standards will provide an extended list of artefacts, with approved methods of correction.

Appendix 1: Required protocols	
	• A written protocol defining the patient journey including referral, appointment and reporting.
	• For each type of test performed there should be a written protocol described data collection
	• For each type of test performed there should be a written protocol described data processing

Appendix 2: Required records	
	• A log containing detail of all staff members
	• A log containing detail of all equipment
	• For each type of test performed there should be a standard form for recording data collection
	• For each type of test performed there should be a standard form for recording data processing
	• A file for each normal database
	• A statement of scope for the laboratory

Statement of Purpose Form

Staff Record Form

Equipment Record Form

Auditor Confidentiality Agreement

Audit Instructions

For this audit you will need:

- Current staff records
- Equipment logs
- Access to laboratory facilities

NB this audit checklist, once completed, must not be removed from the local laboratory, either the original or a copy.

Previous audit

Item		*Yes/No*	*Comments*
RF1	Have all the non-conformances raised in the previous audit been resolved?		

From the current staff records

Item		*Yes/No*	*Comments*
RF2	Does the laboratory have a current staff list?		
RF3	Does the staff list include at least one member of staff with a clinical background and one with a technical background?		
Select one member of staff from the current list		**Name:**	
RF4	Check that either: The member of staff is HPC/GMC registered and their registration details are clearly recorded in the staff log? Or: A named supervisor is listed and their HPC/GMC registration details are clearly recorded in the staff log?		
RF5	Is there evidence of repeatability measures being performed in the last 12 months (if applicable)?		
RF6	Is there evidence of participation in on-going in-service training activities?		
RF7	Is there a list of individual competences for that member of staff?		
Select one member of staff who has joined the team in the last 2 years (if applicable)		**Name:**	
RF8	Is there evidence of training on all local		

	protocols?		
RF9	Is there evidence of shadowing of established staff with signature on completion?		
RF10	Is there evidence of repeat data collection on unimpaired subjects checked against laboratory's normal database for each area of competency?		

From the equipment log

Item		*Yes/No*	*Comments*
RF11	Does the laboratory have a log of all current equipment (see statement of purpose)?		
RF12	Does the laboratory have evidence of annual inspection of simple measurement tools?		
Select one piece of equipment from the current list		**Name:**	
RF13	Does the log list equipment manufacturer, make and model?		
RF14	Does the log list software and version numbers?		
RF15	Does the log list manufacturer's contact details?		
RF16	Does the log specify storage location for manufacturer's operational guidlines?		
RF17	Is there evidence of CE marking if it is a medical device manufactured after 1998?		

From inspection of laboratory facilities

Item		*Yes/No*	*Comments*
RF18	Are the facilities consistent with the statement of purpose?		
RF19	Is there disabled access?		
RF20	Is there access control?		
RF21	Are there disabled toilet facilities?		
RF22	Is there a designated area where the patient can change and be examined in private?		
RF23	Is there a thermometer available?		
RF24	Is the room temperature between 21 and 28ºC?		
RF25	Is the environment quiet and non-distracting?		
RF26	Are there adequate seating facilities for the patient and families?		

RF27	Is the floor surface clean, non-slip, level and free from obstacles?		
RF28	Does the examination couch have a firm surface and adjustable height?		
RF29	Are the examination couch and covers clean?		
RF30	Are there staff hand washing facilities provided?		
RF31	Does the laboratory have a walkway of at least 7m?		
RF32	Does the laboratory have access to simple calibration equipment (eg a set of calibrated weights and a metal pole with markers attached)?		

Audit Instructions

For this audit you will need:

- Laboratory's statement of purpose
- Staff log
- Equipment log
- 2 sets of patient notes (selected at random by the auditor)
- Patient information sheet
- Document defining the patient journey

NB this audit checklist, once completed, must not be removed from the local laboratory, either the original or a copy.

Previous audit

Item		*Yes/No*	*Comments*
RM1	Have all the non-conformances raised in the previous audit been resolved?		

From the Statement of Purpose

Item		*Yes/No*	*Comments*
RM2	Does the laboratory have a clear and current statement of purpose?		
RM3	Does the statement match that given on the CMAS website?		
RM4	Does the statement include test facilities available?		
RM5	Does the statement include clinical expertise?		
RM6	Does the statement specify the level of reporting?		
RM7	Does the statement list any exclusions?		

From the Equipment and Staff logs

Item		*Yes/No*	*Comments*
RM8	Is the list of equipment consistent with the statement of purpose?		
RM9	Is the clinical and technical expertise in the staff log consistent with the statement of purpose?		

From the Patient Notes

Item		*Yes/No*	*Comments*
Select two patients at random from the laboratory diary		**Names:**	

for the last 18 months			
RM10	Does the statement of purpose indicate that the laboratory has the appropriate equipment to answer the referral question?		
RM11	Does the statement of purpose indicate that the laboratory has the clinical and technical expertise to answer the referral question?		
RM12	Does the statement of purpose indicate that the laboratory is able to deliver the required level of reporting?		
RM13	Does the patient seen match the criteria specified in the statement of purpose (The patient does not fit any listed exclusions)?		

Item		*Yes/No*	*Comments*
RM14	Does the laboratory have a standard patient information sheet?		
RM15	Does the information sheet include the CMAS web address to allow patients to read the statement of purpose?		
RM16	Does the laboratory have a written protocol defining the patient journey (including referral, appointment and reporting)?		

Audit Instructions

For this audit you will need:

- Statement of purpose
- Data collection standard
- Access to the laboratory's written protocols
- Access to the laboratory's standard forms (blank)

NB this audit checklist, once completed, must not be removed from the local laboratory, either the original or a copy.

Previous audit

Item		*Yes/No*	*Comments*
DC1	Have all the non-conformances raised in the previous audit been resolved?		

From the protocols

Item		*Yes/No*	*Comments*
DC2	Is there a written data collection protocol of every test named in the statement of purpose?		
Select one test at random from the list and locate the protocol.		**Name:**	
DC3	Does the protocol list the equipment to be used?		
DC4	Does the protocol list the laboratory preparation required (including calibration spot checks)		
DC5	Does the protocol list the patient preparation needed?		
DC6	Does the protocol specify the placement locations for any markers or electrodes		
DC7	Does the protocol identify the minimum dataset required?		
DC8	Does the protocol state which data checks should be performed before the patient leaves?		
DC9	Does the protocol specify the storage location for patient data (electronic and paper records)?		

From the recording method

Item		*Yes/No*	*Comments*
DC10	Is there a standard recording method for every test named in the statement of purpose?		
DC11	Is this method detailed in the protocol?		
Select one test at random from the list and identify the recording methods, locating the appropriate blank forms where appropriate.		**Name:**	
Does the recording method allow recording of the following information (where relevant):			
DC11	Results from calibration checks		
DC12	Results of verification tests involving the patient (as specifed in the local protocol)		
DC13	Comments on compliance/co-operation		
DC14	Indication of whether gait pattern is typical		
DC15	Conditions recorded under (eg barefoot)		
DC16	Staff involved in data collection		
DC17	Problems encountered during data collection		

Audit Instructions

For this audit you will need:

- Statement of purpose
- Data Processing standard
- Access to the laboratory's written protocols
- Access to the laboratory's standard forms (blank)
- Normal data files
- 2 sets of patient notes

NB this audit checklist, once completed, must not be removed from the local laboratory, either the original or a copy.

Previous audit

Item		*Yes/No*	*Comments*
DRM1	Have all the non-conformances raised in the previous audit been resolved?		

From the protocols

Item		*Yes/No*	*Comments*
DRM2	Is there a written processing protocol of every test named in the statement of purpose?		
Select one test at random from the list and locate the protocol.		**Name:**	
Does the protocol specify (where relevant)			
DRM3	The software required and version number		
DRM4	Signal processing requirements (eg filtering)		
DRM5	Definition of an acceptable data trial		
DRM6	Reasons for excluding data trials at the processing stage		
DRM7	Artefact correction techniques (see Appendix 1)		
DRM8	Any secondary processing tools		
DRM9	Any additional specific requirements listed in the processing standard (items 3 – 8)		

From the recording method

Item		*Yes/No*	*Comments*
DRM10	Is there a standard recording method for every test named in the statement of purpose?		

Select one test at random from the list and locate the appropriate blank form.		**Name:**	
Does the method allow recording of the following information (where relevant):			
DRM11	Any problems/artefacts		
DRM12	Signature box/approval method		
DRM13	Software version number used		

From normal data files

Item		*Yes/No*	*Comments*
Select one test at random from the Statement of Purpose		**Name:**	
DRM14	Is there a normal data set for that test, including SD ranges or other acceptable measures of variability?		
DRM15	Is the protocol for the normal database collection available in a controlled location?		
DRM16	Is the protocol used current?		
DRM17	Has the database been checked after any minor changes in protocol?		
DRM18	Does the normal database include at least 10 subjects?		
DRM19	Is there a written policy for including subjects in the normal database?		
DRM20	Has a documented comparison been made between the lab's normal data set and published data sets?		
DRM21	Are all the subject details available (age, sex, date, assessors)?		
DRM22	Do the lab records specify the storage location of the raw data files?		

From the protocols

Item		*Yes/No*	*Comments*
DRM23	Is there a written protocol to define reporting practice, specifying standard content and circulation lists?		

From the patient notes

Item		*Yes/No*	*Comments*
Select two sets of patient notes from the laboratory diary of the last 18 months		**Name:**	

DRM24	Are the report contents consistent with the statement of scope for the laboratory?		
DRM25	Are any treatment recommendations consistent with the statement of scope for the laboratory?		
Do the reports include:			
DRM26	Clinical history		
DRM27	Consistency data		
DRM28	Conditions under which data were collected		
DRM29	Patient compliance/co-operation		
DRM30	Comments on whether data are typical		
DRM31	Comments on any problems identified in the data collection or correction applied.		
DRM32	A dated signature from those taking responsibility for the content		
DRM33	Documentation of the link between the data collected and any treatment recommendations?		
DRM34	Normal reference ranges for values quoted		
DRM35	Normal data plotted on graphs		
DRM36	Normal comparison group identified		
DRM37	References for any validated questionnaires/functional tests used		
DRM38	Clear identification of trial number, date, units and walking condition on any pages of graphs.		
DRM39	Is there a copy of the report kept in the laboratory?		
DRM40	Does this include all raw data, forms and graphs?		

Audit Instructions

For this audit you will need:

- Patient notes and records
- Access to laboratory standards files
- List of staff members
- Access to gait laboratory staff
- Staff records

NB this audit checklist, once completed, must not be removed from the local laboratory, either the original or a copy.

Previous audit

Item		*Yes/No*	*Comments*
DoC1	Have all the non-conformances raised in the previous audit been resolved?		

From the files

Item		*Yes/No*	*Comments*
DoC2	Is there a current copy of the CMAS standards?		
DoC3	Is there a list of all current protocols?		
DoC4	Are all issue dates within the last two years?		
DoC5	Has the list been signed by the head of department within the last 2 years?		
DoC6	Is there a list of recording forms?		
DoC7	Does this list state issue date, author and version number?		
DoC8	Are all issue dates within the last two years?		
Is there a list of all the controlled storage locations for:			
DoC9	Local protocols		
DoC10	Blank recording forms		
DoC11	Completed recording forms		
DoC12	Internal audit checklists		
DoC13	Internal and external audit reports		
DoC14	Is there a backup procedure for electronic files?		

From the protocols

Item		*Yes/No*	*Comments*

Select one test at random from the list of protocols		**Name:**	
DoC15	Does the protocol have an issue date, named author and version number?		
DoC16	Is it edit controlled?		

From the staff

Item		*Yes/No*	*Comments*
Select one staff member from the list		**Name:**	
DoC17	Can the staff member access the relevant laboratory protocols?		
DoC18	Can the staff member access the relevant blank recording forms?		

From the patient notes

Item		*Yes/No*	*Comments*
Select two sets of patient notes from the laboratory diary of the last 18 months		**Name:**	
Do all completed patient records have:			
DoC19	Name, date, date of birth, reference number		
DoC20	A patient reference number on any printed page or each page of a paper form		
DoC21	A signature of the member of staff responsible (cross check staff records for competences) on every page.		
DoC22	No gaps on forms ('N/A' or equivalent should be used)		
DoC23	Are all electronic data stored on a location supported by regular back-up		

NB No confidential information should be recorded on the form eg patient name/number

Audit Summary

Name of External Auditor 1	
Name of External Auditor 2	
Name of Local Observer	

External Audit Number	
Date of Audit	

Audit Checklists Used

	Tick
Resources and facilities	
Referral management	
Data collection	
Data and report management	
Document control	

Previous audits checked

Previous internal audit	*Date*
Comments:	
Previous external audit	*Date*
Comments:	

If any issues remain outstanding from previous audits these should be listed as nonconformances below

List of Nonconformances identified (complete an audit non-conformance report form for each)

Reference Number	Audit checklist item number	Summary	Completion Date for Remedial Action	Verified

Evidence of Good Practice observed

General comments

CLINICAL MOVEMENT ANALYSIS SOCIETY UK and Ireland Audit Nonconformance Report Form	
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NB No confidential information should be recorded on the form patient name/number

Audit Number	
Nonconformance number	
Audit Checklist item number	
Date	

Details of Nonconformance

Auditor	*Signature and Date*

Agreed Remedial Action

Target completion date	
Auditor	*Signature and Date*
Person Responsible	*Signature and Date*

Action Completed

Auditor	*Signature and Date*