INTERNATIONAL STANDARD

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Mechanical vibration and shock — Guidance on safety aspects of tests and experiments with people —

Part 1:
Exposure to whole-body mechanical vibration and repeated shock

Vibrations et chocs mécaniques — Lignes directrices concernant les aspects de sécurité des essais et des expérimentations réalisés sur des sujets humains —

Partie 1: Exposition de l'ensemble du corps aux vibrations mécaniques et aux chocs répétés

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13090-1 was prepared by Technical Committee ISO/TC 108, *Mechanical vibration and shock*, Subcommittee SC 4, *Human exposure to mechanical vibration and shock*.

ISO 13090 consists of the following parts, under the general title *Mechanical vibration and shock — Guidance on safety aspects of tests and experiments with people*:

— *Part 1: Exposure to whole-body mechanical vibration and repeated shock*

— *Part 2: Exposure to whole-body impact*

Annexes A to G of this part of ISO 13090 are for information only.

Introduction

People may be exposed to mechanical vibration and repeated shock intentionally in the course of experiments to determine their response to such environments and in the course of experiments or tests performed for other purposes. It is widely accepted that exposure to mechanical vibration and repeated shock of sufficient magnitude can cause injury or impair health.

In this part of ISO 13090, guidance is provided on the safety aspects of equipment or procedures which are particular to experiments involving mechanical vibration and repeated shock and which affect the safety of those involved.

The purpose of this part of ISO 13090 is to reduce the chance of the subjects, or those monitoring or conducting the experiments, being exposed to undue risk of injury or impaired health arising from such exposure, or of injury attributable to the malfunction or poor operation of the equipment used to generate the mechanical vibration and repeated shock. Guidance on the design of equipment is included in annex E.

In accordance with accepted practice for experiments in which human subjects are involved, the experimenter should obtain approval from an independent Ethical Committee, or "Human Use Committee", giving details of the planned experiment together with a written justification. Some guidelines are included in annex F.

This part of ISO 13090 represents the best international consensus at this time and may be subject to change in the light of future developments in scientific knowledge and experience.

Mechanical vibration and shock — Guidance on safety aspects of tests and experiments with people —

Part 1:
Exposure to whole-body mechanical vibration and repeated shock

1 Scope

This part of ISO 13090 provides guidance on the safety aspects of the design of equipment and the conduct of tests and experiments in the laboratory in which human subjects[1)] are exposed to mechanical vibration and repeated shock.

This part of ISO 13090 is concerned with tests and experiments in which subjects are exposed to whole-body mechanical vibration and repeated shock, as described in ISO 2631-1. Local vibration is not within the scope of this part of ISO 13090, but some of the general procedures may be applicable.

The experiments to which this part of ISO 13090 is applicable include those performed to determine the response of subjects to mechanical vibration and repeated shock stimuli. They also include those experiments in which mechanical vibration and repeated shock are part of the environment in which other investigations are performed, and to experiments or tests to compare the attributes of equipment intended to alleviate the effects of mechanical vibration and repeated shock on the user (e.g. testing of seat suspensions, seat cushions and other attenuating devices, including tests according to ISO 10326-1).

NOTE Measures in addition to those described in this part of ISO 13090 may be necessary in those countries which have relevant national requirements.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 13090. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 13090 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2041:1990, *Vibration and shock — Vocabulary.*

ISO 2631-1:1997, *Mechanical vibration and shock — Evaluation of human exposure to whole-body vibration — Part 1: General requirements.*

ISO 5805:1997, *Mechanical vibration and shock — Human exposure — Vocabulary.*

ISO 10326-1:1992, *Mechanical vibration — Laboratory method for evaluating vehicle seat vibration — Part 1: Basic requirements.*

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1) Hereinafter referred to as "the subject" or "subjects".

3 Definitions

For the purposes of this part of ISO 13090, the definitions given in ISO 2041 and ISO 5805 apply.

4 Hazards of mechanical vibration and repeated shock experiments on human test subjects

4.1 General

Those who engage in experiments which involve exposing subjects to mechanical vibration and repeated shock, and those who supply equipment for such experiments, should address three types of hazard specific to such experiments, in addition to the general responsibility for safety, as follows:

a) the inherent hazard that exposure to the mechanical vibration or repeated shock which the experiment is intended to reproduce may lead to injury or ill-health, either immediately or at some time in the future (see 4.2);

b) the extraneous hazard that malfunction or inadvertent operation of the equipment used to generate the mechanical vibration or repeated shock may cause the subject to be exposed unintentionally to motions so severe as to cause injury or ill-health;

c) the hazard of injury to the subject, the experimenter, or others in the vicinity arising from any of the following:

   1) the relative motion between the vibration equipment and its surroundings,
   2) mechanical, electrical or other failures,
   3) falling.

4.2 Inherent hazards in mechanical vibration and repeated shock experiments

4.2.1 General

The inherent hazard that exposure of a subject to mechanical vibration or repeated shock may lead to injury or ill-health depends on the following two possible causes:

a) use of mechanical vibration or repeated shock that is too severe in terms of magnitude or duration, see 4.2.2;

b) failure to exclude from the test a subject who is medically unfit or otherwise particularly sensitive to mechanical vibration or shock.

NOTE Precautions to be taken with subjects are given in clause 7 and annex D.

4.2.2 Severity of mechanical vibration or shock stimulus

The effects on subjects of mechanical vibration and repeated shock depend on the magnitude, frequency content, direction of action and duration of the stimuli, all of which should be included in assessing the severity.

In all cases, the mechanical vibration is to be measured at the interface of the subject with the vibrating surface. Vibration may be characterized as deterministic (including periodic) or random and, for the purposes of this part of ISO 13090, vibration is restricted to frequencies between 0,5 Hz and 80 Hz. Repeated shocks may be applied with or without the presence of vibration, with various characteristics.

Mechanical vibration and repeated shock should be characterized from measurements of acceleration in three mutually perpendicular axes (see figure 1).

R.m.s. values of acceleration should be obtained using frequency weightings according to ISO 2631-1. The r.m.s. value should be determined using linear integration over the full period of exposure.

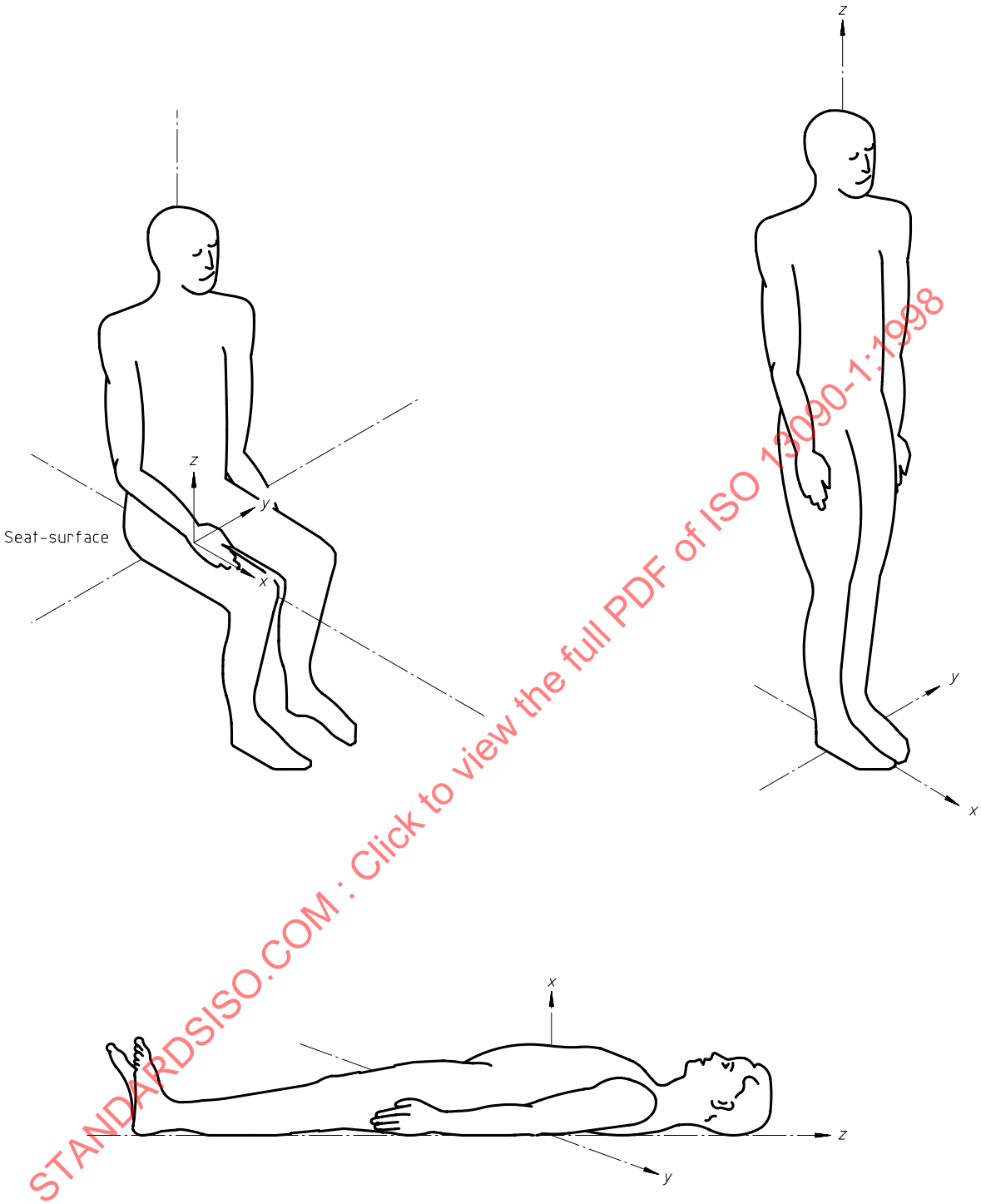

Figure 1 — Basicentric axes of the human body

4.3 Extraneous hazards in mechanical vibration and repeated shock experiments

Many vibrating devices used in experiments have a large quantity of available or stored energy. An inherent problem in the design of vibration systems is that the subject may be exposed to unexpected or frightening transients or, at worst, to potentially dangerous magnitudes of mechanical vibration or shock as a result of an equipment malfunction.

Equipment design should be such that, in the event of malfunction or emergency stop procedures, the subject should not be exposed to accelerations of hazardous magnitude or duration. Equipment should be designed so that no failure could result in magnitudes of mechanical vibration or shock producing accelerations in excess of an acceptable short-term magnitude, unless the experiment is designed to study the effects of higher magnitudes. For such experiments, the magnitude during failure conditions should be only slightly in excess of those being studied.

The equipment should be tested under simulated fault conditions (e.g. as suggested in annex E), to ensure so far as is reasonably practicable that the short-term acceleration does not exceed an acceptable magnitude.

4.4 Physical contact with moving parts

4.4.1 General

Mechanical vibration and repeated shock experiments present the following three particular physical hazards:

a) the experimenter or another person in the vicinity of the equipment may receive a blow through inadvertent contact with the moving parts;

b) the subject on a moving part may receive a blow through inadvertent contact with a fixed object;

c) anyone on the equipment or in the vicinity may be at risk from pinching or shearing between fixed and moving parts.

4.4.2 Restraint of subjects

In experiments where subjects are restrained, special care should be taken to ensure that during normal operation or malfunction the restraint itself does not present a hazard.

5 Classifying experiments according to severity of vibration exposure

5.1 General

The recommendations in this part of ISO 13090 provide for two categories of experiment which are differentiated, according to the degree of risk, as to whether or not a physician or medical doctor should be in attendance or on call. The decision is based on an assessment of the degree of severity of mechanical vibration or repeated shock to which the subjects are to be exposed.

An independent Ethical Committee (see annex F) shall be required to review any proposed experiment involving the exposure of human subject to vibration. This committee shall decide whether an experiment carries "greater than minimal risk", and what is required by way of medical supervision.

5.2 Experiments involving minimal risk

Ethical Committees may not require that a physician or medical doctor be in attendance or on call for tests or experiments in which the subjects are exposed to magnitudes of mechanical vibration or repeated shock comparable to those found in common forms of transportation and in any but the most severe of civilian working environments (see annex A).

5.3 Experiments involving some inherent risk

For experiments in which any subject is exposed to mechanical vibration or repeated shock in excess of that which would be consistent with the safe exposure of workers (see annex A) a physician or medical doctor should be in attendance or on call (see 6.2.4). Prior advice should also be sought from a relevant medical specialist on the inherent risk of the experiment and on the criteria for the selection of subjects (see clause 7).

It is recognized that for certain tests or experiments involving the exposure of subjects to vibrations which simulate real work conditions, the above criterion may require the continuous attendance of a physician or medical doctor when this would be neither expected, nor practicable in the work conditions themselves. In such cases, the advice of the Ethical Committee should be sought as to whether or not the presence of the physician or medical doctor is warranted.

6 Practice for laboratory tests and experiments

6.1 General

The risk of injury in experiments involving human test subjects can be reduced by observing good practices. These include the selection and training of personnel, adherence to well-defined procedures, and the discipline of maintaining adequate records.

6.2 Manning

For any experiments in which a subject is on apparatus capable of causing mechanical vibration or shock stimulus, there should be an operator at the control panel for that apparatus who has a clear view of, or otherwise maintains contact with, both the subject and the apparatus. In some circumstances it may be desirable for a second person to be present as an observer.

For experiments involving greater than minimal risk, i.e. in which the subjects are exposed to mechanical vibration and repeated shock whose severity exceeds that which is consistent with the safe exposure of workers (see annex A), the Ethical Committee may require that a physician or medical doctor be in attendance (see 5.3).

At the time of any test or experiment, there should be, within the laboratory or in close proximity to it, a person trained in first aid, and a means of communicating with the local emergency services.

6.2.1 Experimenter

In any test or experiment, one of those present should be designated as the person responsible for the test or experiment and be recognized as such by all concerned.

6.2.2 Operator

It is imperative that the operator has received training in operation of the equipment either from the manufacturer or from a responsible person experienced in the use of the equipment. The main need is for experience and proficiency in running the equipment, but the operator should also be fully conversant with emergency procedures. The operator should be backed by an adequate maintenance staff.

6.2.3 Observer

The observer should have a good understanding of the test or experiment being conducted and be familiar with emergency procedures for the equipment.

6.2.4 Physician or medical doctor

The physician or medical doctor should be a qualified medical practitioner, fully conversant with possible effects of mechanical vibration and shock on human subjects. The physician or medical doctor should be concerned primarily with the well-being of the subjects and should have absolute discretion to halt the experiment or any part of it.

6.3 Procedures

6.3.1 General

Procedures should be defined for start-up of the equipment and general pre-trial checks, as well as for the operating sequence for each particular trial. These procedures should be displayed where they can be seen clearly from the position of the operator, who should have practised them thoroughly, without a human subject, before starting any trials in which such a subject is used.

It is recommended that the sequences detailed in 6.3.2 and 6.3.3 be included in laboratory procedures.

6.3.2 Start-up and pre-trial checks

A start-up sequence should be formalized to include checks on all monitoring equipment and limiting systems, and on the integrity of the controls and input circuits.

The intended magnitudes of stimulus should be checked to assess the severity of exposure, and the equipment should be operated without a human subject to ensure that the intended stimulus is reproduced correctly. If the dynamic response of the equipment is affected significantly by the presence of a human subject, this check should be made with a substitute. This substitute may be a simple mass, but may in some cases be required to have more representative dynamic properties.

All emergency stop devices should be tested for correct functioning.

Support and restraint features (e.g. seats and harnesses) should be checked.

At regular intervals, and at least before and after each series of trials, the calibration of transducers and circuits used for feed-back control and for monitoring should be checked, as should the accuracy with which the equipment reproduces the full range of stimuli used in the series of trials.

6.3.3 Normal operating sequence

The normal operating sequence for each trial should follow a predetermined routine which is familiar to the operator and to any observer. This should include the sequence of stimuli and their durations, the sequence of any activities in which the subject is to be engaged, and the times at which responses are required of him/her, or at which objective measurements are to be made (e.g. of attributes of his/her physiological state).

The normal operating sequence should also include the times for regular checks that the magnitudes of stimuli in use are within predetermined limits. Preferably, the signals from transducers used to monitor stimuli should be recorded so that any unplanned incident can be assessed against accepted indicators of the severity of mechanical vibration and shock.

The subject(s) should enter or mount the equipment only when it is stationary and in a safe condition. Where appropriate the physician or medical doctor, otherwise the operator or observer, should check that the subject is fit to take part, either by reference to records of previous trials and/or with the requirements of clause 7. It is essential that no trials be made with any subject who has not been checked and authorized as being fit for mechanical vibration and shock experiments by a physician or medical doctor (see 5.3) or another person able to assess the risk.

The operator or observer should also check that the subject is familiar with the experimental procedure and, in particular, that for emergency shut-down, and that the subject is adequately supported and, when necessary, restrained.

The operator should maintain observation of, or otherwise maintain contact with, the subject and any other personnel in the experimental area throughout any period when the equipment is in motion.

The equipment should be brought to rest and made safe before the subject leaves or dismounts.

6.3.4 Subject

The subject should have complete freedom to resign from the experiment, and to stop the experiment during any part of it.

The subject should be provided with an opportunity to report any adverse reaction to the mechanical vibration and repeated shock.

6.4 Documentation

6.4.1 Documentation associated with mechanical vibration and repeated shock experiments on human subjects should include the following:

a) an operational record of the use of mechanical vibration and shock equipment: durations of use and characteristics of the mechanical vibration and repeated shock used; results of start-up and pre-trial checks (see 6.3.2); servicing and maintenance;

b) an experimental protocol of the experiment conducted and documentation of the authorization to proceed;

c) a record of each exposure of any subject to mechanical vibration and repeated shock;

d) check lists for start-up and operational sequence for current trials;

e) a list of people authorized to operate the mechanical vibration and shock equipment;

f) copies of the consent forms as a record that each subject has been questioned or examined with regard to fitness to participate;

g) report of any unexpected reactions or incidents.

6.4.2 The record of exposure of each subject to mechanical vibration and shock should include the following:

a) purpose of the experiment;

b) date of the experiment;

c) identification of the subject;

d) any medical certification provided;

e) nature of mechanical vibration and shock exposure (frequency or bandwidth, acceleration magnitude, duration, whether random or periodic, direction and point of application on the subject);

f) any unusual reactions or after-effects noticed, either by the subject or by the experimental team;

g) name of the experimenter(s);

h) name of the operator in charge of the test or experimental run;

i) name of the observer (if present);

j) name of the physician or medical doctor (if present);

k) name of the chaperone/parent/guardian (if present); children can only be subjects in non-hazardous experiments because of problems with proper informed consent.

NOTE Information regarding the subject should be considered to be confidential and treated appropriately.

7 Selection of human test subjects

It is the duty of the experimenter (in consultation with the physician or medical doctor where appropriate) to ensure that no subject is at risk as a result of being, for example, pregnant, medically unfit or otherwise particularly sensitive to mechanical vibration or shock (see annex C).

For those experiments in which the exposure to mechanical vibration or repeated shock is not so severe as to warrant the attendance of a physician or medical doctor, subjects should be at least fit to travel in public transport without assistance and to accept the stress of a normal day's work. The experimenter should ensure that all subjects understand in general terms the medical conditions which would render them unfit for the experiment prior to obtaining their consent (see annex B and annex D). Care is required in this because some subjects ignore or forget their own weaknesses in their desire to take part in an activity which they perceive as more interesting than their routine. Experimenters also need to be particularly careful if the experiments involve exposure to mechanical vibration or shock which, even though of low magnitude, may be greatly different from that to which the subjects are accustomed.

For those experiments in which the exposure to mechanical vibration or repeated shock involves more than minimal risk (i.e. is so severe as to warrant the attendance of a physician or medical doctor), a higher degree of fitness may be required. It is the responsibility of the physician or medical doctor to assess this fitness. The physician or medical doctor should question potential subjects to ascertain this fitness, having cognizance of the contra-indications listed annex C, and should decide on any need for medical examinations and certification.

Occasionally it may be necessary to conduct experiments using people who would normally be ruled as unfit as subjects for mechanical vibration and repeated shock experiments. It is essential that competent medical advice be sought before undertaking such work, that the Ethical Committee should approve it, and that a physician or medical doctor be in attendance.

All participation of human test subjects should be on the basis of written informed consent.

Annex A
(informative)

Severity of exposure

In planning a test or experiment involving the exposure of human subjects to mechanical vibration or repeated schock, severity of exposure is the measure on which is based the criterion for deciding whether or not a physician or medical doctor should be in attendance.

The criterion is a combination of vibration magnitude and duration of exposure, such that an increase in one would require a decrease in the other. This criterion is taken from the health caution zones in ISO 2631-1:1997, annex B, which apply to people in normal health who are regularly exposed to vibration (see figure A.1).

These are mainly based on exposures in the range of 4 h to 8 h, for which most occupational observations exist. Most tests and experimental work involve the exposure of human subjects on an occasional, rather than a long-term daily basis. For this reason, the criterion is based on the upper limit in figure A.1. For any tests or experiments in which human subjects are to be exposed to mechanical vibration regularly over an extended period, greater caution may be required.

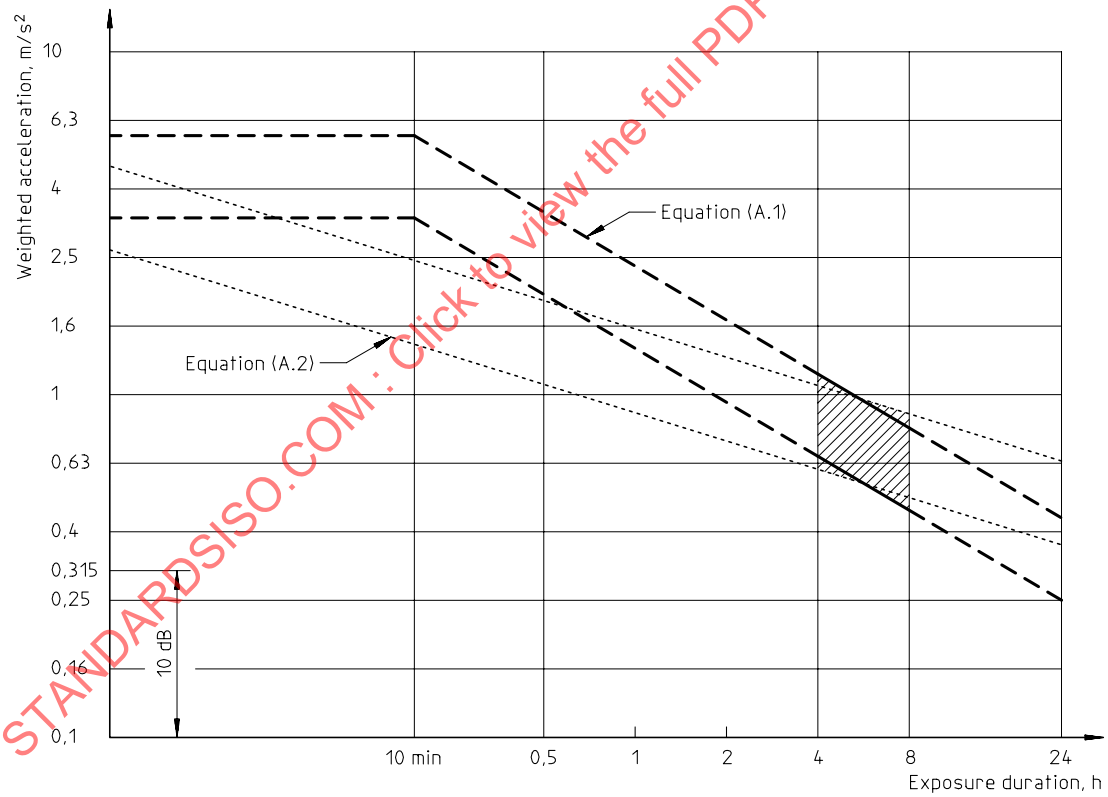

Figure A.1 — Health guidance caution zones (from ISO 2631-1:1997, annex B)

Note that exposure in the most severe civilian working environments is above the upper limit at the 4 h to 8 h duration.

For exposure durations shorter than 4 h per day, or longer than 8 h per day, the guidance of ISO 2631-1:1997, annex B, is tentative. The guidance states that there are not sufficient data to show a quantitative relationship between vibration exposure and risk of health effects. However, it does include two possible relationships, which are used to develop the alternative caution zones in figure A.1.

These are:

$$a_{w1} \cdot T_1^{1/2} = a_{w2} \cdot T_2^{1/2} \quad \text{(A.1)}$$

and

$$a_{w1} \cdot T_1^{1/4} = a_{w2} \cdot T_2^{1/4} \quad \text{(A.2)}$$

Concern has been expressed about the magnitudes of vibration for short durations which would be considered as not involving any inherent risk. According to equation (A.1), these could be as much as 6 m/s^2 for 10 min. For this reason, the guidance proposed in table A.1 is based on equation (A.2).

Table A.1 — Exposure to vibration and repeated shock requiring attendance of a physician or medical doctor

Duration of exposure in any one 24 h period	16 min	1 h	4 h	8 h
Acceleration magnitude, m/s^2 (frequency-weighted r.m.s. acceleration)	2,2	1,6	1,1	0,9
NOTE Repeated shock is quantified only very approximately by r.m.s. acceleration values.				

The criterion for requiring the attendance of a physician or medical doctor is therefore that the frequency-weighted r.m.s. acceleration, measured over periods of exposure in the direction giving the greatest magnitude, is intended to exceed values given in table A.1.

In tests or experiments in which subjects are exposed to vibration or repeated shock exceeding the magnitudes in table A.1, a minimum of 48 h is recommended between repeated exposures for an individual, with no more than two exposures in any 5-day period.

It is recognized that for certain tests or experiments involving the exposure of subjects to vibrations which simulate real work conditions, the above criterion may require the continuous attendance of a physician or medical doctor when this would be neither expected, nor practicable in the work conditions themselves. In such cases, the advice of the Ethical Committee should be sought as to whether or not the presence of the physician or medical doctor is warranted.

Annex B
(informative)

Example of consent form for a human test subject in mechanical vibration and repeated shock experiments

IN CONFIDENCE

Consent to act as a subject in an experiment/demonstration involving exposure to mechanical vibration and repeated shock

1 Personal details

1.1 Name:

1.2 Age: years **1.3** Sex: Male/Female

1.4 Address:

2 Declaration

2.1 I hereby volunteer to be an experimental subject in a mechanical vibration and shock experiment with the designation or reference number:

to be conducted by:

at:

during the period to

2.2 I understand that any information about myself which I have given, and may give in the course of the experiment, will be treated as confidential by the experimenter(s) whose signature(s) is/are given below.

2.3 Explanations of the purpose of the experiment, the nature of the mechanical vibration and shock to be used, and the potential hazards and the precautions taken against them have been given to me.

2.4 While agreeing to attend for the purposes of the experiment at the time(s) and place(s) requested by the experimenter(s), I fully understand that I may at any time withdraw from taking part in the experiment and that I am under no obligation to give a reason for my withdrawal or to attend again for experimentation.

2.5 While in the laboratory, I undertake to observe the regulations in force governing its use. I also agree to obey instructions given to me by the experimenter(s) regarding safety, subject only to my right to withdraw declared above.

2.6 I understand that acceptance of the risks does not abrogate my right to legal redress, and possible compensation.

Signature: Date:

Witnessed by: Date:

Experimenter (signature):

Annex C
(informative)

Medical contra-indications to participation in experiments involving whole-body mechanical vibration and repeated shock

C.1 General

It is accepted that any person suffering from a disease process or pathology likely to be aggravated by mechanical vibration and shock exposure or emergency stop acceleration should not be an experimental subject. If the experimenter is uncertain that the well-being of a potential test subject with a particular medical or surgical disability or disorder will not be impaired by a particular mechanical vibration and shock exposure or emergency stop acceleration, then the opinion of an experienced medical practitioner should be sought.

C.2 Mental health

The subject should be of sound mind and understanding and not suffering from any mental disorder that would raise doubt that his/her consent could not be relied upon as being a true and informed consent.

C.3 Recent trauma and surgical procedures

Persons who have recently had surgical operations or suffered traumatic lesions (e.g. fractures) and are still under medical supervision should not act as test subjects. The period for which such persons should not be exposed to mechanical vibration and shock depends on many factors and, in certain cases, their medical history may exclude them from any further participation in experiments involving such exposure. The opinion of the person's surgeon or medical adviser should be sought if there is any doubt about his/her suitability as a test subject.

C.4 Prostheses

The presence of an internal or external prosthesis usually renders the person unsuitable as a test subject, although dentures, external hearing aids, spectacles and contact lenses should not preclude participation.

C.5 Specific disorders

Persons with any of the following conditions may be unsuitable as test subjects:

a) active disease of the respiratory system, in particular a recent history of haemoptysis (coughing up blood) or chest pain;

b) active disease of the gastro-intestinal tract, in particular the presence of an internal (e.g. hiatus) or external (e.g. inguinal) hernia, peptic ulceration, recent history of gall bladder disease, rectal prolapse, anal fissure, haemorrhoids or pilonidal sinus;

c) active disease of a genito-urinary system, in particular renal calculi, urinary incontinence or retention, or difficulty in micturition, female genital prolapse and other uterine disorders (e.g. large fibroids);

d) active disease of the cardiovascular system, in particular hypertension requiring treatment, angina of effort, valvular disease of the heart, or blood dyscrasias with prolongation of bleeding time (e.g. haemophilia);

e) active disease or defect of the musculo-skeletal system, in particular degenerative or inflammatory disease of the spine, long bones or major joints, or a history of repeated injury with minor trauma;

f) active or chronic disease or disorder of the nervous system, including organs of special sense (the eye and the ear), in particular, any disorder involving impairment of motor controls of the limbs or head, wasting of muscles, epilepsy and retinal detachment.

C.6 Pregnancy

Only such women who are sure that they are not pregnant should participate as subjects in mechanical vibration or shock experiments. For any experiments in which the exposure to mechanical vibration or repeated shock involves more than minimal risk, i.e. is so severe as to warrant the attendance of a physician or medical doctor, a test for pregnancy is recommended.

C.7 Experiments of minimal risk

For experiments of minimal risk, it may be sufficient for the experimenter to obtain satisfactory answers to the following questions:

C.7.1 Have you ever suffered from a serious illness? (YES/NO)

If YES, please give brief particulars and approximate date(s):

C.7.2 Have you ever been injured seriously (i.e. badly enough to be treated by a doctor or taken to a hospital)? (YES/NO)

If YES, please give brief particulars and approximate date(s):

C.7.3 Are you at present under medical treatment of any kind? (YES/NO)

If YES, please indicate what kind of treatment (e.g. medicines, appliances, physiotherapy, psychotherapy, dressings):

C.7.4 Do you suffer from any defect or disability affecting your daily life, work or travelling? (YES/NO)

If YES, please give brief particulars:

C.7.5 Do you suffer from, or have you in the past suffered from, any of the following conditions: back or neck problems, cardiovascular disorders, diseases of the ears or eyes, retinal detachment? (YES/NO)

If YES, please give brief particulars:

Only in the event of negative replies to all of these questions should a subject be accepted without medical advice.

Annex D
(informative)

Principles pertaining to the use of human subjects

D.1 General

There are certain ethical responsibilities incumbent on both the individual investigators and their superiors, who should be familiar with the "Code of Ethics of the World Medical Association" (Declaration of Helsinki) (see annex G). It is essential that the subjects be volunteers who have been fully informed of the risks involved. As well as the obvious responsibility to minimize risk, there is also the responsibility to protect the dignity, physical and mental welfare and privacy of the subject.

D.2 Shared risks

It is a fallacy that exposing volunteers to novel or risky procedures (and these might include severe whole-body mechanical vibration and shock) is somehow made respectable by the experimenter exposing himself or herself to the same risk. The fallacy resides in the assumption that all people share the same threshold of distress or injury and the same criteria of personal dignity and privacy.

D.3 Over-investigation

It is occasionally the practice, when subjects have volunteered for exposure to severe experimental conditions, to submit them to elaborate investigation "because they are there". This is undesirable.

D.4 Validity of consent

D.4.1 General

The principle of free and informed consent is crucial to all ethical human experiments. A commonly held belief is that, by signing a consent form, blood-chit or disclaimer, a subject releases the experimenter from liability in the event of his/her being injured during the experiment. Such waivers are neither valid nor ethical, and should not be used.

D.4.2 Free consent

For consent to be free, the subject will need to be fully aware that he/she is able to withdraw from the experiment at any time and the experimenter will have to agree to respect his/her wishes. Particular caution is necessary when the subject is directly or indirectly subordinate to the experimenter or when remuneration is offered as an inducement to take part. No attempt at unreasonable persuasion or coercion should be made under any circumstances.

D.4.3 Informed consent

For consent to be informed, it is crucial that all essential aspects of the experiment, including any foreseeable hazards, will need to be understood by the subject. He/she may also reasonably be considered as entitled to a general explanation of the purpose of the experiment which should be available in a written form.

An example of a suitable form for recording the subject's consent is shown in annex B.

D.5 Children

In general, children should not be allowed to participate in experiments without an ethical justification which has been accepted by the Ethical Committee.

Children should participate in experiments only when arrangements for their chaperoning, approved by the Ethical Committee, are in operation.

Annex E
(informative)

Design of equipment

E.1 General

The equipment should be designed and constructed so that under normal operation the motion stimulus can be controlled by the operator and that the magnitudes of mechanical vibration or shock do not exceed the expected values.

Other than as indicated in 5.3, the subject should not be exposed to sustained or transient acceleration in excess of either

— one-second frequency-weighted running r.m.s. value of 10 m/s^2 (see ISO 2631-1:1997, 6.3.1), or

— fourth-power vibration dose value (VDV) of 17 $m/s^{1,75}$ (see ISO 2631-1:1997, 6.3.2)

in the event of the failure of any of the following:

1) the operator,
2) the electrical or mechanical components of the device,
3) the software in programmable systems.

In order to ensure safe operation, the designer and user of the equipment should pay particular attention to the following features.

a) Mechanical and electrical components should be chosen for high reliability and should be conservatively rated.

b) Moving parts should be adequately guarded in order to protect the subject, the operator and any observer in the vicinity of the machine.

c) The subject should be adequately restrained, particularly where malfunction would jeopardize the safety of an unrestrained subject.

d) The device and any electrical equipment used in conjunction with the machine should be adequately earthed so that the subject and operator are protected from electric shock.

e) Emergency stop and shut-down procedures should render the device safe so that the subject can escape from the equipment with the minimum of delay in the event of an emergency. The purpose of emergency stop devices is to remove the hazard in a safe and controlled manner. They should not in themselves create a hazard.

f) Safety and control wires and fluid power lines should be positioned and secured in such a manner that the risk of accidental disconnection or breakage is minimized.

In addition to these general design features, points relating to the operational controls and displays, the control and associated limit circuits, end-of-stroke snubbing and test facilities are dealt with in clauses E.2 to E.6. However, this list covers only features which experience has shown to be important for particular systems (mainly electrohydraulic). It is the duty of the system designer and user to examine a particular system and attempt to predict and combat all possible modes of failure.

E.2 Operator controls and displays

E.2.1 Due attention should be given to the ergonomics of operator controls and displays.

E.2.2 The start-up and shut-down procedures should follow a logical sequence and be sequence interlocked to prevent improper operation.

E.2.3 The operator should be provided with displays which unambiguously indicate the following:

a) the status of the safety circuits and the nature of a malfunction if this is detected by a safety circuit;

b) when the device is in a safe mode (e.g. when the actuator is not energized or is physically locked) in order that the subject may safely be positioned on, or leave, the motion platform;

c) the magnitude of the motion stimuli being generated by the device (e.g. displacement, velocity, acceleration of the platen);

d) the levels at which any pre-set limit circuits will operate.

It is recommended that the equipment incorporate a facility which demonstrates, each time the equipment is switched on, that all malfunction displays are operative and that system parameters are within normal limits.

E.2.4 It is recommended that the operator has sight, either directly or by closed-circuit television, of the subject and relevant equipment so that normal or abnormal operation can be visually assessed. Alternatively, the operator should be in voice communication with the subject so that the operator may terminate the motion stimulus in a controlled manner if requested by the subject. Where possible, both visual and voice communication should be available.

E.2.5 There should be ready access to the subject in the event of his/her distress or equipment malfunction.

E.2.6 Controls, such as a decade switch, which by inappropriate action could cause undesirable transients or excessive movement of the subject, should not be used.

E.2.7 The operator should have immediate and ready access to a clearly labelled control which initiates an emergency stop. If this control does not provide complete electrical shut-down and isolation of the system and associated equipment, the operator should have ready access to an isolating switch. Convenient shut-off valves on relevant fluid power lines (e.g. compressed air), not controlled directly by the emergency stop logic, should be provided.

E.2.8 The operator should have control of a scaled input attenuator which determines the magnitude of the demand signal fed to the control system. This should be designed to avoid the sudden application of an excessive demand function, e.g. by use of a multiturn, or single turn progressive or log-law, control.

E.3 Subject controls

The subject shall be able to stop the motion stimulus by the operation of an emergency stop control, usually a push-button switch, which can be held in the hand or is placed in a position to which he/she has immediate and ready access. Depending upon the design of the equipment, this control may either initiate an emergency stop, which in some equipment may produce relatively high transient accelerations, or a more gentle controlled stop in which the motion stimulus is removed by the application of an appropriate function to the control system.

Communication between the subject and the operator also allows him/her to request the termination of exposure to the motion stimulus.

E.4 Control system

E.4.1 General

There are a number of design features of the control system and actuator which contribute to safe operation, although in a particular device all the features detailed in E.4.2 to E.4.5 may not be required.

E.4.2 Input monitor

This circuit monitors the demand function to the control system and, if pre-set limits are exceeded, the demand function is modified. In its most basic form, this circuit may act as a simple limiting device, which may be acceptable

if the platen acceleration follows the input signal. However, if the input determines platen velocity or displacement, clamping the input signal could give rise to an unacceptable acceleration transient.

More complex circuitry allows limits of displacement, velocity, and/or acceleration to be pre-set and for the input signal to be modified in such a manner that excessive platen accelerations are not generated if these limits are exceeded.

E.4.3 Platen motion monitor

An input monitor does not protect the subject from aberrant motion stimuli generated by failures within the control system. Consequently, it is highly desirable that the motion of the platen be monitored by circuitry which stops the motion if this exceeds pre-set limits. Whether the withdrawal of the motion stimulus is achieved through the control system (i.e. a controlled stop), or the control system is disabled and an emergency stop sequence is initiated, depends upon the detailed design of the equipment.

As malfunction of the equipment can arise from failure of transducers of platen motion, which lie within the control loop of the device, it is highly desirable that separate transducers be used for monitoring platen motion.

E.4.4 System monitor

This circuit monitors parameters within the control system which are indicative of normal operation, such as the supply rail voltages, amplifier current, servovalve operation, integrity of transducer circuits, etc. If any of these parameters exceeds pre-set limits then a shut-down procedure is initiated with an emergency stop of platen motion.

Careful consideration should be given to the behaviour of the system when failure of the main electrical supply occurs. For example, electrohydraulic machines are likely to have considerable stored energy which has to be dissipated without excessive acceleration of the platen. Preservation of the power supply to electronic circuits for sufficient time for a controlled stop to be completed is thus highly desirable and can be achieved by the provision of suitable batteries or equivalent stand-by power supplies.

E.4.5 Other limiting techniques

For any mechanical vibration or shock machine there are performance boundaries which are determined by the peak power available, the displacement of the actuator, and the frequency response of the system. In those situations in which it is not necessary to achieve the maximum performance of the device, it is desirable to restrict performance by means which are not dependent upon input or output (platen motion) monitoring circuits.

In electrohydraulic mechanical vibration machines, peak platen velocity can be limited by restricting flow (e.g. by operating with a minimum number of servovalves in a multiple valve system); peak accelerations can be controlled by adjustment of system working pressure or by a bi-directional relief valve connected across the ports of the actuator. In electrodynamic machines, acceleration can be controlled by limiting the peak current available to the actuator.

E.5 Displacement limiting and snubbing

Provision should be made for the motion of the platen to be limited, in the event of failure of the monitoring circuits and the platen being driven into the end stops at the maximum velocity achievable, to either

– one-second frequency-weighted running r.m.s. acceleration of 10 m/s^2 (see ISO 2631-1:1997, 6.3.1), or

– fourth-power vibration dose value (VDV) of 17 $m/s^{1,75}$ (see ISO 2631-1:1997, 6.3.2).

Several techniques are available to limit acceleration and dissipate the energy of the moving structure when the actuator exceeds its normal displacement. It should be noted that optimum performance, with stopping over the