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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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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

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.

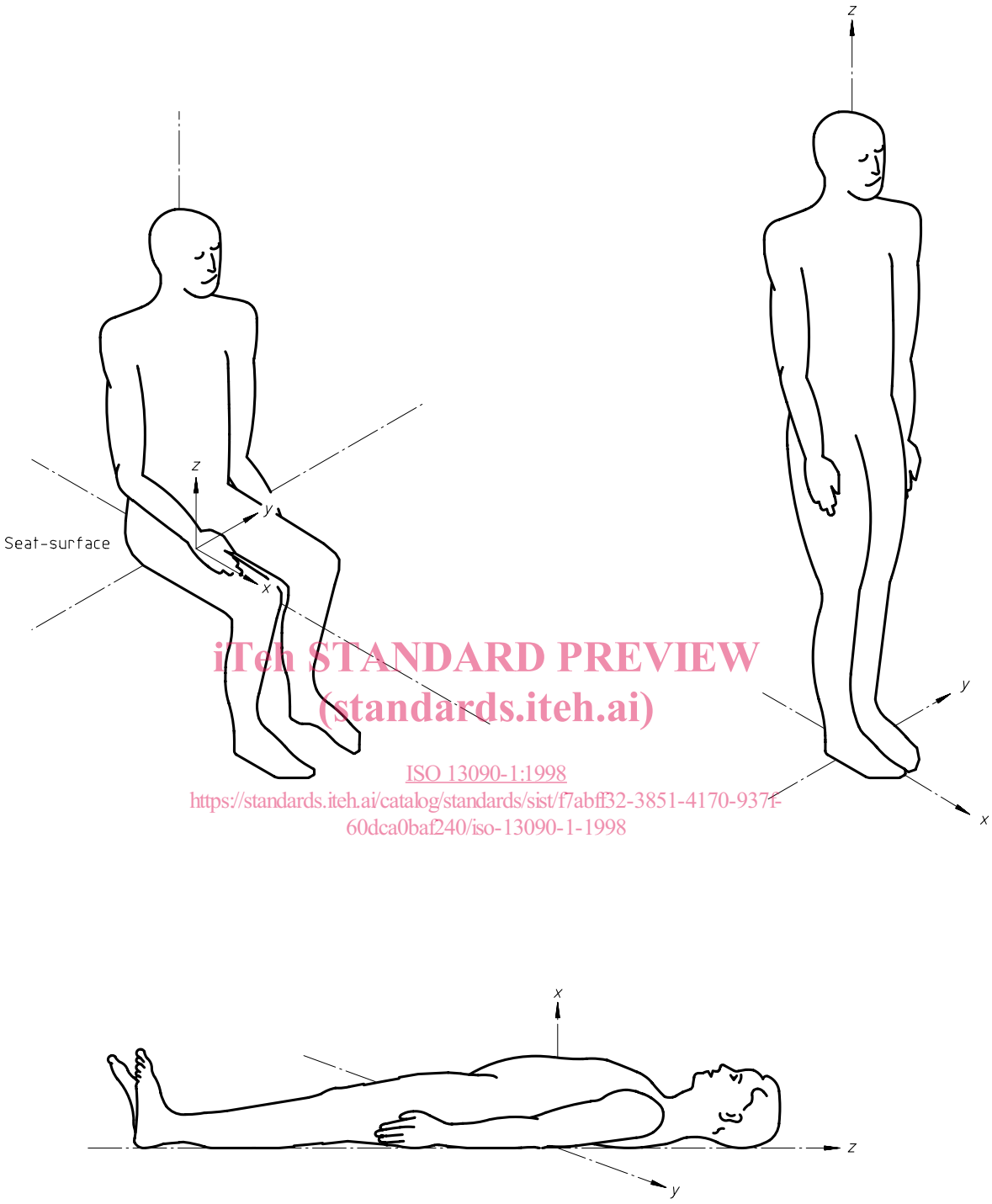

Figure 1 — Basicentric axes of the human body

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 assessee 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 bserver, 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);