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BMJ Open Grasping rehabilitation using motor imagery with or without neurofeedback after tetraplegia: a study protocol for a bicentric randomised controlled trial

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ABSTRACT

Introduction Tetraplegia causes extensive sensorimotor deficits affecting activity, participation and quality of life. People with C6-C7 tetraplegia can learn to grasp objects by performing wrist extension movement (ie, tenodesis grasp), and motor imagery (MI) added to rehabilitation significantly improved tenodesis grasp. We hypothesise that this improvement can be further boosted by adding neurofeedback during MI. Thus, we design a randomised controlled trial investigating the effect of MI training on grasping ability in people with C6-C7 tetraplegia.

Methods and analysis We will perform a bicentric, assessor-blinded, randomised controlled study. During rehabilitation, 21 inpatients with C6-C7 tetraplegia will be allocated to MI with neurofeedback (MI training with graphical display on a computer screen based on mu (8–13 Hz) and beta (18–25 Hz) frequency rhythms measured with 32-channel electroencephalography), MI alone (only MI training) and control (watching movies and visualisation of geometric shapes). All participants will receive three 45-min training sessions per week for 5 weeks.

The primary outcome measure will be wrist extension angle immediately after the intervention during tenodesis grasp measured with a 3D motion analysis system (VICON). Secondary outcomes will include a range of measures: kinematic, grip strength, upper limb range of motion, upper limb strength (manual muscle test and hand-held dynamometer measure), dexterity (box and block test, 9-hole peg test, Jebsen test, capabilities of upper extremity questionnaire), quality of life (WHOQOL-Bref), daily life autonomy (Quadriplegic Index of Function), MI capacity and brain reorganisation (magnetoencephalography only available in Lyon, n=15). We will measure all outcomes five times: during weeks 1, 3 and 5 (baseline), week 11 (immediately after the intervention end) and week 18 (8 weeks after the intervention end).

Ethics and dissemination Ethical approval was granted on 29 September 2017 (CPP Nord-Ouest-IV 17/25, N°2017-A00990-53). Dissemination will occur via presentation of results in scientific meetings and publication in peer-reviewed academic journals.

Trial registration number NCT03190863 (ClinicalTrials.gov).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This bicentric study (Lyon, Montpellier) is randomised, controlled and assessor-blinded.
- ⇒ Outcomes will be grasping kinematics (primary) and measures related to impairment, activity and participation.
- ⇒ Outcomes will be measured before the intervention (three times during the baseline phase), immediately after the intervention and 2 months later (follow-up).
- ⇒ By covering all aspects of the International Functioning Classification, we will measure a large number of outcomes, which may place an additional burden on participants in terms of time commitment.
- ⇒ The large number of outcomes could lead to a high drop-out rate from the study.

INTRODUCTION

Background and rationale

Cervical spinal cord injury (SCI) mostly occurs in young people (60% of SCI patients are under 30).¹ A neurological lesion at C6 and C7 causes paralysis of the finger flexors and extensors which severely impairs grasping and limits activities of daily-life and restricts participation (eg, involvement in social, family and work roles).² C6-C7 lesions spare the extensor carpi radialis longus muscle and people can learn compensatory prehension mechanism (the tenodesis grasp). This uses wrist extension to shorten the tendon of the thumb or finger flexors resulting in a passive lateral or palmar grip.³ Studies of functional electrical stimulation and wrist extension have demonstrated that increasing wrist extension angle increases grip strength, which is associated with improved performance in daily life activities.^{4–6} Intensive rehabilitation after C6-C7 tetraplegia is crucial for learning to perform the tenodesis grasp and to use it effectively during functional activities.⁴ The time and effort involved in learning



is, however, rewarded by enhanced participation and improved quality of life.^{5,6}

Motor imagery (MI— the mental representation of an action without concomitant physical execution⁷) is a rehabilitation method that can be added to usual neurological rehabilitation to potentiate rehabilitation effects.⁸ Pairing MI with rehabilitation is thought to enhance rehabilitation effects because similar brain areas are recruited during actual and imagined movement (the functional equivalence principle).^{9–11} Despite its potential, a review of the literature found only one non-randomised controlled study of MI in individuals with C6-C7 tetraplegia.¹² This study reported improved compensatory prehension after MI, above-and-beyond the plateau of recovery observed after usual care, and increased wrist extension angle during grasping.

The accompanying functional neuroimaging data revealed that this change was associated with a reduction in contralateral somatosensory cortex activity.¹³ Neurofeedback training protocols that provide patients with a graphical representation of their brain activity can help them learn to alter their sensori-motor rhythms.¹⁴ One of the main factors hindering progress in MI rehabilitation protocols is the fact that patients receive no feedback about their performance.¹⁵ Providing graphical neurofeedback of cortical activity during MI could overcome this limitation and lead to better outcomes for patients. Given the accumulating evidence that neurofeedback facilitates plasticity and improves neurological rehabilitation outcomes,¹⁶ we hypothesise that the addition of neurofeedback to MI will result in greater improvements in tenodesis grasp than MI alone and that both of these interventions will improve tenodesis grasp more than usual care.

Objectives

This multicentric randomised controlled trial (RCT) including three parallel groups aims to investigate the effect of MI training (with and without neurofeedback) on tenodesis grasp.

METHODS AND ANALYSIS

Study design

This will be an 18-week, assessor-blind, 3-arm, bicentric (Lyon and Montpellier) RCT. The study trial complies with the Standard Protocol Items: Recommendations for Interventional Trials recommendations and guidelines.¹⁷

Population

People will be eligible if they meet the following inclusion criteria: (i) aged between 18 (ie, majority in France) and 55 (ie, conservative upper limit set to prevent the potential shift from the first to third MI perspective reported in older people¹⁸), (ii) presenting with a neurological level of injury at C6 or C7 as defined by the American Spinal Injury Association (ASIA) and an ASIA Impairment Scale A (ie, no sensory or motor function preserved in the

sacral segments S4-5) or B (sensory but not motor function preserved below the neurological level including the sacral segments S4-5 (light touch or pin prick at S4-5 or deep anal pressure) and no motor function preserved more than three levels below the motor level on either side of the body), with complete finger flexor paralysis limiting grasping capabilities to tenodesis, (iii) tetraplegic for at least 6 months (the time at which recovery reaches a plateau evidenced by no further increase in wrist extensor strength despite ongoing rehabilitation¹⁹) with no upper limit in time since injury, (iv) able to sit for more than 1 hour to complete the assessments and intervention, and (v) eligible for French social security healthcare. Exclusion criteria will be (i) inability to perform tenodesis grasp due to upper limb pain or restricted wrist and/or finger range of motion, (ii) inability to imagine grasping movements, (iii) surgical tendon or nerve transfer aimed at improving grasping capabilities (eg, restoration of active finger flexion) on the upper limb targeted by our intervention, (iv) participation in another ongoing study with potential confounding effects and (v) for participants included in Lyon, the presence of metallic fragments inside the body contraindicated for magnetoencephalography (eg, pacemaker, neurostimulator, cochlear implants, steel dental implant).

Patient and public involvement

People with C6 and C7 tetraplegia who had already completed their rehabilitation were involved in the research design. During routine, follow-up hospital visits, they were asked if they would be interested in speaking with a clinician/researcher about the construction of a study protocol. Those who replied positively took part in a one-on-one interview with the principal investigator, who considered their views and ideas while constructing the final protocol.

Setting and recruitment

Eligible people will be recruited from two French University teaching Hospitals (Hôpital Henry Gabrielle, Hospices Civils de Lyon in Lyon and Centre Mutualiste Neurologique Propara in Montpellier). All assessment measures will be obtained within these hospitals, with the exception of magnetoencephalography data which will be collected at the imaging centre in Lyon (Centre d'Exploration et de Recherche Multimodale et Pluridisciplinaire—CERMED). The first participant has already been enrolled (date: 28 March 2018). Under normal (non-pandemic) circumstances, the average number of patients hospitalised with C6-C7 tetraplegia is 3/year in each hospital. Since late 2019, this number has drastically decreased; thus, we anticipate that recruitment will be slower than for previous studies of this population. Indeed, since the beginning of the study, the actual enrolment rate has been 1.8 per year (as of 15 March 2024 11/21 participants have been enrolled in the study).

The principal investigators (PIs) will provide clear information about the study prior to enrolment to allow

enough time for eligible people to provide their informed consent. The PI will answer any questions asked during the enrolment visit. To consent to participate in the study, people with C6-C7 tetraplegia will be asked to provide informed consent by signing a consent form or, if unable to sign themselves due to their SCI, a proxy will sign the consent form for them in their presence (see online supplemental material).

Interventions

The study will include three phases: baseline (weeks 1 to 5), intervention (weeks 6 to 10) and follow-up (weeks 11 and 18). During the study, all participants will continue their usual, inpatient rehabilitation programme. The risk of hospital discharge before the end of the study is very low, since in France, rehabilitation after SCI lasts more than 12 months. In some cases, discharge might occur after week 11 in which case, the participant will return to the hospital (day hospitalisation) for the follow-up visit at week 18.

An independent statistician used a computer-generated random number generator to randomise enrolments by block separately for each centre. Before enrolment of the first participant, information related to group allocation for each participant in each centre was placed in an opaque and sealed envelope numbered in ascending order. All unopened envelopes are secured in a locked cupboard accessible only by the PI. The PI reveals group allocation to the participant at the end of the baseline phase (week 5) by opening the appropriate envelope in their presence. To maintain assessor blinding, the participant will be instructed not to reveal details about their group allocation to other study participants or to members of their rehabilitation team.

The three experimental interventions will each consist of three 45-min training sessions per week for 5 weeks (total practice duration 675 min). This duration is similar to that previously used in MI training protocols with people with C6-C7 tetraplegia.^{13 20–22} All training sessions will be supervised by a therapist not involved in the assessment measurements.

Control intervention

Participants allocated to the control intervention will watch one episode of a science programme²³ and perform a mental imagery task.^{13 20} This combination of a passive and an active task provides comparable intervention time for all three groups. One episode of a popular science programme aimed at the general public (*'C'est pas sorcier'*, Multimedia France Production) will be shown to participants per training session (mean duration 26.3 min (SD=38s)). Following this, participants will be asked to complete a 10-min mental imagery task in which they will visualise 2-dimensional shapes. A geometric figure chosen randomly from a total of 776 geometric shapes (see online supplemental annexe 1) will be displayed for 4s on a computer screen using E-prime3. Participants will be asked to visualise the same figure for 4s

(mental imagery) and to rate the vividness of the image they generated (from 1: no image to 5: as clear as the image displayed on the computer screen). The visualised shapes will be different in every session and the number of shapes to be visualised will increase from 40 in week 1 (ie, during the three first sessions) to 60 in week 5. Brain activity will also be recorded during this mental imagery task using a 32-channel EEG cap (eego™ sport, ANT neuro, Enschede—The Netherlands). EEG will be recorded during one of the three weekly sessions.

Motor imagery intervention

Participants allocated to the two motor imagery groups (ie, with and without neurofeedback) will follow the same 5-week MI grasping training procedure, three 45-min sessions per week. A different grip/requirement of the tenodesis grasp will be trained for all three sessions in a given week and will change each week with some variability introduced by changing the object to be grasped (see online supplemental annexe 2). The training order will be pseudo-randomised; the order in weeks 1 and 2 will be randomised between palmar and lateral grips, and the order in weeks 3 to 5 will be randomised between grip requiring strength, grip requiring accuracy and grip towards objects of daily life chosen by the participant. Each of these training sessions will be divided into blocks. In a single block, the training sequence will consist of one actual execution (physical practice: PP) followed by five consecutive imagined movements (motor imagery: MI). In order to train visual and kinaesthetic MI separately, for a given movement, the training sequence will be repeated twice with the order of repetition counterbalanced across blocks to control for potential effects of order or fatigue.¹³ Each week, the ratio of physical practice to imagined movements will be increased from 1:5 to 1:9 by introducing an additional repetition of the imagined movement into the training blocks. A single session will consist of 6 training blocks (see table 1 for an example). Participants will be instructed to keep their eyes open (to maintain consistency between participants with and without neurofeedback) and to use a first-person perspective during MI training.

All training sessions for a given participant will be supervised by the same therapist (either a physical therapist or occupational therapist). Instructions will be displayed on a computer screen and movement durations will be recorded by the experimenter pressing a key at the start and finish of a physical movement or in response to the start/stop signal given by the participant for imagined movements. After each single MI trial, participants will be asked to rate the vividness of their MI using a 5-point Likert scale (1 corresponding to the absence of image/sensation, 5 to a full and clear image/sensation—as intense as during physical practice). Scores are based on the clarity of the image for visual MI and the intensity of the sensation for kinaesthetic MI (see figure 1). In addition, the participant will be asked to provide a short description of their visions/sensations. Using both the

Table 1 Example of one training session focusing on lateral grip (LG) using tenodesis grasp and consisting of 6 blocks of practice starting with a warm-up (ie, wrist extension movements without grasping) alternating physically practiced movement (PP, number of trained movements n=1) and motor imagery (MI, n=5)

Block	Aim	Object	PP (n)	MI modality (n)	PP (n)	MI modality (n)
1	Warm-up ²	No object	(1)	V (5)	(1)	K (5)
2	LG	Cube35	(1)	V (5)	(1)	K (5)
3	LG	Pen	(1)	K (5)	(1)	V (5)
4	LG	Marble15	(1)	K (5)	(1)	V (5)
5	LG	Trombone50	(1)	K (5)	(1)	V (5)
6	LG	Screw35	(1)	V (5)	(1)	K (5)

The training order will be pseudo-randomised; the order in weeks 1 and 2 will be randomised between palmar and lateral grips, and the order in weeks 3 to 5 will be randomised between grip requiring strength, grip requiring accuracy and grip towards objects of daily life chosen by the participant, and that the order of visual (V) and kinaesthetic (K) MI modalities will be randomised for each session and each participant. This training will be repeated three times per week with some variability introduced by changing the object to be grasped (see online supplemental annex 2).

MI, motor imagery; PP, physical practice.

numerical ratings and the qualitative report, the PI will be able to gauge compliance with training instructions as well as fatigue and will introduce rest periods when appropriate. Each training session will start and end with an assessment of fatigue and pain using a Visual Analogic Scale (VAS, 0 corresponding to no fatigue or pain, 10 to the worst). E-prime software will deliver instructions and record response times, imagery vividness ratings and VAS scores of fatigue and pain. Brain activity will be recorded during each of the three weekly sessions from

all participants during PP and MI using a 32-channel electroencephalography cap.

Neurofeedback intervention

During MI training, the neurofeedback group will receive continuous neurofeedback derived from on-line EEG recordings via a graphical representation of their brain activity while imagining performing a tenodesis grasp. Similar to the method described by Zhou *et al.*,²⁴ our neurofeedback protocol is designed to reinforce

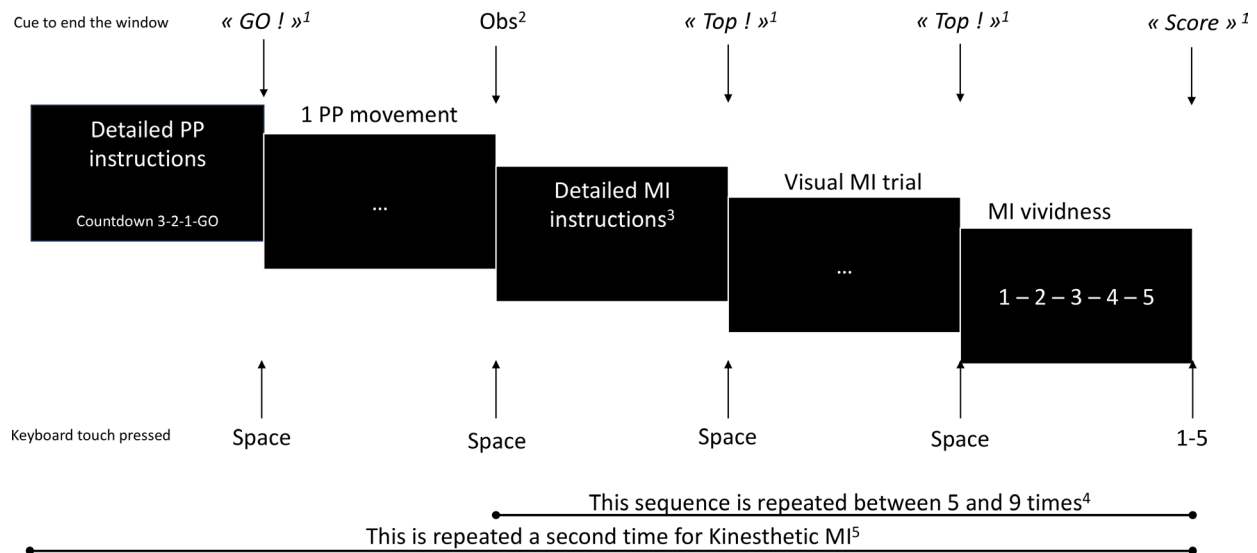


Figure 1 Organisation of one block of motor imagery (MI) training. E-prime will display detailed instructions (ie, describing the movement from its beginning to its end) for physically practiced movement (PP) followed by performing the PP movement itself starting at the GO instruction¹ of the examiner after a countdown and observing (obs²) when the participant will stop the PP movement. Then, E-prime will display detailed MI instruction (similarly to the description used for PP) focusing on one of the two modalities to be trained depending on randomisation (in this example visual MI). The participant will perform a single MI trial verbally indicating its beginning and end with 2 'Top'. The participant will then rate the MI vividness with a score between 1 (no image) to 5 (image as clear as PP). All windows will be end by pressing the spacebar of the keyboard by the examiner. Alphanumeric touches (from 1 and 5) will serve at providing the exact MI vividness by each participant. ¹verbal cue; ²Obs: observation of movement end; ³the instruction will either focus on visual of kinaesthetic component of the movement depending on the randomisation; ⁴there will be 5 repetitions of the sequence at week 1 of the training, plus one each subsequent week; ⁵the order of MI training is randomised for each participant, each session and each block.

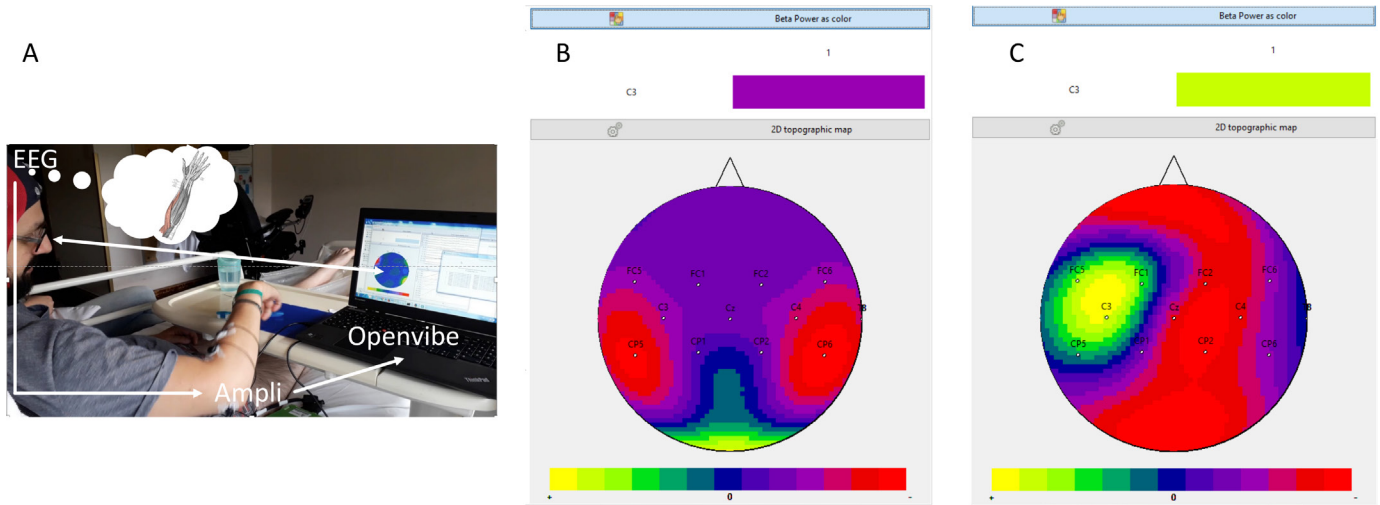


Figure 2 EEG-based neurofeedback. (A) Photo showing a participant with C6-C7 tetraplegia imagining performing the tenodesis grasp with his right hand. (B,C) Illustrations of the graphical feedback displayed during training. The horizontal gauge at the top of the figure represents the C3 power and the 2D topographical map represents activity from all 32 electrodes. (B) represents a trial with no motor imagery (MI) and (C) represents a single motor imagery trial with the right hand. Note the green colour of the gauge at the top of the image and the green zone on the right-hand side of the 2D map, which corresponds to brain activity during successful motor imagery. This pattern contrasts with that seen in panel B, which shows red-purple colours on both the gauge and the 2D topographic map.

the sensorimotor rhythm by upregulating the alpha (8–13 Hz) and beta (18–25 Hz) power bands recorded over the sensorimotor cortex.²⁵ We will use the OpenVibe software (<http://openvibe.inria.fr/>) to process the EEG signal and provide graphical and real time feedback about brain activity in the form of both a gauge and a 2D topographic map generated from the 32 channels.²⁶ This method is similar to that used in previous neurofeedback studies.^{27–28} EEG signal processing will consist of (i) referencing to the AFz channel (ie, the reference channel in the ANTS EEG cap), (ii) filtering to select only alpha and beta bands, (iii) selecting 1 s of signal (ie, 1 epoch) from every channel, (iv) squaring the signal in each epoch to compute the power spectrum density for that channel and (v) averaging the last four epochs for each channel. In this way, signal power on channels centred around C3 and C4 (ie, FC5, FC1, FC2, FC4, CP5, CP1, CP2 and CP6) will be continuously displayed on a 2D topographic map along with signal power at the C3 or C4 electrode (depending on whether the imagined movement is performed by the right or left hand). Participants will be told that their goal is to change the colour of the gauge from red (rest) to yellow-green (MI) and to elicit and maintain a similar change in colour around C3 (or C4) attesting to activity in the contralateral sensorimotor region (see [figure 2](#)).

Outcome measures

Primary outcome

The primary outcome will be wrist extension angle in degrees (measured using a 3D motion analysis system—Vicon Motion Systems Ltd. UK) during grasping of a 6-petal sphere (diameter=6 cm, weight=32 g) (similar to a small apple) using the palmar grip of the tenodesis grasp

in a full pronated position. This measure was chosen since (i) it has been repeatedly used by our group over the last 10 years to investigate the tenodesis grasp,⁷ (ii) it was used in the previous non-randomised controlled study that provided preliminary data suggesting the efficacy of MI training for improving tenodesis grasp¹⁶, (iii) its design forces people to use full pronation when grasping, thereby controlling for a possible stabilisation effect due to gravity that is present during supination and (iv) because combined with the kinematic recordings, it enables simultaneous measurement of grip strength and wrist extension angle.

After transfer from their wheelchair, participants will sit in a standardised chair with their chest strapped to the chair (seat height=54 cm). The chair will be positioned in front of a table (table height=73 cm). They will be instructed to grasp the sphere (aligned with their midline and placed 35 cm from the edge of the table), lift it and bring it to their mouth (ie, the sphere touching the lips to simulate eating). They will then replace it at its initial position and return their hand to the starting position, at the edge of the table in front of their torso. This movement will be repeated 12 times.

Following the recommendations of the International Society of Biomechanics²⁹ and kinematic protocols used in previous studies,^{4,13} 10 reflective markers will be placed on the (i) the dorsal surface of the first phalanx of the thumb, (ii) the dorsal surface of the second phalanx of the index finger, (iii) the dorsal surface of the second metacarpal bone head, (iv, v) the two styloid processes, (vi) the middle third dorsal part of the radius bone, (vii, viii) the two epicondyles, and (ix, x) on the surface of both the medial and ventral biceps brachii. We will analyse

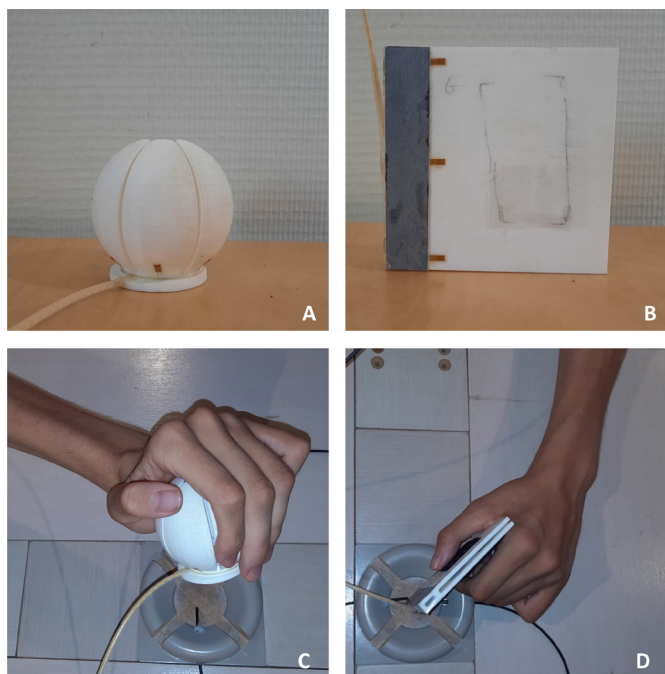


Figure 3 Detail of the instrumented objects of an apple-like object with 6 petals with six built-in Wheatstone bridges (A). An envelope-like object with six built-in Wheatstone bridges (B). Lateral view of a tenodesis palmar grip of the apple-like object in a participant with C7 tetraplegia (C). Superior view of a tenodesis lateral grip of the envelope-like object in a participant with C7 tetraplegia (D). The grip strength of the palmar and lateral grips will be measured based on variation in resistance as a function of object deformation.

wrist extension angle from movement onset until the end of the grasping phase—determined as the maximum wrist extension angle when in full pronation immediately—before the start of the manipulation phase (defined as the time at which the object is lifted and determined by a vertical velocity of the radius marker of more than 20 mm/s).⁴ Kinematic measures are highly reliable for repeated measurements of wrist joint movements in healthy individuals³⁰ and in people with SCI.^{4,13} Minimal reported difference in healthy people is 6°.³¹ No minimal clinically important difference (MCID) for people with SCI.

Secondary outcome measures

Impairments (body function and body structure) measurements

Secondary outcome measures will include wrist extension angle and grip strength during lateral tenodesis grip of an object resembling a thick, square envelope.⁴ We will also measure grip strength during palmar tenodesis grip of an apple-like object. The objects used to obtain these measures have been validated for use during kinematic recordings.⁴ The apple-like object is a 6 cm-diameter sphere and the envelope-like object is a square (height and width=8 cm, thickness=1 cm, weight=49 g); both were adapted and instrumented with 6 Wheatstone bridges and 6 strain gauges 120Ω (RS Pro, Japan). Grip strength is measured using the variation in resistance as a function

of object deformation³² (see figure 3). We specially designed these instrumented objects to directly measure grip strength during tenodesis considering that the grip force produced by the tenodesis grasp is extremely small (ie, <2 n) and may be indistinguishable from zero force using standard clinical grip metres.³³ Since these instruments were designed, in-house and custom-made data are not yet available concerning reliability, validity and MCID.

Additional clinical outcomes will include (i) upper limb passive range of motion (RoM) measured with a universal goniometer while sitting in a wheelchair. Passive RoM will be measured for the shoulder (flexion, abduction and external rotation), elbow (flexion, extension, pronation and supination) and wrist (flexion and extension). Shoulder and elbow joints are included because of their importance for reaching while performing tenodesis grasp.⁴ This measure has high intratester reliability and small error measurement (less than 7° for the wrist³⁴). No MCID is available for individuals with tetraplegia; (ii) We will use the manual muscle test (MMT) performed in supine position and will follow the most recent International Standards for Neurological Classification of Spinal Cord Injury scoring from 0 (no contraction) to 5³⁵ (normal strength); a total MMT score between 0 and 25 will be calculated for each participant, each upper limb and each visit. This will be the sum of the score for the elbow flexors (tested together: biceps brachii, brachioradial and anterior brachialis, max score=5), wrist extensor (extensor carpi radialis longus), elbow extensor (triceps brachii), finger flexor (flexor digitorum profundis) and little finger abductor (abductor digiti minimi). We will also measure the maximal voluntary concentric contraction force using a hand-held dynamometer (HHD—Microfet 2, Biometrics) while the person is sitting in a wheelchair. We will test first the right then the left upper limb after a warm-up. We will measure the peak of strength through the range of motion of each muscle in the following order: anterior deltoid, lateral deltoid, elbow flexors, elbow extensors and extensor carpi radialis longus. This sequence will be repeated three times on each limb.³⁶

Both the MMT and HHD measures have good reliability and validity for individuals with tetraplegia.³⁶ Furthermore, the HHD measure was not used in Mateo *et al* (2015) and its addition to this protocol should overcome the problem encountered in this previous study of limited sensitivity and poor responsiveness of the MMT for detecting changes when initial scores are $\geq 3.5/5$.^{37–40} No MCID is available for the MMT in individuals with tetraplegia. HHD strength changes should be greater than the HHD error measurement of 11%.³⁷

Activity limitation measures

We will use kinematic analysis to measure spatial and temporal parameters during three movements: a pointing movement (reaching only) and two reach-to-grasp movements (see figure 2B,C for objects to be grasped).^{4,41} Parameters of interest will be movement time, peak velocity, time to peak velocity and trajectory

smoothness/variability. These measures have been widely used and display good to excellent between-session reliability in people with SCI.^{13 20 21 32} MCIDs have not yet been reported for these kinematic parameters in individuals with C6-C7 lesions.

Additional clinical outcomes will include:

- i. the Box and Block Test (BBT—dependent variable: number of cubes moved with one hand during 60 s). The BBT is widely used to evaluate unilateral gross manual dexterity and has high reliability.^{36 42} No MCID has been established in people with SCI, but a study of people with other neurological conditions identified an MCID of 6 cubes following an intervention aimed at increasing upper-limb dexterity.⁴³
- ii. the Nine Hole Peg Test (NHPT—dependent variable: time required to place and remove nine pegs on a board). The test-retest reliability of this test is moderate in healthy individuals³⁶ but good in people with stroke.⁴² No MCID is available for people with SCI.
- iii. the Jebsen-Taylor Hand function test (JTHFT—dependent variable: time required to complete seven different subtasks with a maximum of 120 s for a single subtask). The tasks are (i) writing a 24-letter, third grade reading-level difficulty sentence, (ii) card turning, (iii) picking up small common objects (eg, small coins, paper clips, bottle caps) and placing them in a container, (iv) simulated feeding, (v) stacking checkers, (vi) lifting light objects (eg, empty cans) and (vi) lifting heavy objects (eg, 500 gram weighted cans).⁴⁴ The test-retest reliability is excellent in people with tetraplegia in all subtasks but adequate for dominant hand writing, non-dominant hand feeding and lifting large light objects,⁴⁴ with an excellent intra-rater reliability.⁴⁵ No MCID is available for people with SCI.
- iv. the capabilities of the upper extremity questionnaire (CUE) is a 32-item questionnaire that assesses the capability of each upper limb separately and together. It uses a 7-point Likert scale (1 ‘totally limited’ to 7 ‘not at all limited’) and results in a total score between 32 and 224. This questionnaire has good homogeneity, reliability and validity in people with SCI.⁴⁶
- v. the short form of the quadriplegic index of function (QIF-SF) is a 6-item questionnaire that scores an individual’s capacity to wash/dry their hair, turn supine-to-side in bed, put on lower body clothing, open a carton/jar (feeding), transfer from bed to chair and lock wheelchair. It uses a 5-point Likert scale (0 ‘dependent’ to 4 ‘independent’).⁴⁷ The QIF is reliable, is recommended for use in people with SCI and is more sensitive to change than the Barthel Index.⁴⁸

Participation restriction measures

In line with recommendations for studies including people with SCI, we will use the WHO Quality of life-Bref (WHOQOL-Bref) to assess quality of life.⁴⁹ This 26-item questionnaire assesses physical, psychological, social and environmental factors in an individual’s environment,

has good-to-excellent reliability⁵⁰ and is validated to assess quality of life after SCI.^{49 51}

Additional outcomes

Behavioural measurements

Assisted by the PI, each participant will complete the Kinaesthetic and Visual Imagery Questionnaire 10-item (KVIQ for evaluating the representation of trunk and single-joint movements of the upper and lower limb).⁵² This questionnaire assesses the ability to imagine a movement from an internal perspective (equivalent to first person perspective, that is, seeing or perceiving oneself as an actor) with reference to physically executed movement sequences. Individual self-assessment of vividness after MI will be measured using a 5-point Likert scale (1 corresponding to the absence of image/sensation, 5 to image/sensation as clear/intense as during physical practice). This questionnaire has excellent internal consistency for assessing MI ability in healthy people and in individuals with stroke.⁵² It has been repeatedly used in individuals with tetraplegia.^{13 53}

Neurophysiological measurements

The CTF magnetoencephalography (CTF-MEG) system with 275 radial gradiometers (third order) over the scalp and 33 reference channels for ambient field correction will be used to investigate changes in local current sources in response to independent variables (CERMEP, France). This system has high temporal resolution and relatively good spatial resolution.⁵⁴ The MEG set-up will be identical to that used in previous studies with people with SCI.^{13 20 55} Its physical constraints make it compatible with recording reach-to-grasp movements while sitting. Based on the results of a previous study, we will compute the number of activated voxels within the contralateral sensorimotor cortex.¹³ This measure will be completed by additional exploratory functional connectivity analyses⁵⁶ to investigate whether the reduction in contralateral brain activity in somatosensory areas (around the hand area of the motor cortex)¹³ is related to increased activity in deep brain structures (including basal ganglia and cerebellum).

Each MEG recording will be separated into two parts. The first part will consist of three blocks of 15 auditory-paced (0.125 Hz) wrist extension movements (WRI), three blocks of 15 beeps with no movement (REST) and two blocks with no beep and no movement (free rest—FR). The second part will commence after a pause during which we will make the technical changes necessary to perform grasping movements in the MEG. It will consist of three blocks of 15 auditory-paced (0.07 Hz) tenodesis palmar grip (PG), three blocks of tenodesis lateral grip (LG), three blocks of 15 beeps with no movement (REST) and eight blocks with no beep and no movement (free rest—FR). Blocks will be delivered in the following order (part 1: REST, WRI, FR, WRI, REST, FR, WRI, REST; part 2: PG, FR, LG, FR, REST, FR, LG, FR, REST, FR, PG, FR, REST, FR, LG, FR, PG). Auditory instructions

will be delivered at the beginning of each block. For the WRI movement, participants will perform a single maximal wrist extension (with no associated movement of the proximal joints). The PG and LG tenodesis grasping movements and objects (apple-like and envelope-like) will be identical to those performed during the kinematic recordings (described above). During the MEG recordings, participants will fixate on a visual target on the wall in front of them and the experimenter will visually control compliance with instructions and will place the appropriate object in front of them at the beginning of each block. EMG activity of the extensor carpi radialis longus will be recorded by placing two bipolar surface electrodes over the muscle and a reference electrode on the olecranon). Any potential technical problems will be monitored by the engineer in charge of the recording and if necessary, the recording will be interrupted to resolve the problem and the interrupted block will be repeated. Since MEG recordings are only possible in Lyon, these data will only be recorded for participants included at the Lyon site.

Brain activity during experimental (or control) tasks will be recorded by the therapist supervising the intervention using the eegoTM sport EEG cap (ANT neuro, Enschede—The Netherlands) and Openvibe software (<http://openvibe.inria.fr/>) with a sampling frequency of 256 Hz. The 32 EEG scalp electrodes will be positioned using the international 10–20 system, enabling off-line analyses of the relationships between MI ability, training and brain activity.

Data collection

We will measure all outcomes five times: during weeks 1, 3 and 5 (baseline), week 11 (immediately after the end of the intervention) and week 18 (8 weeks after the end of the intervention). Three measures will be performed during the 5-week period before the intervention to ensure baseline stability. All measurements of MI ability will be performed by the PI. All assessments for a given participant will be performed by the same blinded assessor, thus limiting variability due to inter-assessor differences (figure 4). To prevent unmasking randomization, participants will be told not to give any information about the content of the intervention sessions to either the blinded assessor or to other participants. In addition, to ensure that assessors do not inadvertently discover group allocation, intervention sessions will be conducted in a dedicated room separate from all other assessment and rehabilitation spaces. Participants will be instructed to perform no additional MI training throughout the duration of the study. This will be verified regularly throughout the study.

Sample size calculation

Our sample size calculation is based on data from healthy participants collected during a similar MI intervention. Mateo *et al*¹³ reported that wrist extension angle in people with SCI was an average of 17.8° before MI tenodesis grasp training and increased up to an average of 26.9° after, thus representing a medium effect size.¹³ We expect this MI-related gain to increase by a further 10°

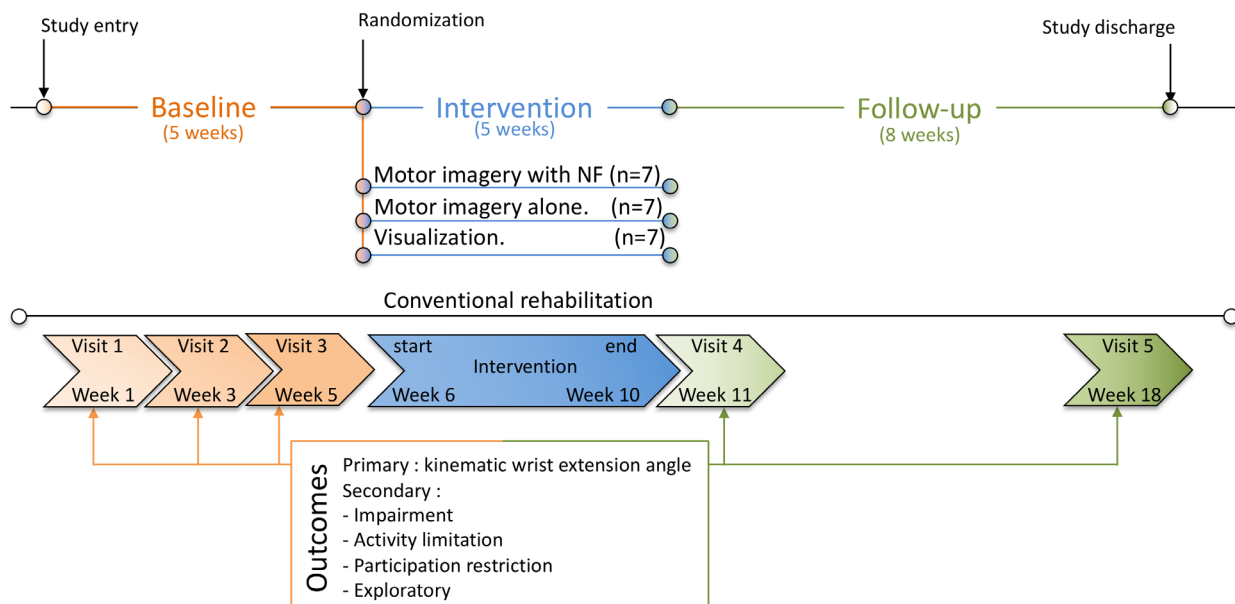


Figure 4 Study timeline. Secondary measures will assess impairments (kinematic grip strength, upper limb passive range of motion, upper extremity strength using both the manual muscle test (MMT) and a hand-held dynamometer (HHD)), activity limitations (kinematic spatio-temporal parameters, Box and Block Test, Nine Hole peg Test, Jebsen-Taylor Hand function test, capabilities of upper extremity questionnaire, short form of the quadriplegic index of function) and participation restrictions (WHO Quality of life-Bref). These measures will be complemented by exploratory measures (Kinaesthetic and Visual Imagery Questionnaire, neurophysiological MEG and EEG recordings). Note that three measures were chosen for baseline to verify that participants showed a stable behaviour as expected with the chronic status of the spinal cord injury (SCI).

in participants who receive MI training with neurofeedback. Based on these assumptions, we used the R software package 'pwr' and the associated function to compute the power for a general linear model 'pwr.f2.test'.⁵⁷ We considered an interaction between GROUP (three levels, ie, MI with neurofeedback, MI and control) and VISIT (three levels: baseline grouping visits 1, 2 and 3, visit 4 and visit 5), that is 3×3 factorial design. We then computed the degrees of freedom (df) for the numerator ($u = (3 - 1) * (3 - 1) = 4$); considering $n=7$ participants in each of the 9 cells (GROUP * VISIT) of the design, a total N of 63, the denominator df was $v=63-9=54$; with alpha set to 5% ($\alpha=0.05$) and a medium effect size as previously reported¹³ ($f^2=0.35$), the calculated power is 85%.⁵⁷ This indicated that seven participants should be included in each group, thus requiring a total of 21 participants.⁵⁸ Based on our experience of patient motivation to improve hand-arm function we do not expect any participants to withdraw from the study after giving their consent to participate.

Data collection, management, monitoring

For a given participant, the assessment case report form (assessment CRF) will be completed by the same physical or occupational therapist (blinded assessor) for all five assessment visits. The training CRF will consist of the log files of the computer running E-prime. This will be separate from the assessment CRF and will not be accessible by the blind assessor. For each participant, after each visit data in the CRF will be transferred by two independent investigators into appropriate electronic formats. Kinematic, EEG and MEG data will be analysed by independent and blinded engineers and kept in electronic format. All data will be de-identified and subsequently used for statistically blinded analyses.

Data monitoring

There will be no independent data monitoring committee. This is justified by the non-invasive nature of the intervention (MI), of the material used, and the low risk and constraints associated with participating in the study as evaluated by the ethical committee 'Comité de protection des personnes Nord Ouest IV'. The conditions under which participation in the study will be terminated include withdrawal of consent, change of health status of exclusion criteria during the study, or any event compromising the rights, security or health of the person, or the integrity of the research (including a severe adverse event—SAE). The study can also be interrupted (partially or completely) if the sponsor or main investigator estimates that the study or any other SAE poses a risk for patient safety, or in case new evidence makes the study obsolete.

Statistical methods

The statistical analyses will be performed using R software V.4.1.2.⁵⁹ Baseline demographic and descriptive characteristics will be summarised as mean (SD) or median (IQR) for continuous variables as appropriate. We will

verify the efficacy of the randomisation by checking for the absence of significant differences between the three groups at baseline (across the visits 1, 2 and 3) and stability of performance baseline within each group.

The primary outcome measure to investigate the effect of MI training is wrist extension angle during palmar tenodesis grasping of an apple-like object. The primary endpoint is at visit 4. Secondary outcome measures include spatial and temporal kinematic parameters (including wrist extension angle during lateral tenodesis grasping of an envelope-like object), grip strength measured with instrumented objects, RoM, MMT, HHD, BBT, NHPT, JTHFT, CUE, QIF-SF WHOQOL-Bref and contralateral sensorimotor cortex activity (respectively during palmar and lateral tenodesis grips). All measures (primary and secondary) will be analysed using the same statistical methods. We will examine MI effects immediately after the intervention (week 11) and a retention of MI effects 2 months after training (week 18). We will use the retained mixed model to test the null hypothesis of non-significant differences among groups (H_0); the alternative hypothesis H_1 is: MI with neurofeedback \geq MI alone $>$ control. Outcome measures for which better performance is associated with lower values will be tested against H_1 : MI with neurofeedback \leq MI alone $<$ control.

We will use generalised linear mixed-effects models fitting each outcome explained by an interaction between the following fixed factors GROUP (three levels, MI alone, MI+neurofeedback, control) and VISIT (three levels), including a common intercept; this model will include the following random effects: PARTICIPANT (21 levels) to account for repeated measures among individuals; SITE (two levels). This model will use a gamma distribution due to the non-negative and continuous nature of the outcome measures. Each model will be compared with each other and to the null model using analysis of variance (ANOVA) and the retained model will be selected using Bayesian information criteria. Standardised residuals from each model will be tested for normality using the Kolmogorov–Smirnov test. We will then compute the 95% CIs for each parameter of the retained model. If the 95% CI does not include 0, we will perform post-hoc pairwise comparisons with Holm corrections. We will report the estimated standard errors, t-values, df and p values. We will also report effect sizes and the model's power using Cohen's f (values of 0.10, 0.25 and 0.40 represent small, medium and large effect sizes, respectively).

Mixed model analyses will be performed because they can handle non-normally distributed data, nested data (PARTICIPANT within SITE) and individual variability, and tend to have more statistical power than repeated measures ANOVA.⁶⁰

All analyses will be conducted on the basis of intention-to-treat, with the population defined as participants who have completed all three baseline measurements and have been randomised. We will use an overall two-sided, type-I error rate of $p<0.05$.



ETHICS AND DISSEMINATION

Ethical approval for this study was granted by the ‘Comité de protection des personnes Nord-Ouest-IV’ on 29 September 2017 (CPP 17/25, N°2017-A00990-53). The study sponsor will conduct audits at a rate that will depend on the enrolment rhythm (minimum once every 2 years) to verify that the study does not deviate from the initial experimental protocol and conforms with regulations. The competent authority (health authority) can also audit trial conduct at any stage of the study including after its completion, by inspecting data, documents and/or reports related to study participation. Any adverse effects will be documented in the CRF, and the sponsor will be informed of their occurrence by the PI who will assess their severity. The results of this protocol will be published in peer-reviewed academic journals and presented at scientific meetings and conferences. Information regarding informed consent, confidentiality, data access, ancillary and post-trial care and dissemination policies are fully disclosed in the participant information form.

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Contributors SM and GR came up with the idea/research design. GC, KTR, DS, SD, JL, YR, CC, AG, GR and SM were involved in writing the protocol and in project management and consultation (including planning, conduct reporting and reviewing of the manuscript before submission). GR and AG will recruit participants. GR, AG and CC will provide facilities/equipment and institutional links. GC, DS, SD, AG and GR will participate to acquisition of data. KTR, DS, SD, YR, CC, AG, GR and SM will participate in analyses. GC, KTR, DS, SD, JL, YR, CC, AG, GR and SM will participate in the interpretation of data. SM is the guarantor.

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Disclaimer Name and contact information for the trial sponsor: Dr Alexandre Pachot, Direction de la Recherche en Santé, Hospices Civils de Lyon, F-69229 Lyon Cedex 2. Study sponsor and funders had no role in study design, collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication will be performed independently of study sponsor and funders. The study will be coordinated by Dr SM, P.T. PhD, Université Claude Bernard Lyon1 INSERM U1028; CNRS UMR5292; Centre de Recherche en Neurosciences de Lyon, Equipe Trajectoires & Hospices Civils de Lyon, Hôpital Henry Gabrielle, Plateforme Mouvement et Handicap. This includes the preparation of the different study meetings to prevent cancellation of routine rehabilitation sessions of the participant, as well as verification of the correct and timely completion of assessments and intervention sessions. SM will also be

responsible for transferring the anonymised data in order to perform statistical analyses (CC). The Hospices Civils de Lyon, study sponsor will supervise the different steps of the study including participant enrolment, completion of the different assessments and intervention sessions, along with verification of the absence of adverse effects. No one else will be implicated in data management and overseeing the trial.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Consent Forms Version 2 dated June 29, 2017

Patient Consent Form to be Signed

ATTESTATION OF INFORMATION PROVIDED TO THE PATIENT AND COLLECTION OF PATIENT CONSENT THERAPEUTIC TRIAL: Grasping Rehabilitation through Neurobiofeedback Coupled with Motor Imagery in C6-C7 Tetraplegic Patients. Randomized Controlled Study.

I, the undersigned, Last Name First Name _____ certify that the investigator _____ has explained to me in understandable terms, the purpose of the proposed research, its methodology, duration, expected benefits, constraints, and potential risks, including in case of early termination of the study. I have been informed that the study has received approval from an authorized Ethics Committee for Human Research, as well as my right to refuse participation in this study or to withdraw my consent at any time without incurring any liability. I have also been informed that I have the right to access, correct, and object to the use of my computerized data, which can be exercised through the investigator or directly through a physician of my choice. If needed, the contact information is: Professor Gilles Rode, Henry Gabrielle Hospital, 20 Route de Vourles, 69230 Saint Genis Laval (tel: 04.78.86.50.66).

I have received an information letter about the study. In accordance with French legislation (Public Health Code: Law No. 2012-300 of March 5, 2012 on research involving human subjects), the protocol has been approved by an Ethics Committee for Human Research and the competent authority.

The protocol was approved on September 29, 2017 by CPP Nord-Ouest IV. Insurance has been obtained by the Hospices Civils de Lyon, Sponsor.

I hereby consent to participate in this study.

Signed at (city) _____ on |_|_|/|_|_|/|_|_|_|_|

Signature of the volunteer/patient:

Signed at (city) _____ on |_|_|/|_|_|/|_|_|_|_|

Signature of the investigator:

Document provided in duplicate: one copy given to the participant and the other retained by the investigator.

Consent Forms Version 2 dated June 29, 2017

Proxy Consent Form for patient who cannot sign for themselves

ATTESTATION OF INFORMATION PROVIDED TO THE PATIENT AND OBTENTION OF PATIENT CONSENT

THERAPEUTIC TRIAL: Grasping Rehabilitation through Neurobiofeedback Coupled with Motor Imagery in C6-C7 Tetraplegic Patients. Randomized Controlled Study.

I, the undersigned (accompanying person) Last Name First Name _____
 _____ Certify that Dr. _____
 has explained to Ms/Mr Last Name First Name _____
 _____ in understandable terms, the purpose of the proposed research, its methodology, duration, expected benefits, constraints, and potential risks, including in case of early termination of the research. I have also informed them that the study has received approval from an authorized Ethics Committee for Human Research, as well as my right to refuse participation in this study or to withdraw my consent at any time without incurring any liability. I have also explained their right to access, correct, and object to the use of their computerized data, which can be exercised through the investigator, either directly or through a physician of their choice. If needed, the contact information is: Professor Gilles Rode, Henry Gabrielle Hospital, 20 Route de Vourles, 69230 Saint Genis Laval (tel: 04.78.86.50.66).

An information letter about the study has been provided. In accordance with French legislation (Public Health Code: Law No. 2012-300 of March 5, 2012, on research involving human subjects), the protocol has been approved by an Ethics Committee for Human Research and the competent authority.

The protocol was accepted on 29/09/2017 by CPP Nord-Ouest IV. Insurance has been obtained by the Hospices Civils de Lyon, The study's sponsor.

Ms/Mr Last Name First Name _____
 _____ **has expressed their consent to participate in this study. Name, First Name of the patient's proxy:** _____

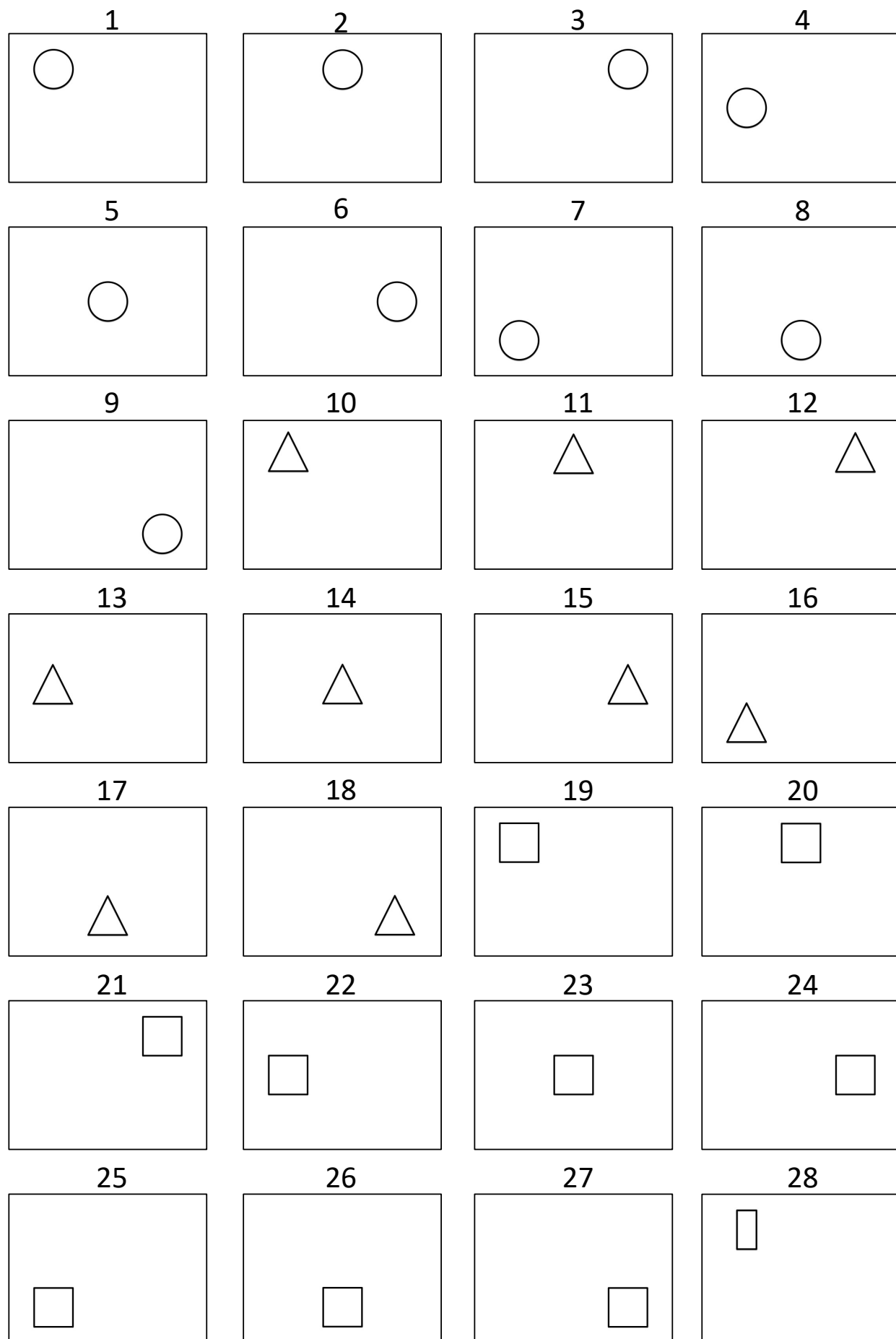
Signed at (city) _____ on |_|_|/|_|_|/|_|_|_|_|

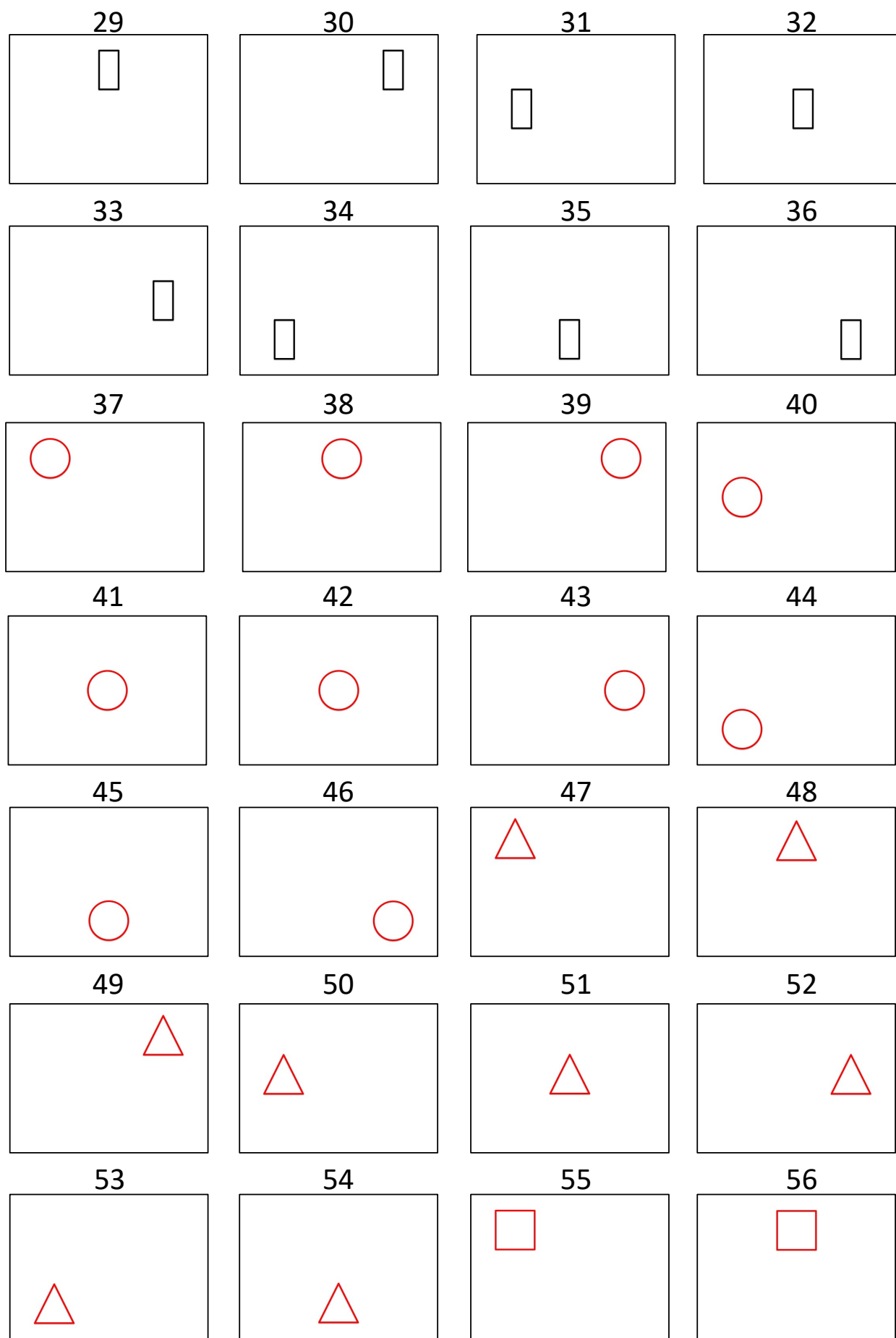
Signature of the person accompanying the patient:

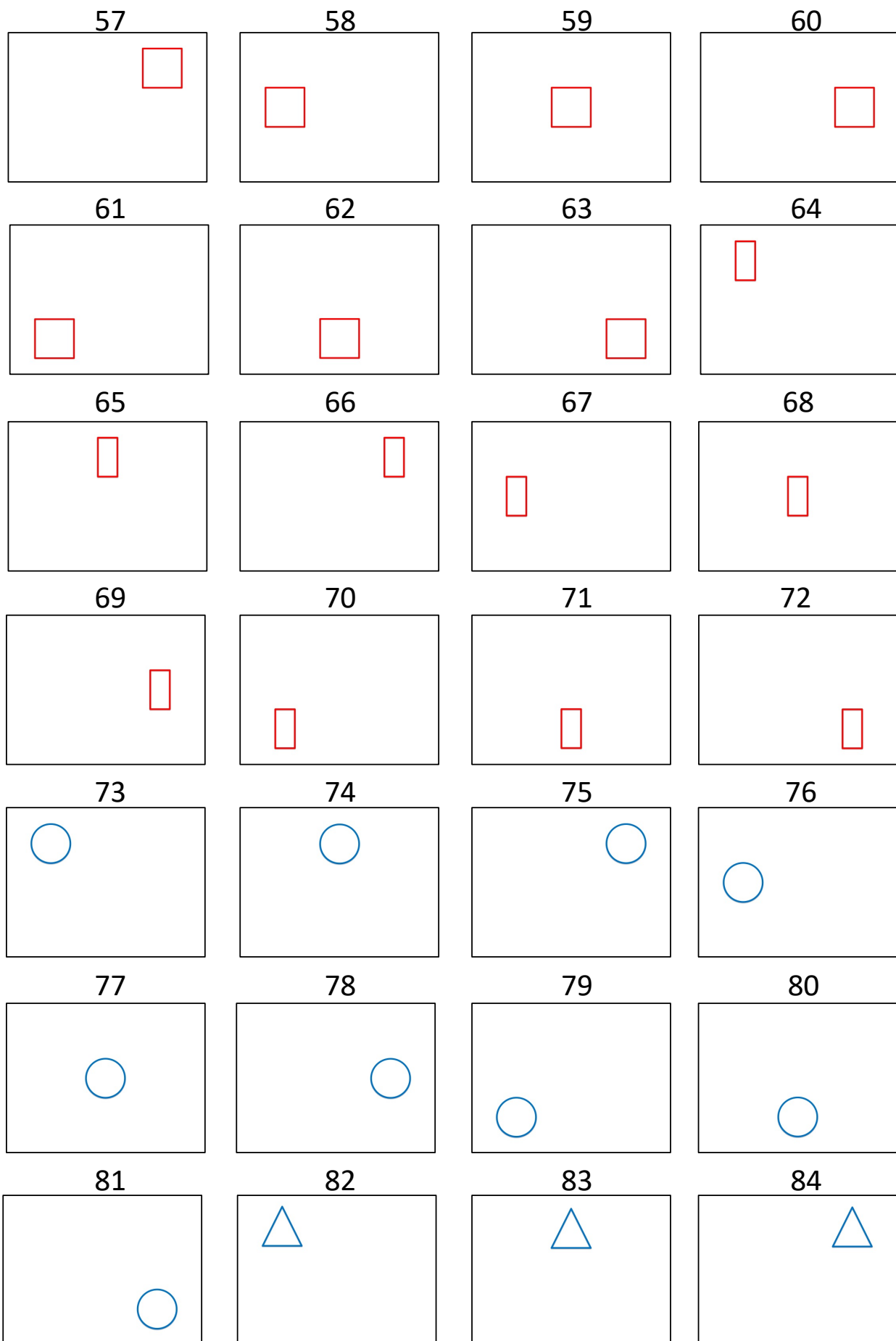
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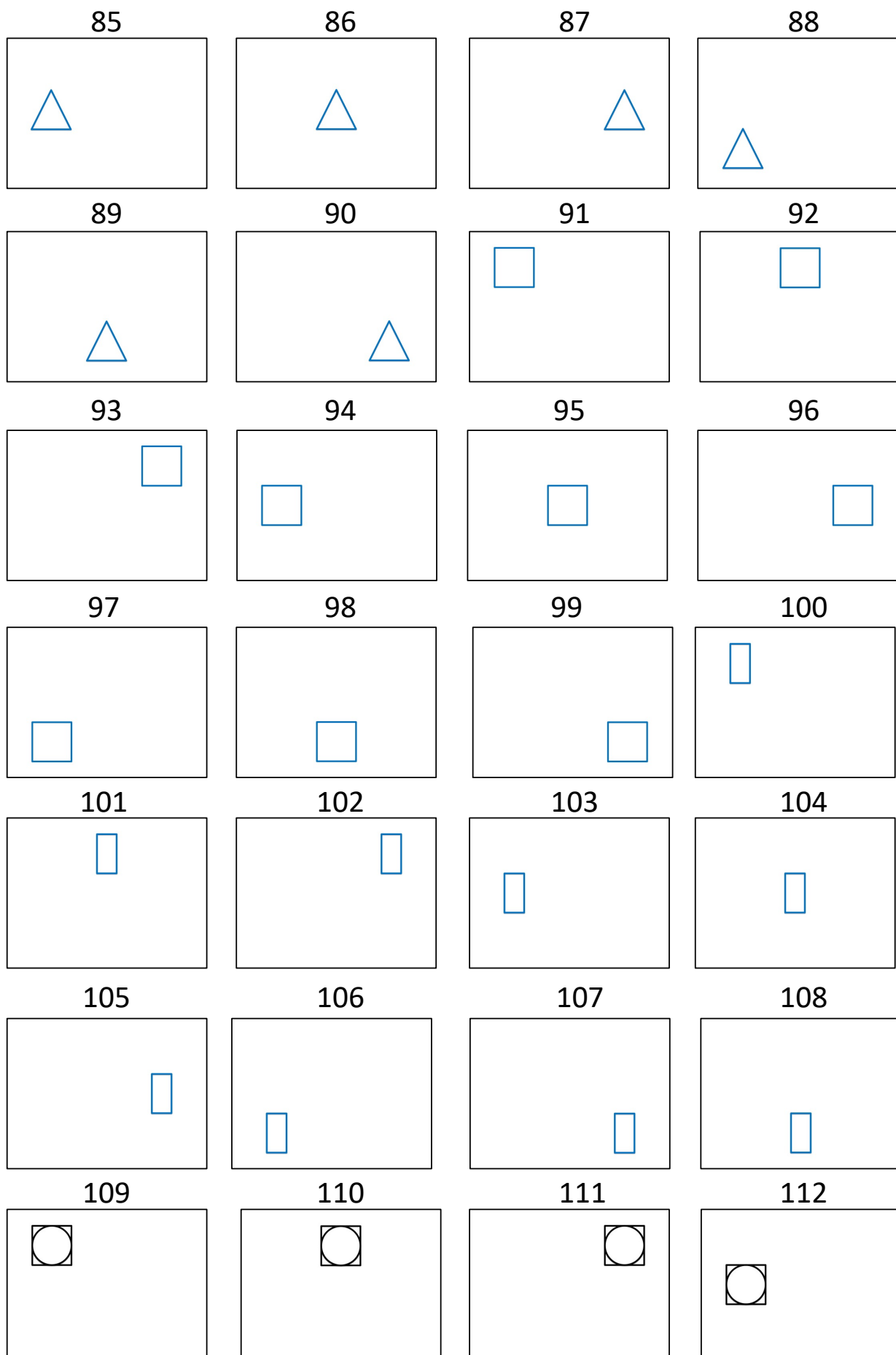
Signature of the investigator:

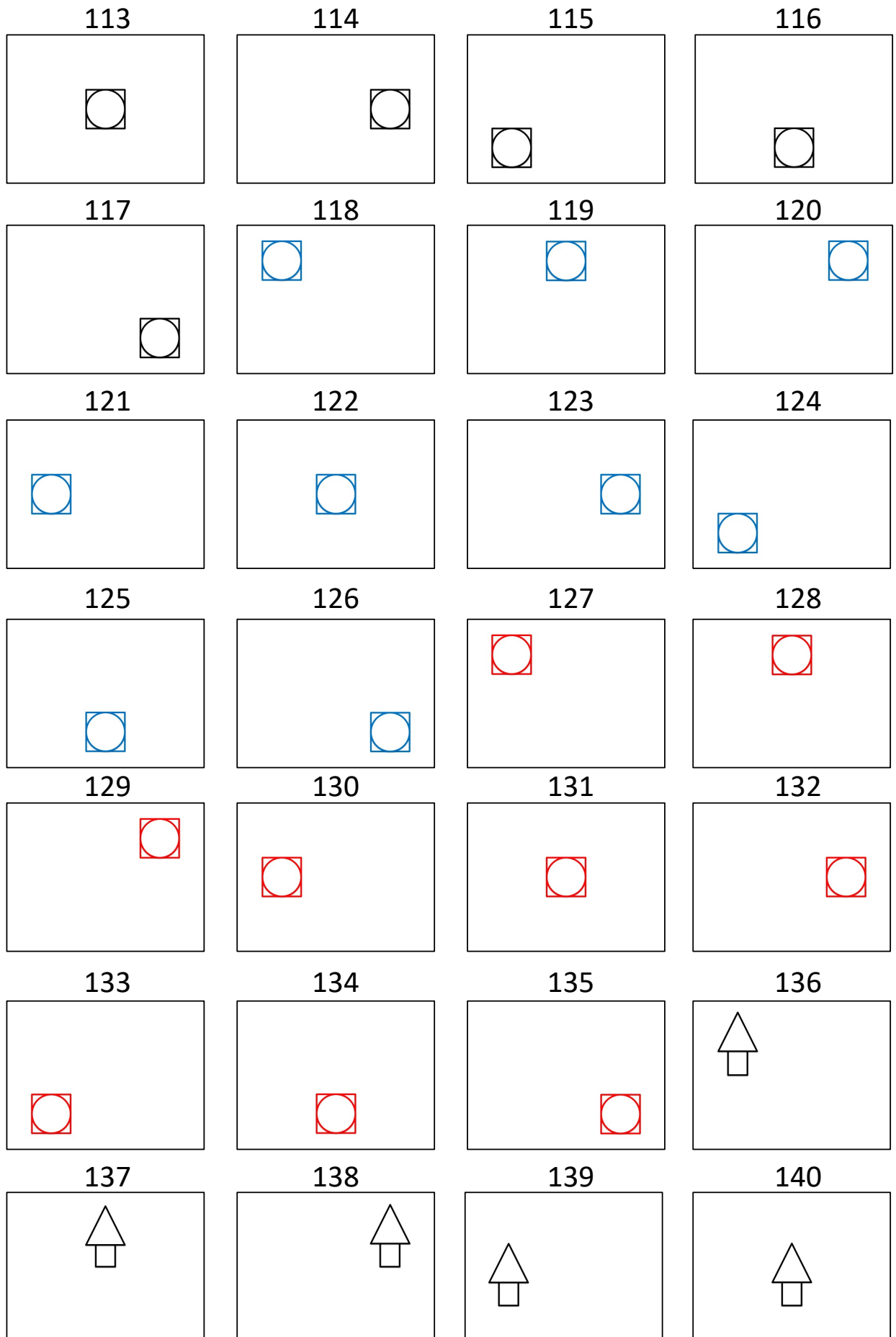
Document provided in duplicate: one copy given to the participant and the other retained by the investigator

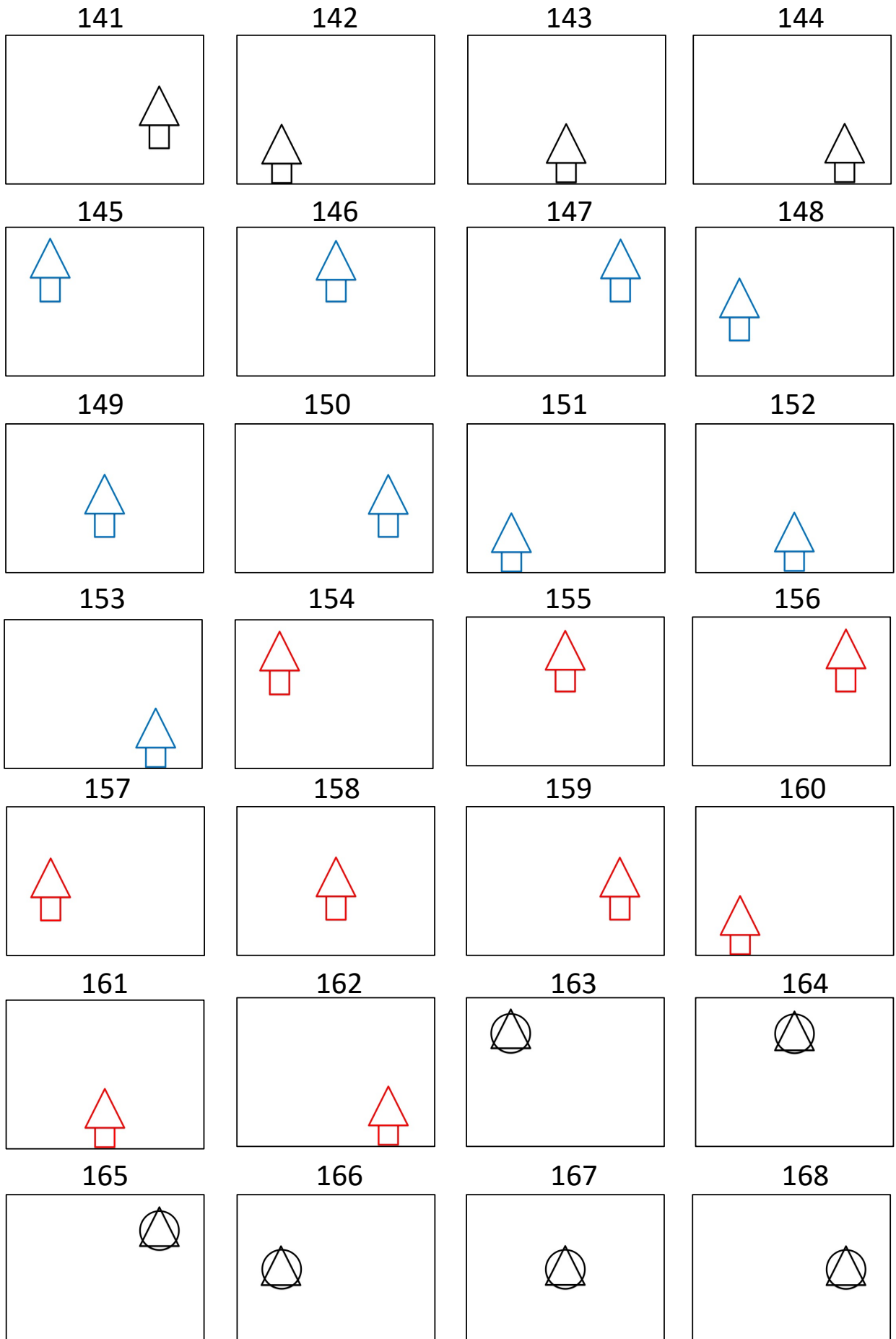


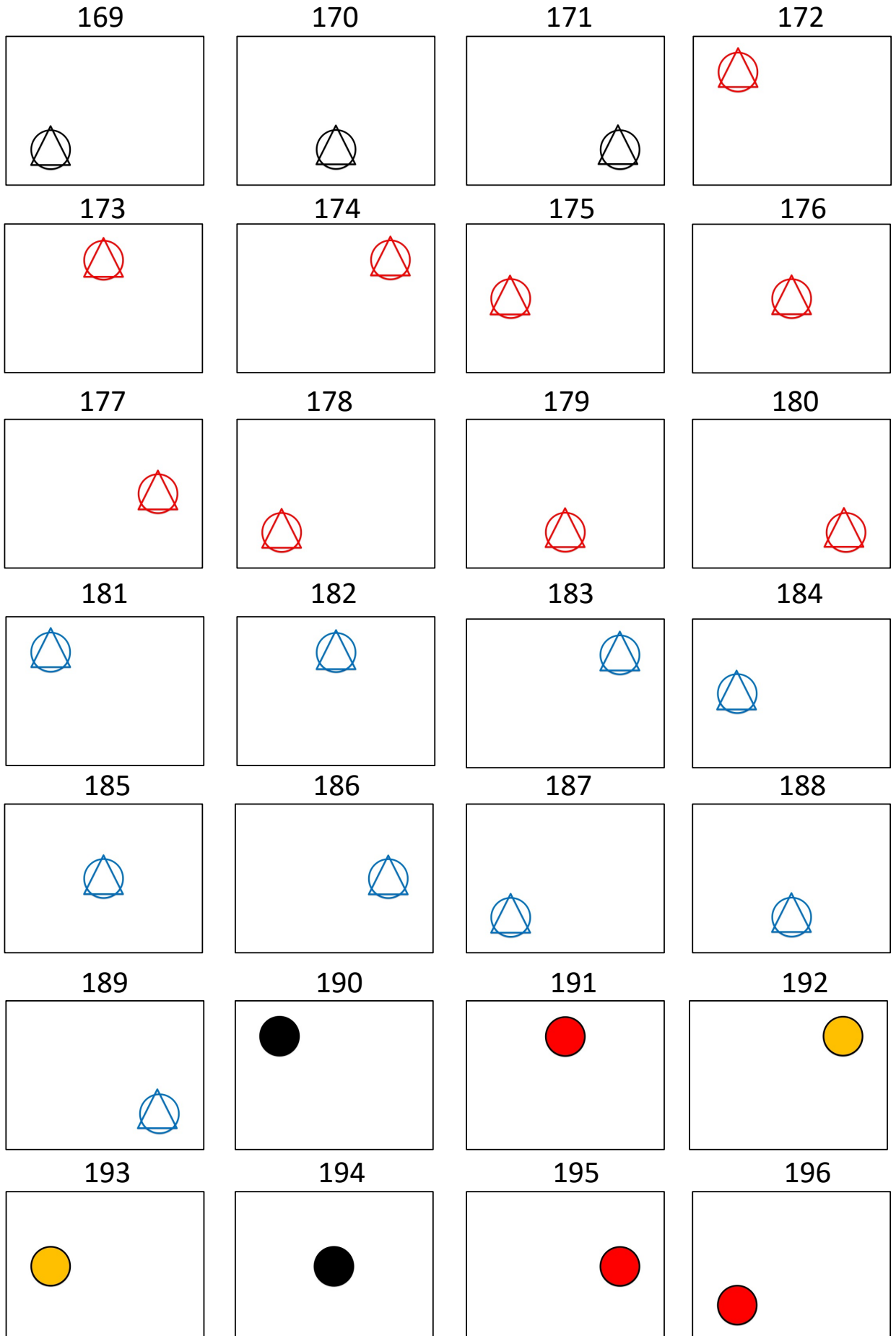


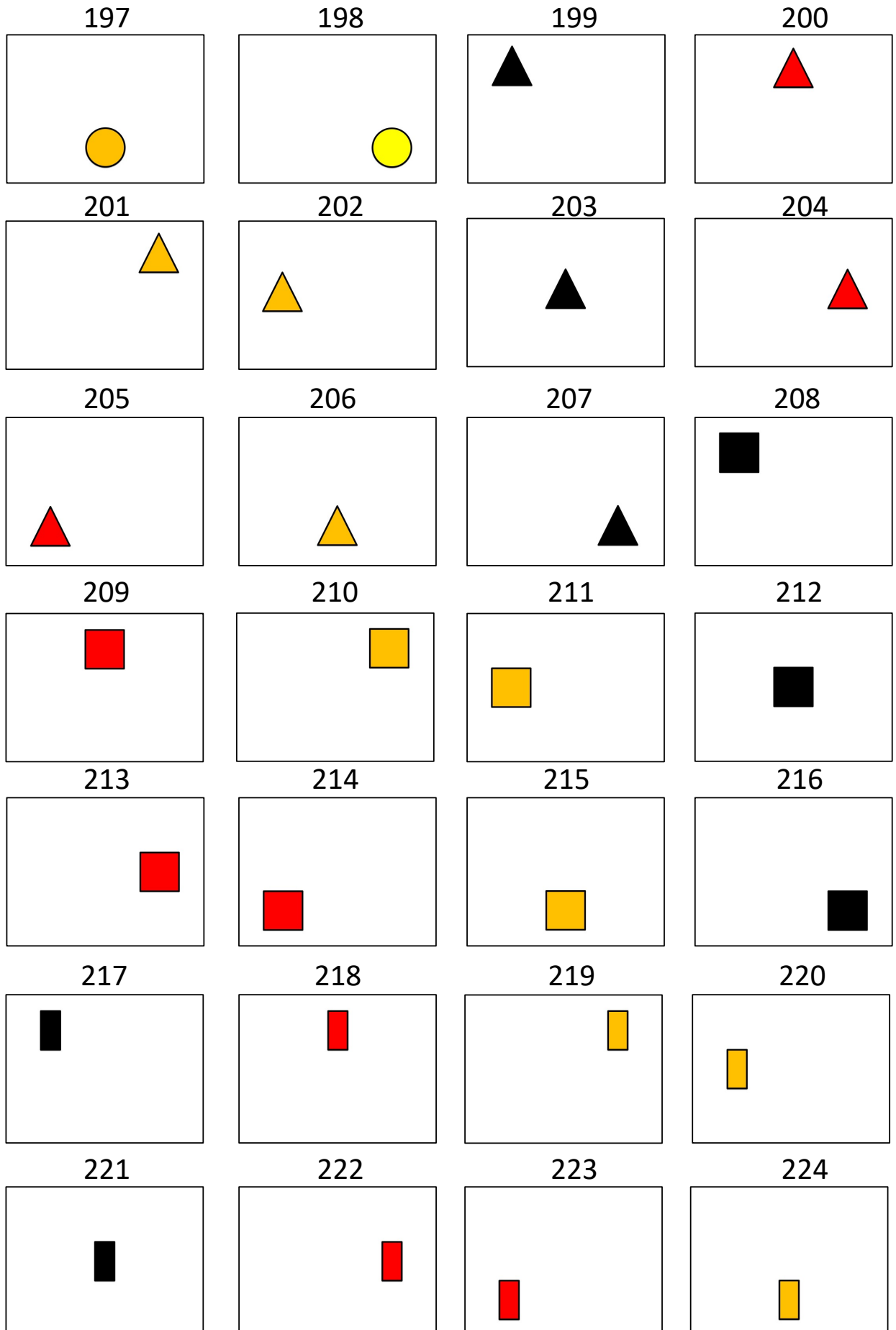


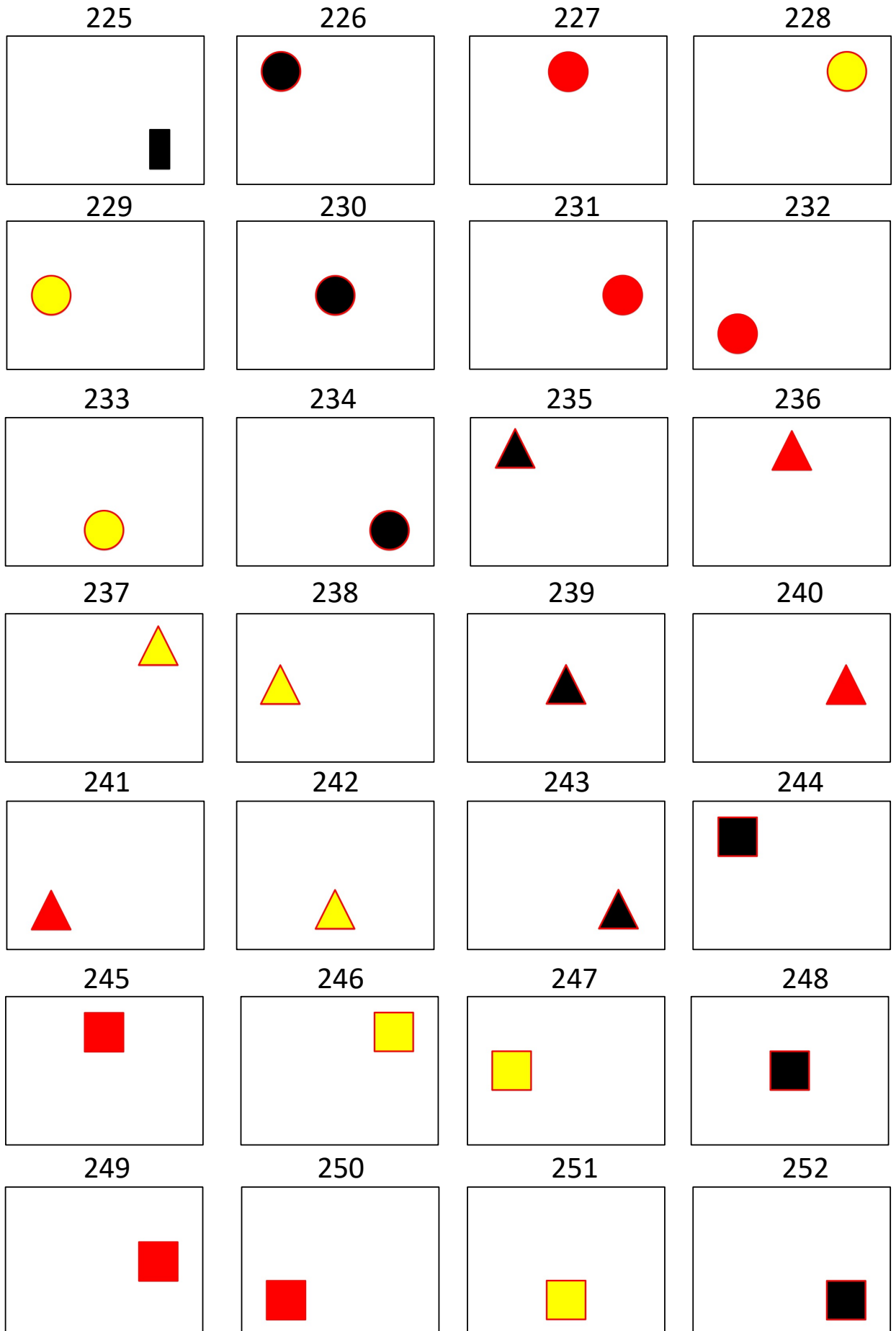


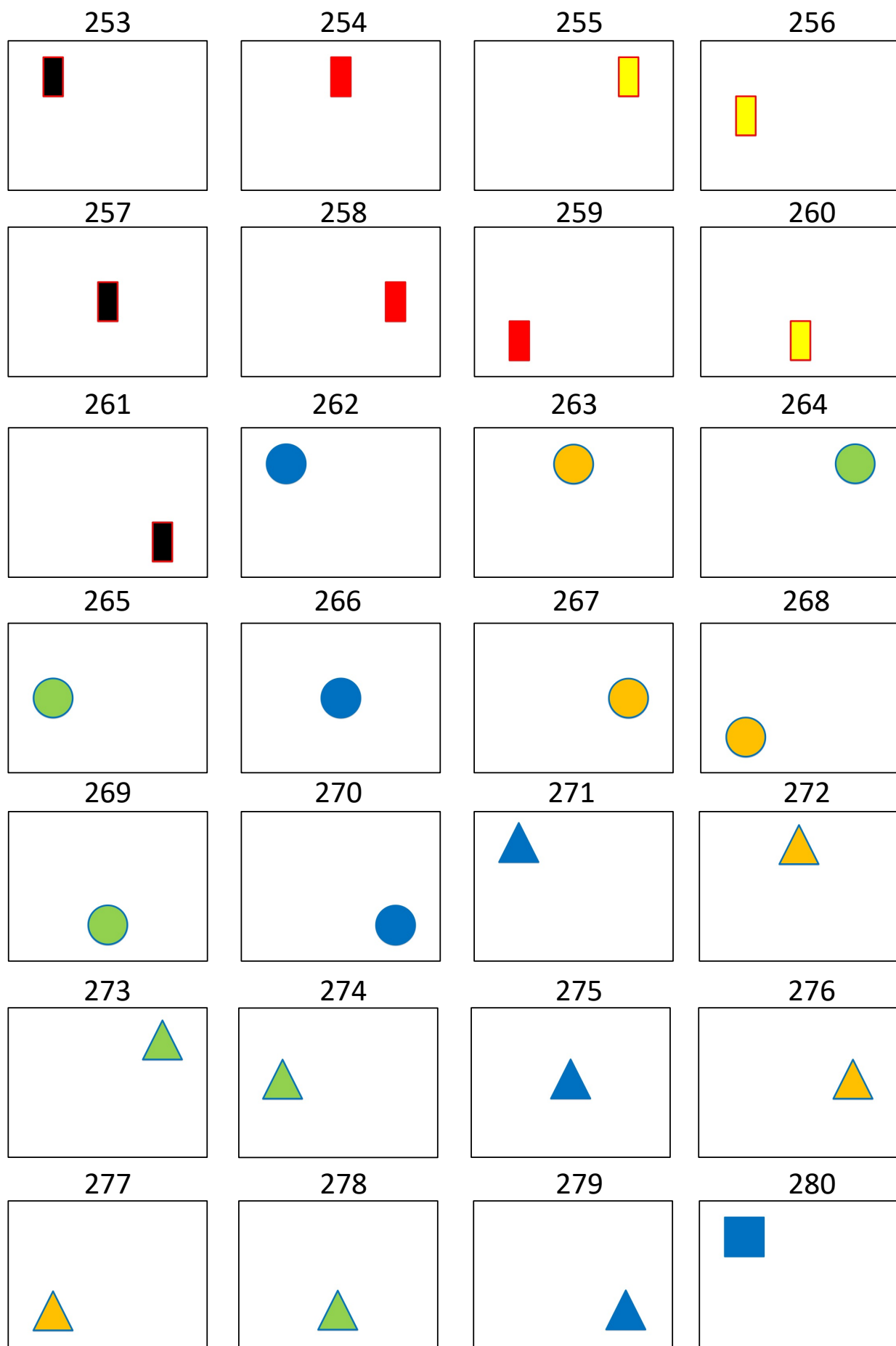


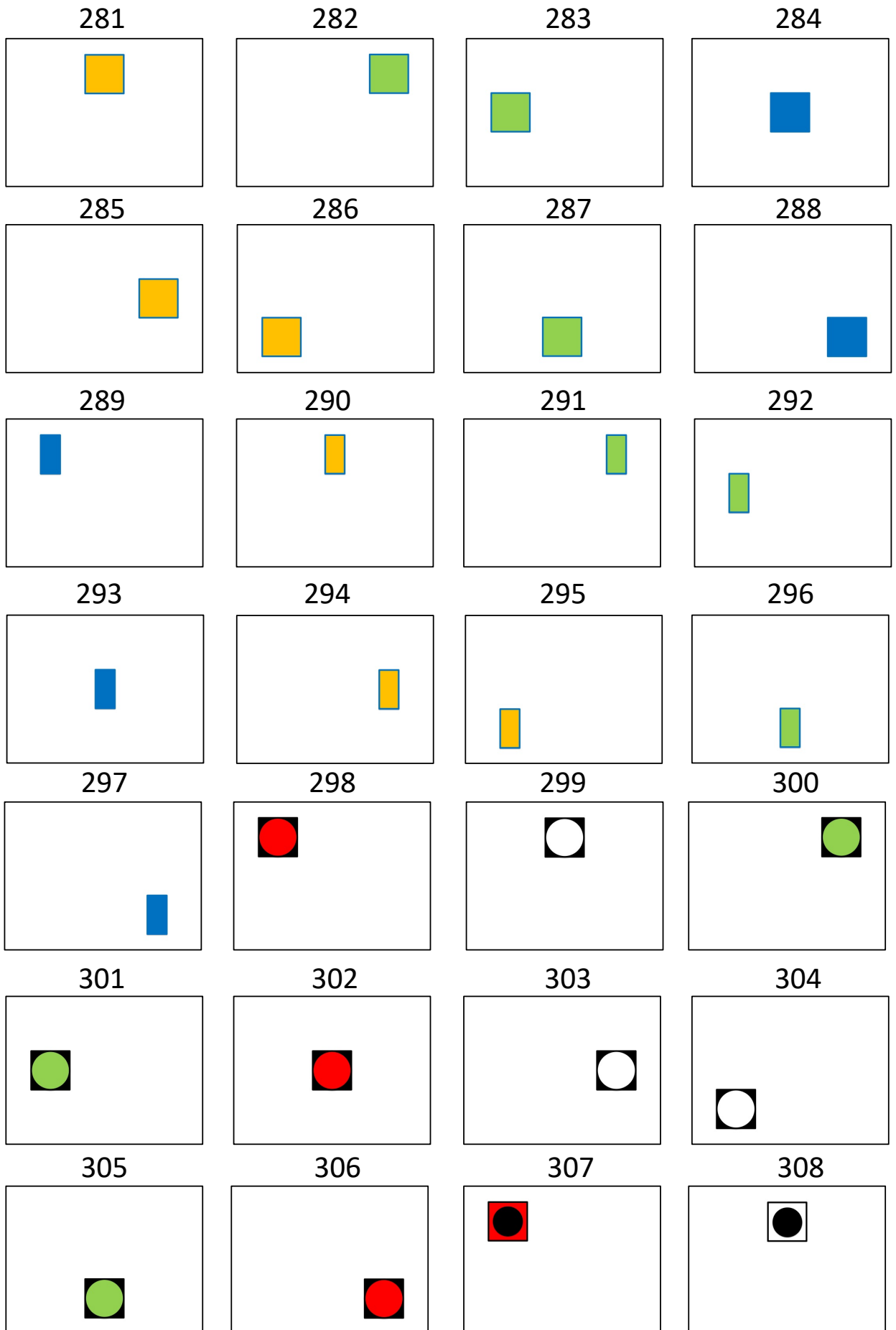


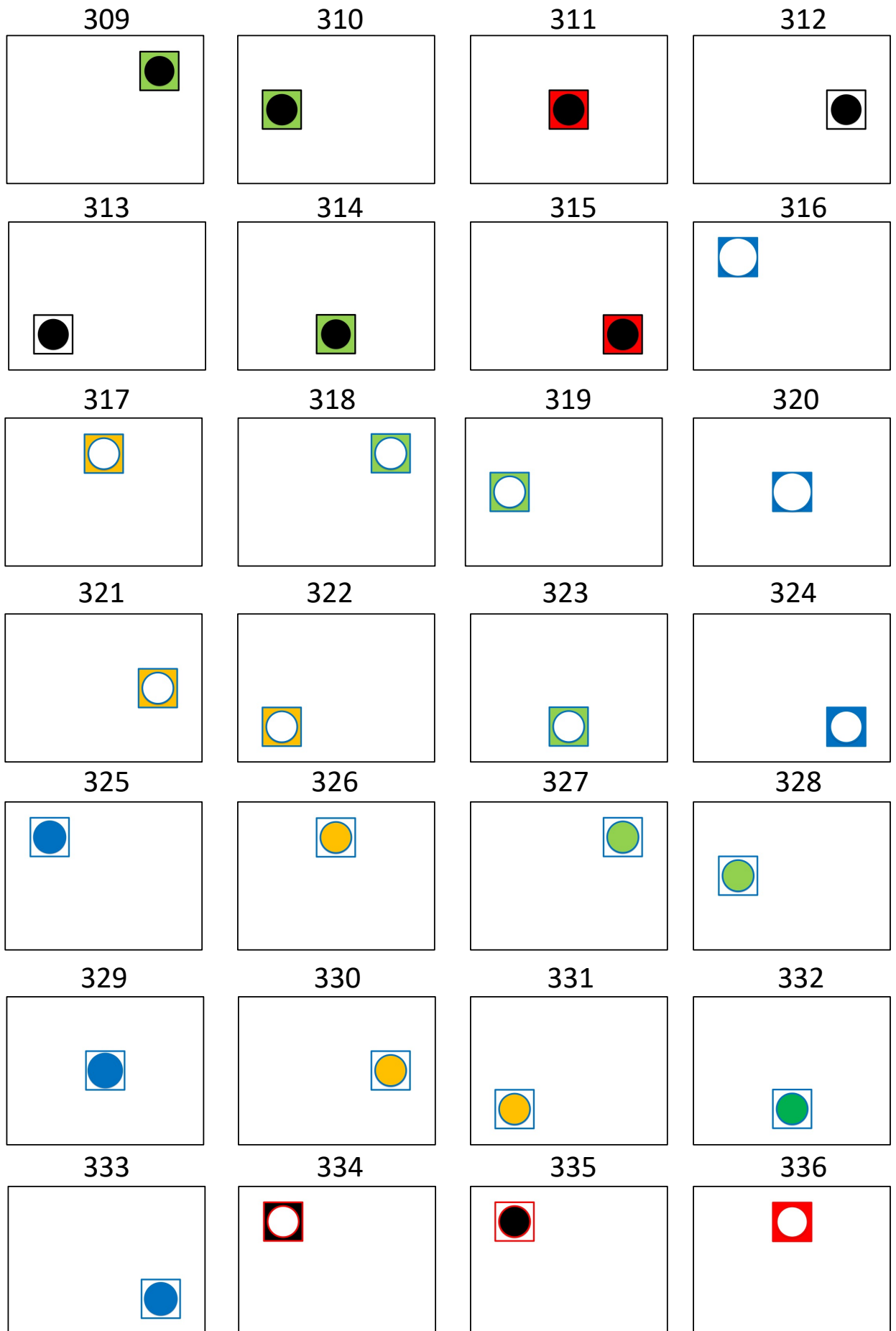


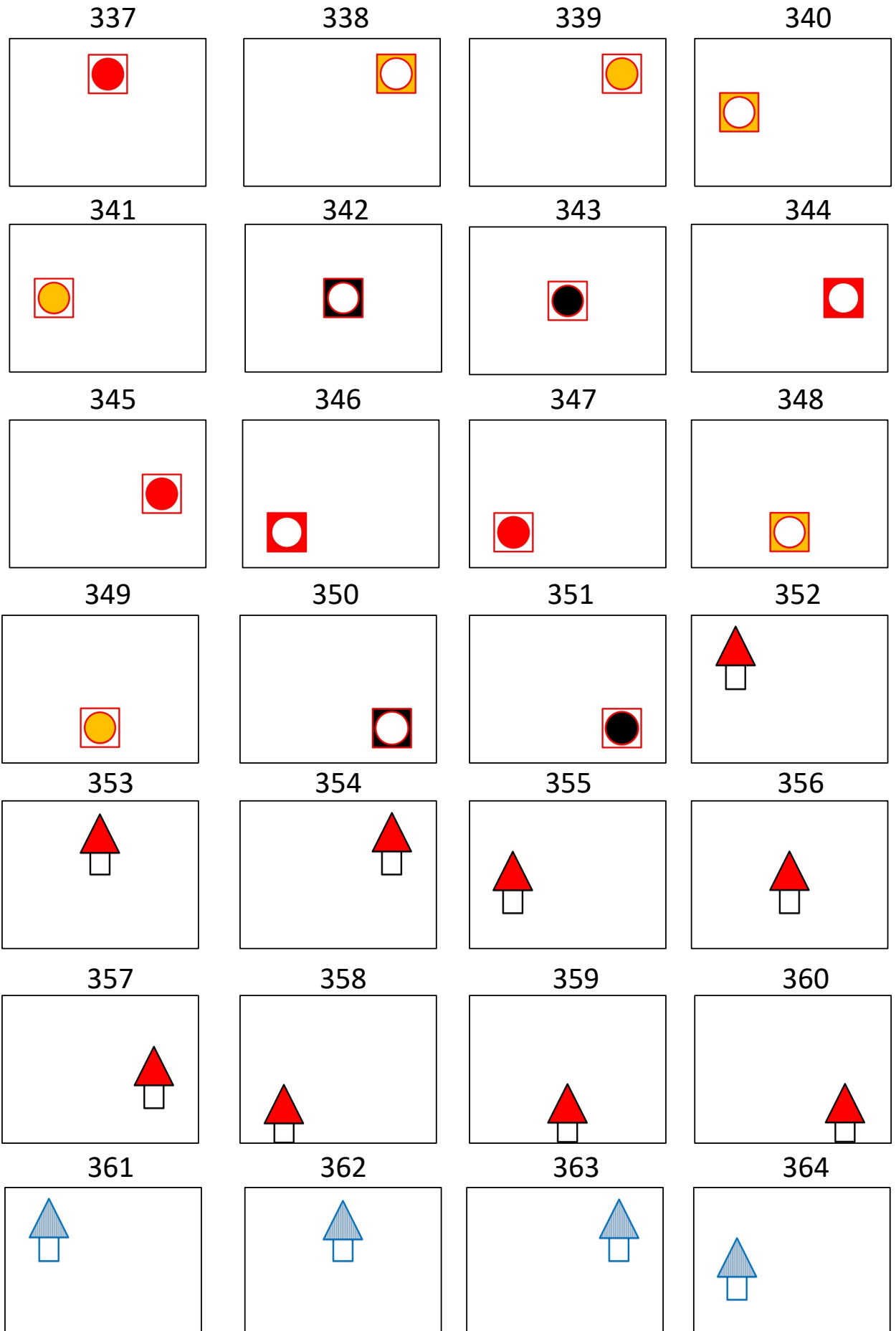


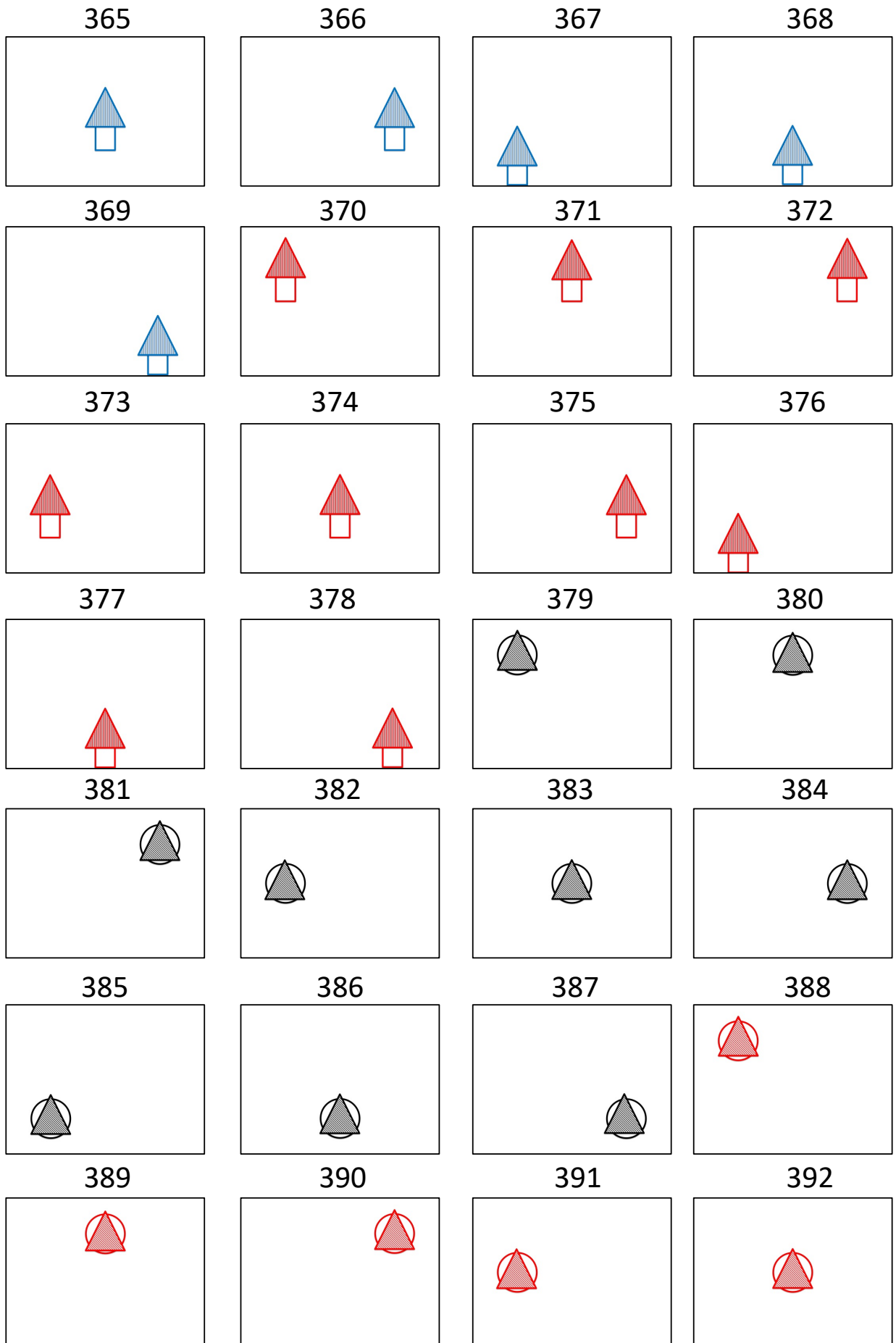




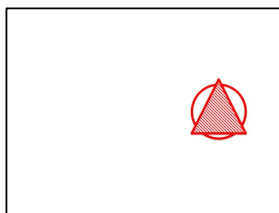




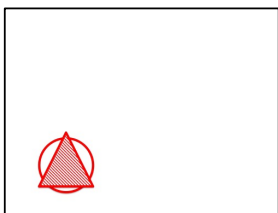




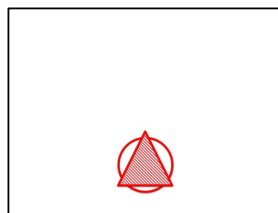
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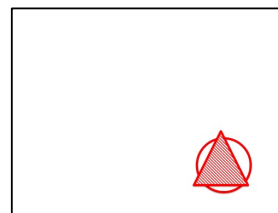
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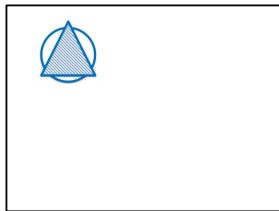
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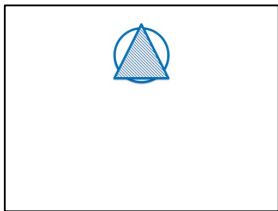
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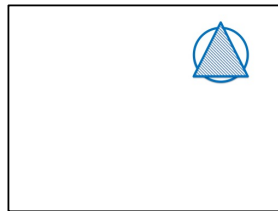
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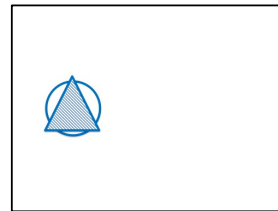
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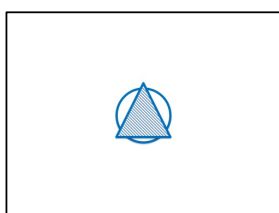
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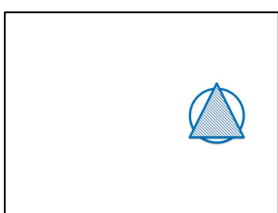
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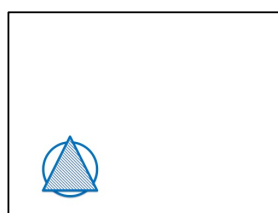
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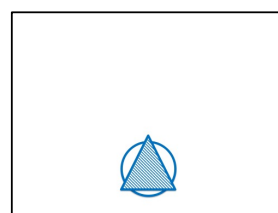
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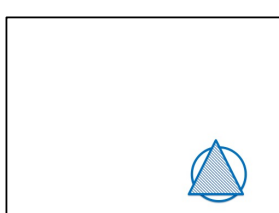
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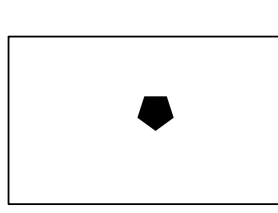
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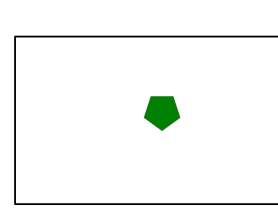
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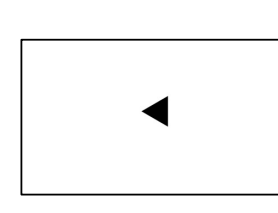
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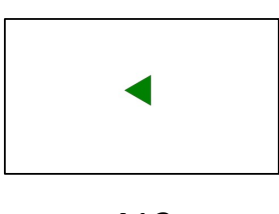
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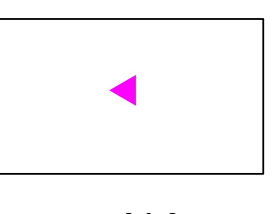
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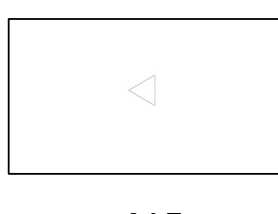
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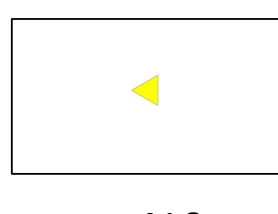
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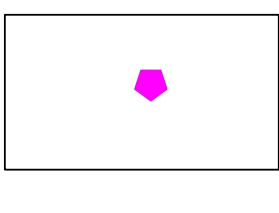
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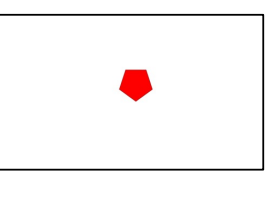
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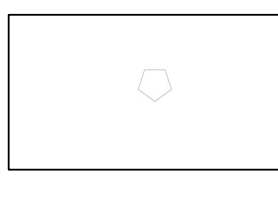
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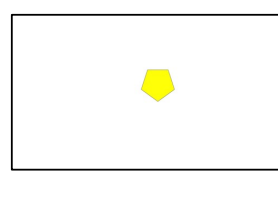
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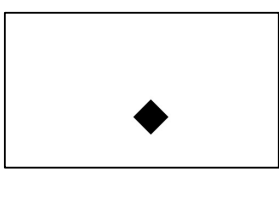
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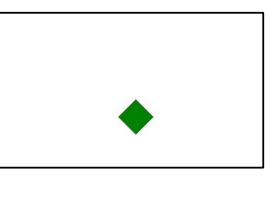
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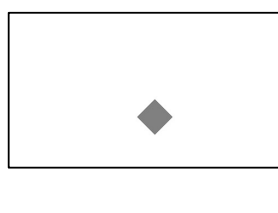
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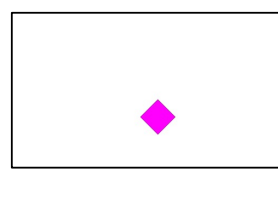
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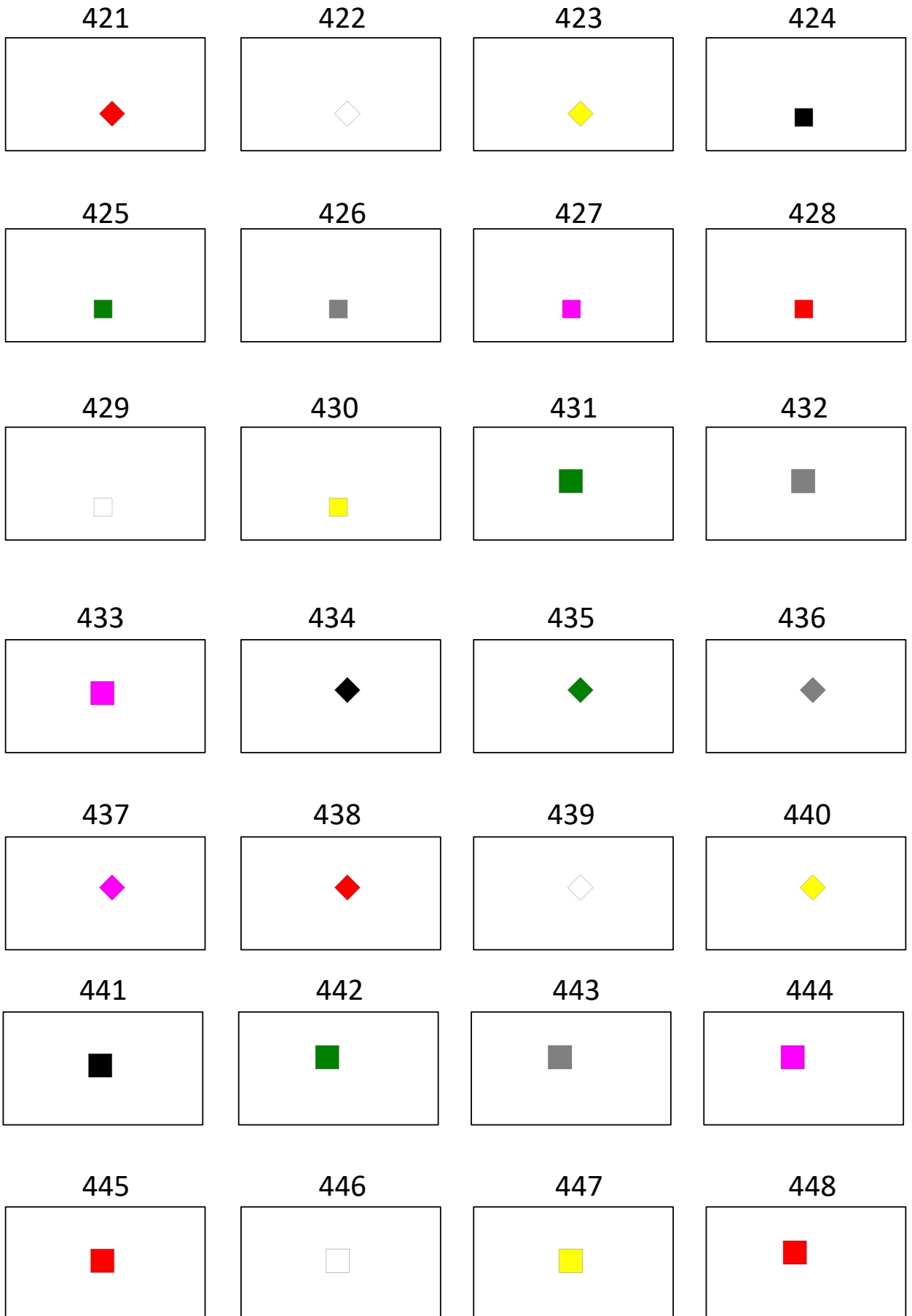


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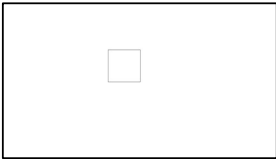


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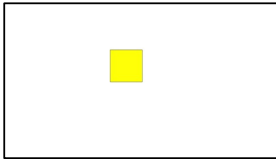




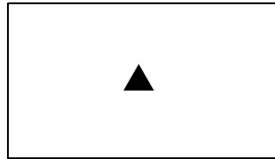
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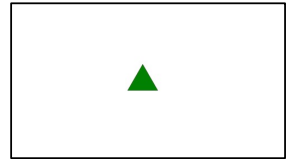
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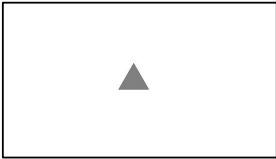
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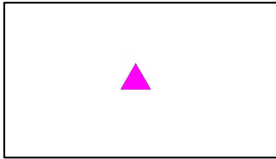
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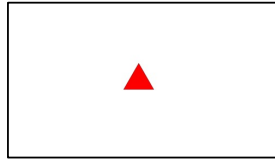
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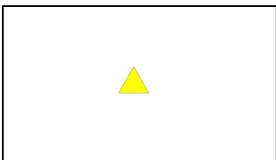
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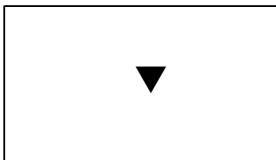
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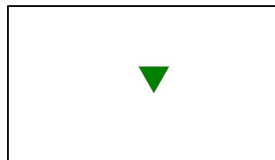
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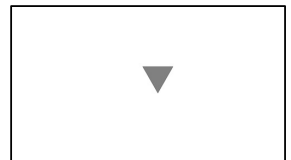
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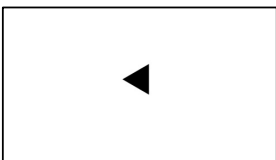
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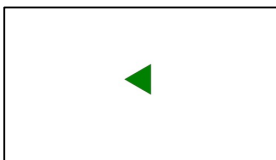
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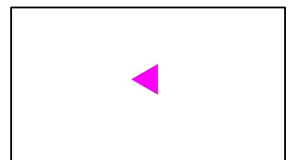
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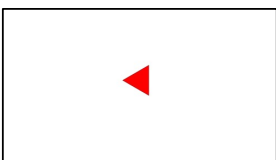
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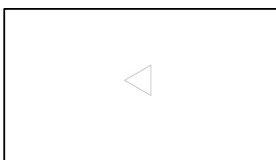
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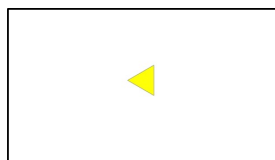
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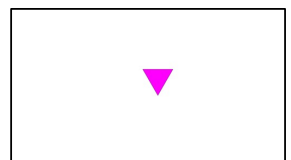
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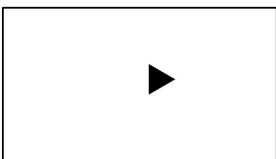
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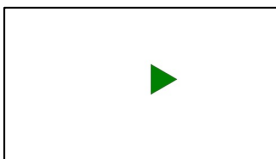
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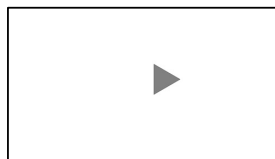
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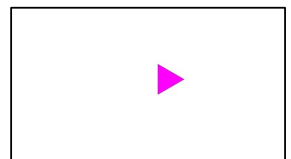
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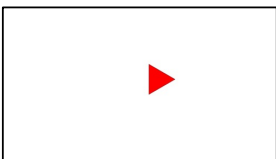
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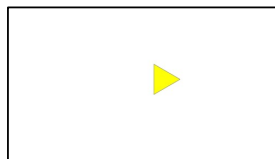
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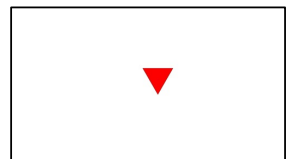
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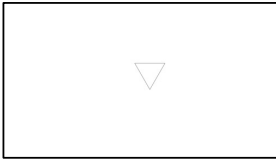
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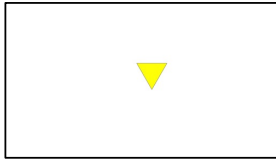
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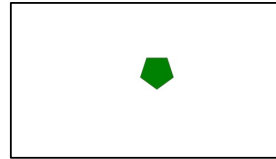
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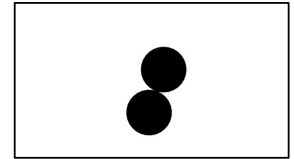
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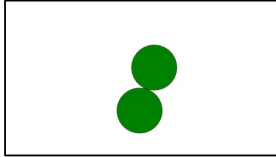
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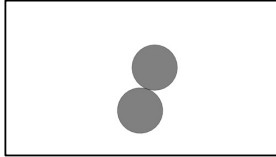
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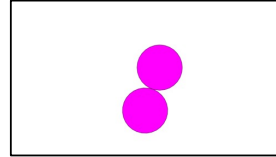
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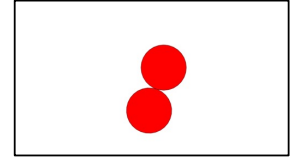
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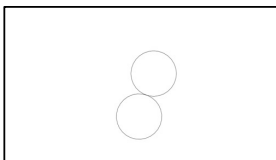
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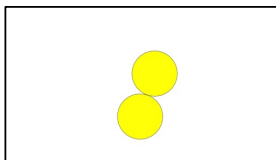
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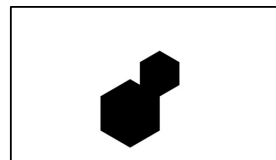
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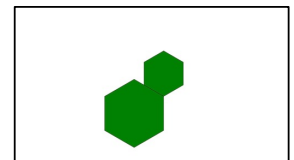
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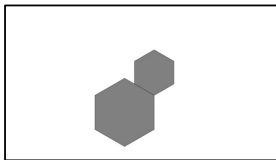
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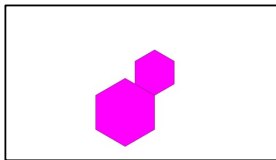
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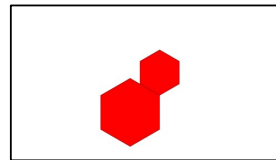
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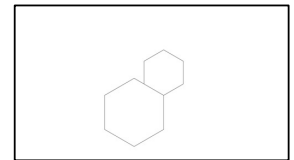
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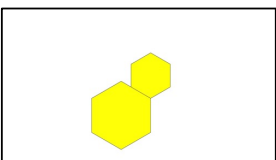
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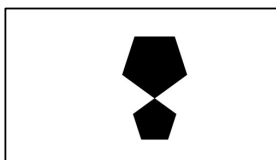
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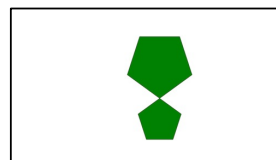
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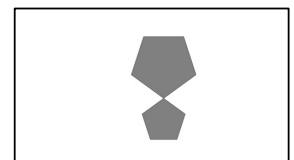
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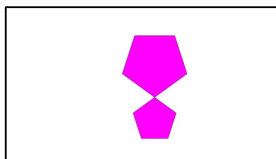
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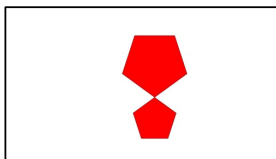
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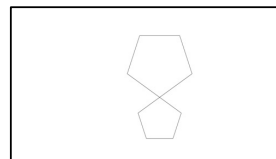
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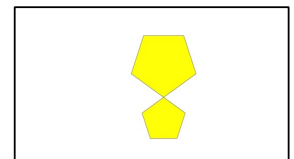
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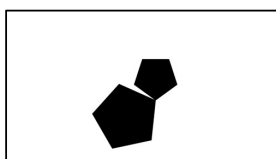
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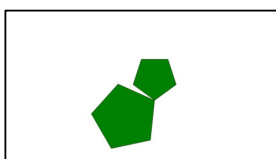
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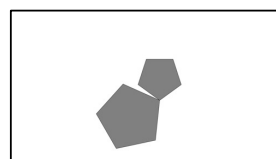
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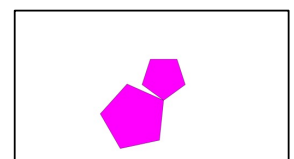
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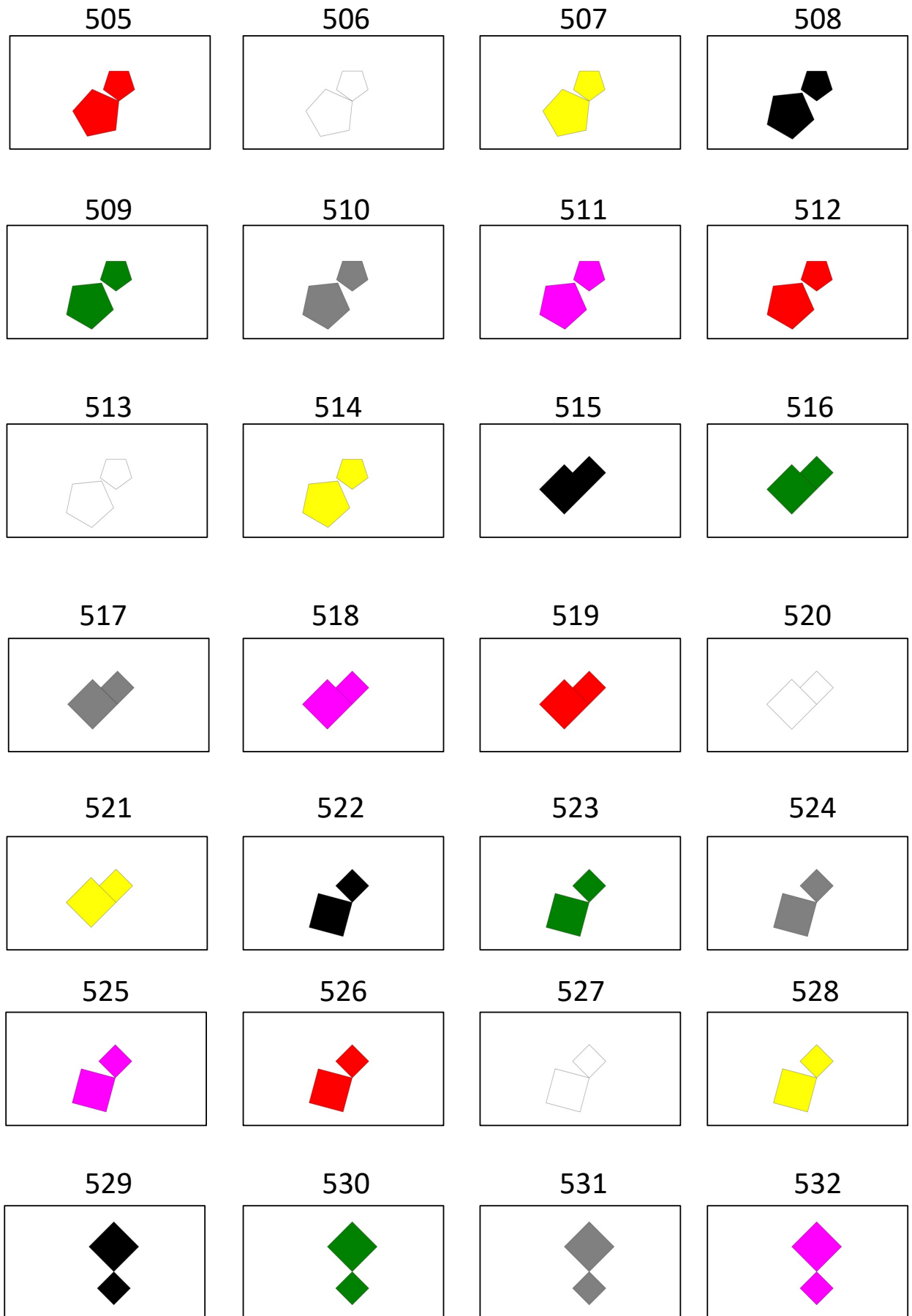


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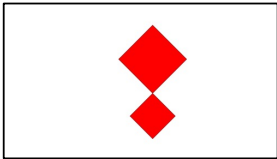


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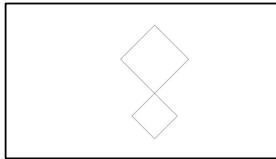




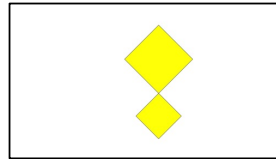
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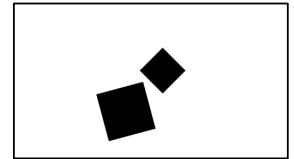
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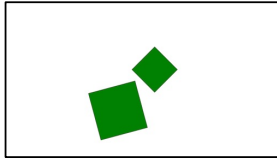
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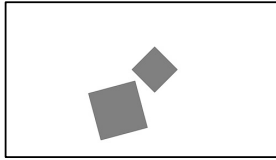
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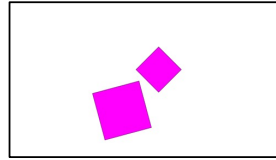
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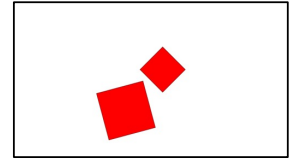
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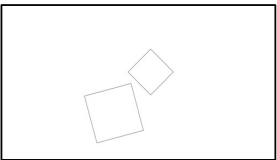
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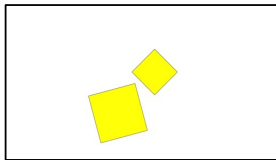
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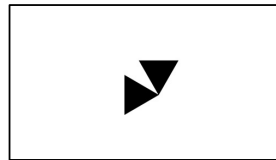
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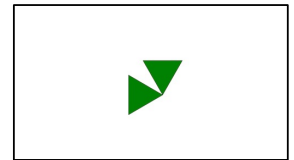
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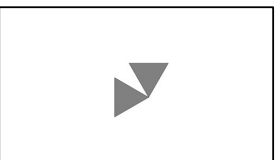
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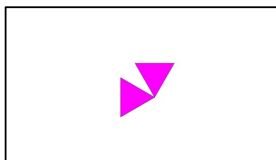
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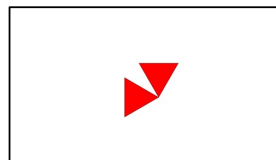
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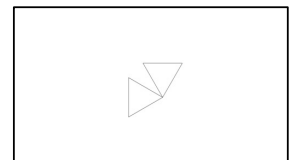
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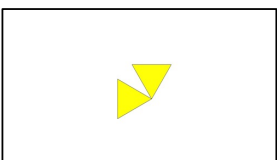
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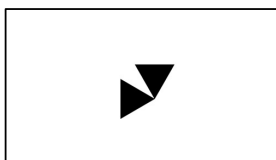
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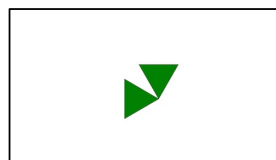
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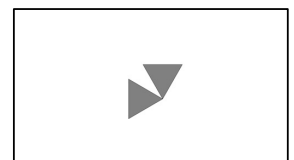
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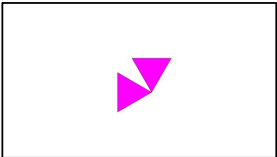
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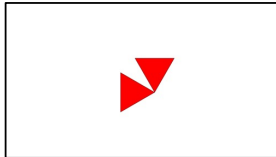
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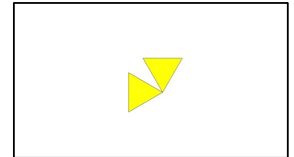
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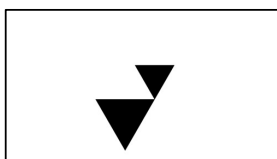
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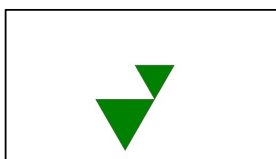
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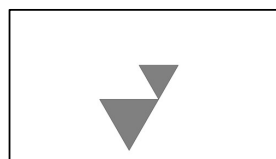
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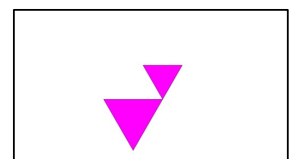
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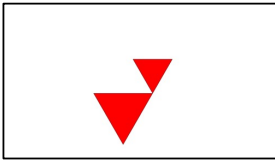
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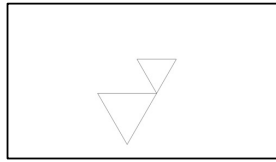
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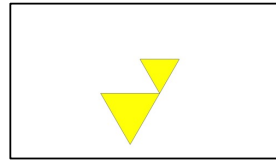
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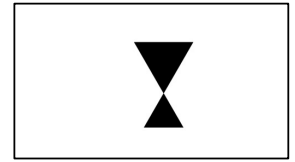
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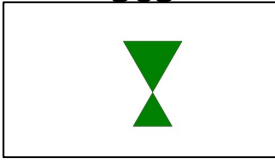
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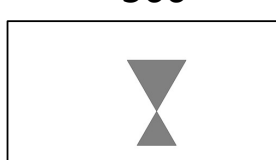
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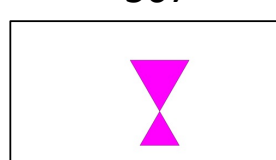
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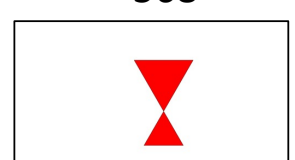
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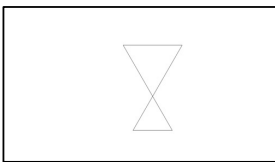
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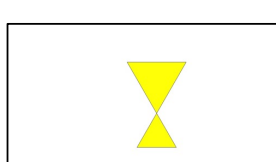
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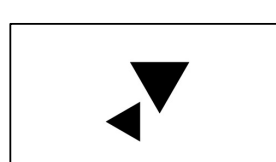
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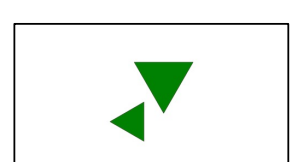
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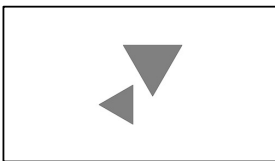
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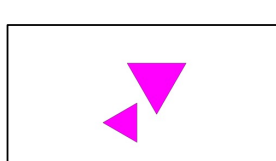
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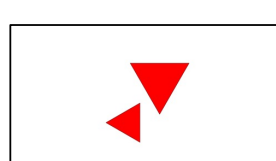
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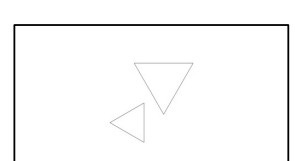
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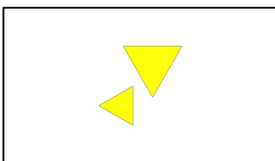
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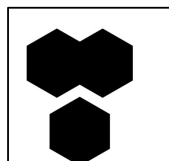
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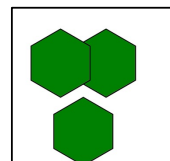
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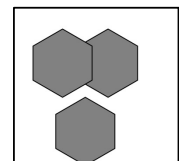
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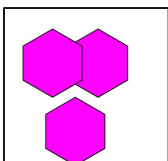
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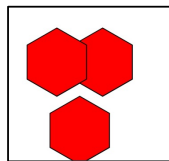
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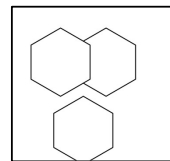
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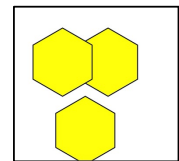
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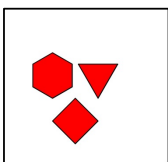
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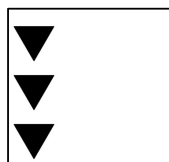
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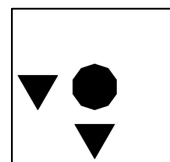
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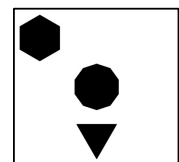
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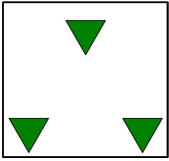
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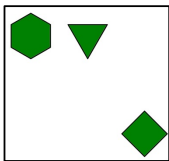
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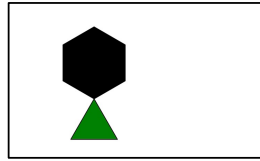
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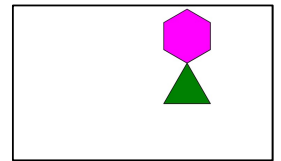
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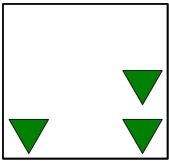
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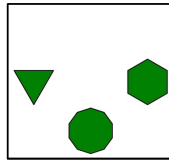
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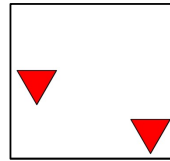
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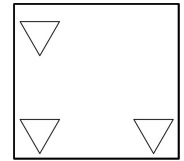
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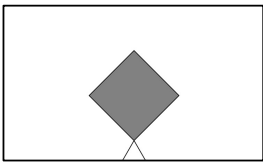
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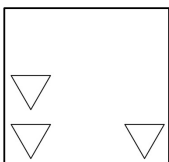
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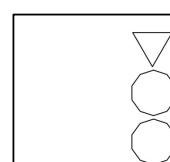
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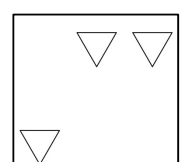
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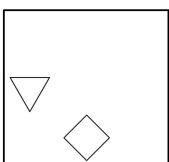
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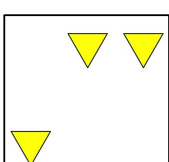
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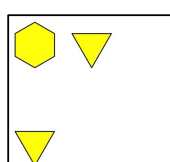
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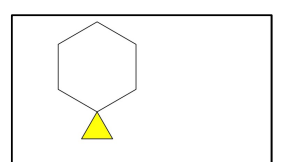
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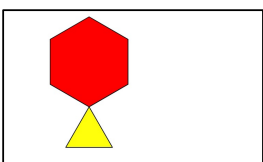
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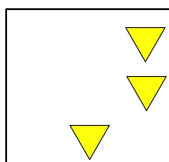
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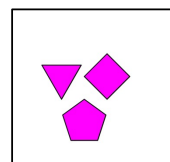
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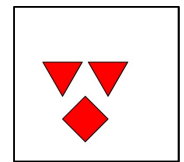
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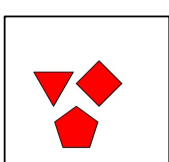
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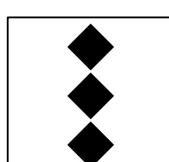
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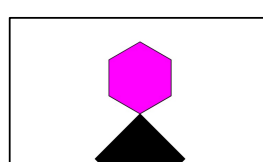
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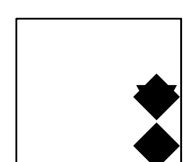
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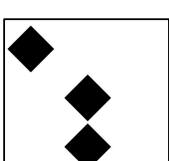
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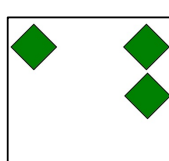
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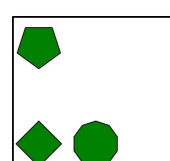
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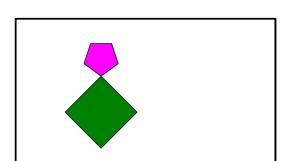
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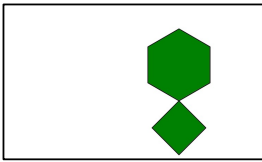
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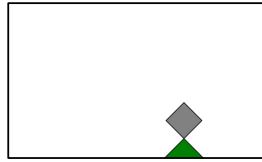
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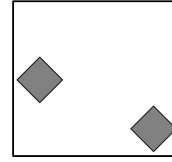
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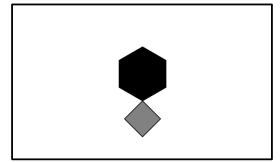
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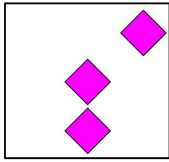
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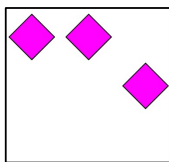
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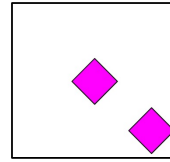
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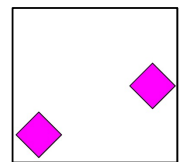
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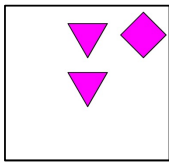
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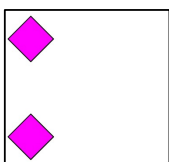
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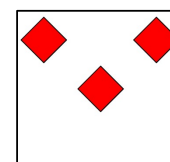
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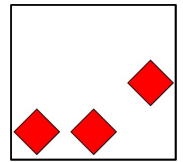
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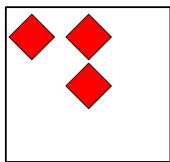
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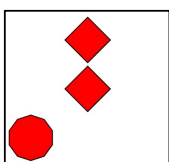
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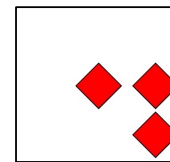
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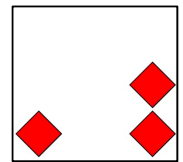
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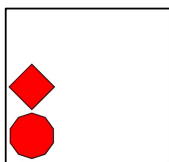
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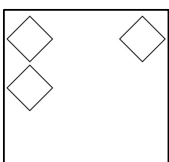
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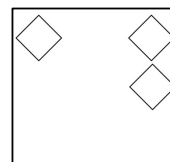
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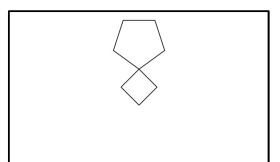
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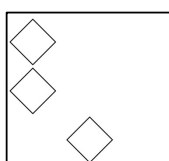
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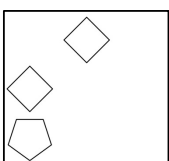
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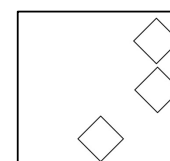
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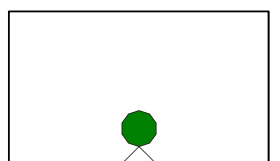
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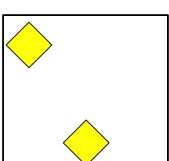
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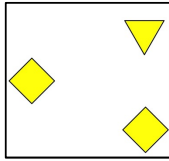
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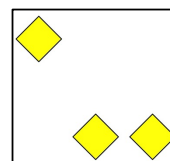
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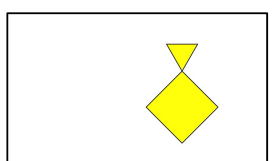
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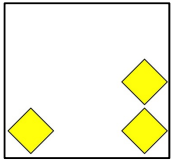
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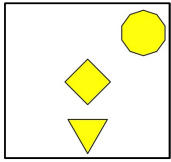
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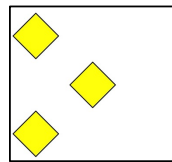
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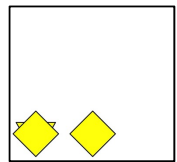
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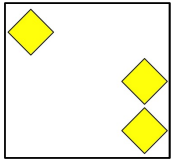
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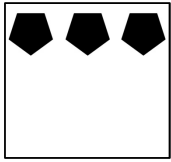
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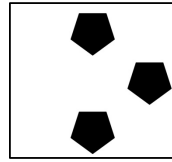
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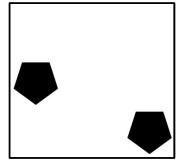
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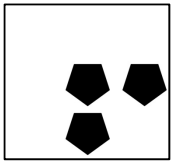
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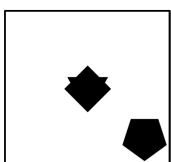
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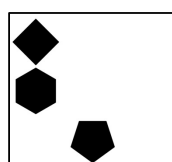
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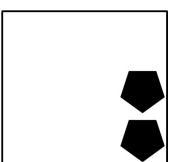
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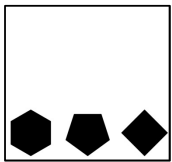
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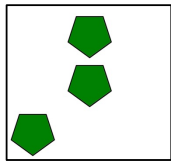
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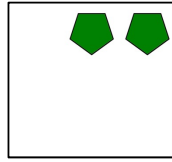
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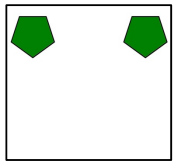
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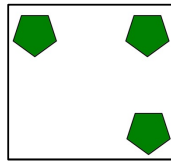
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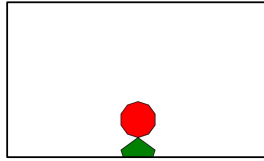
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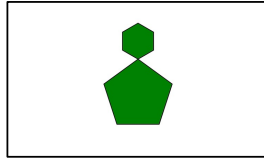
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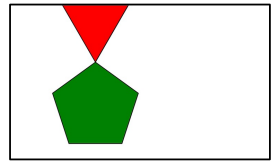
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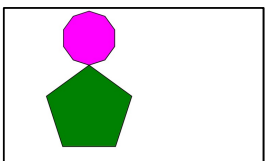
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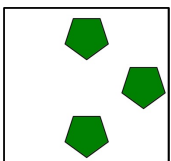
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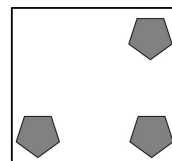
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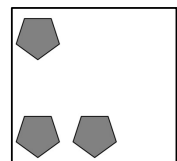
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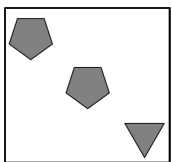
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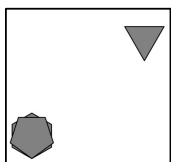
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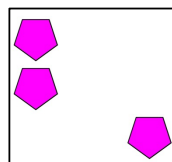
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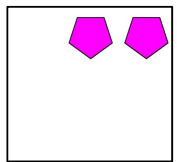
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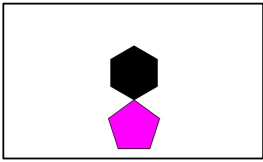
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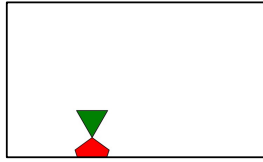
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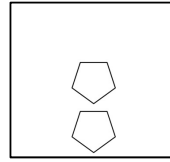
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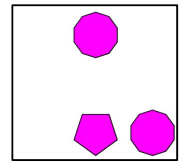
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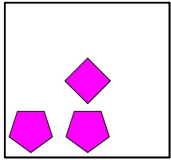
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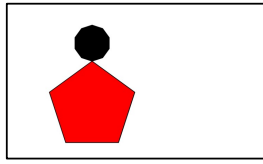
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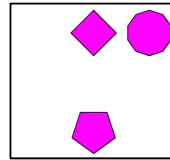
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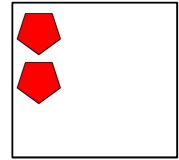
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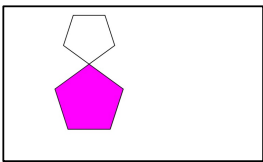
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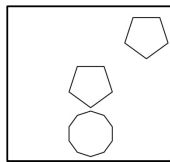
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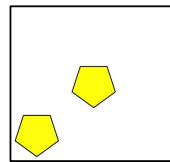
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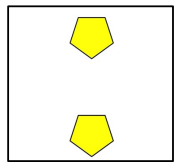
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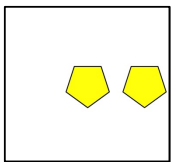
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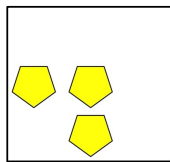
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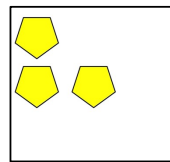
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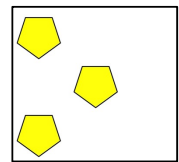
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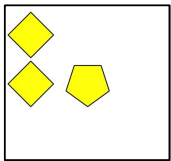
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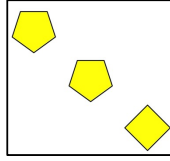
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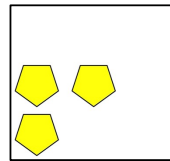
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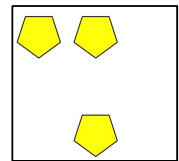
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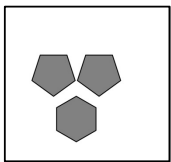
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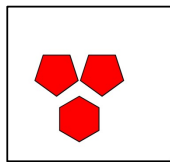
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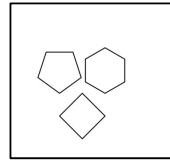
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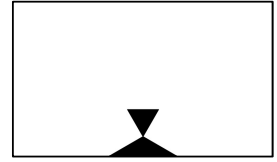
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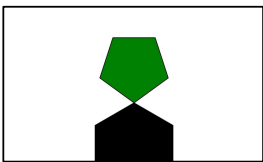
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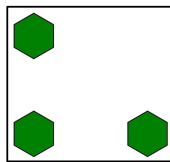
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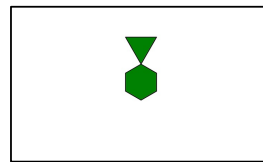
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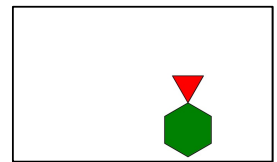
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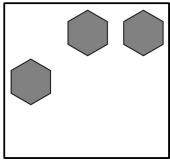
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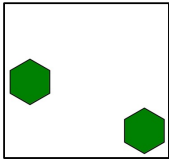
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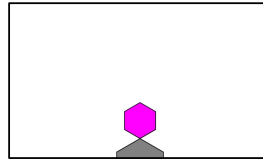
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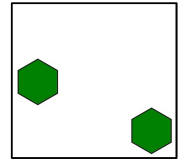
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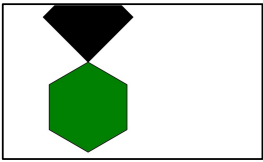
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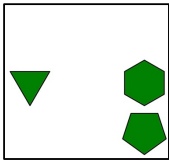
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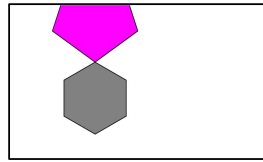
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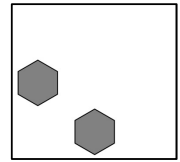
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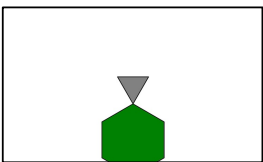
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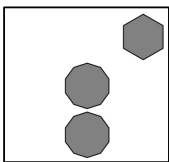
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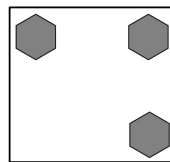
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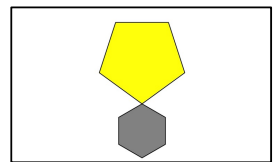
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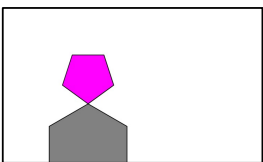
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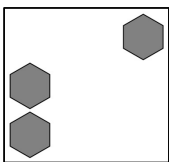
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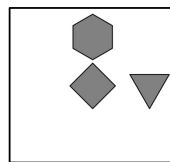
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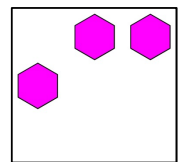
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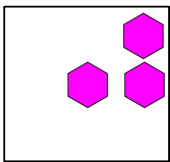
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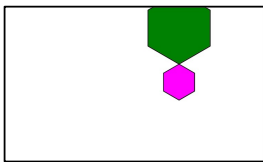
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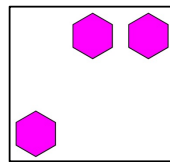
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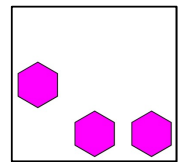
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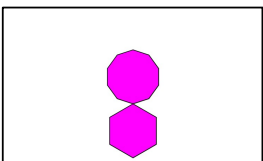
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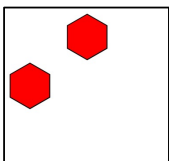
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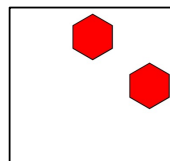
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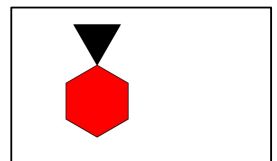
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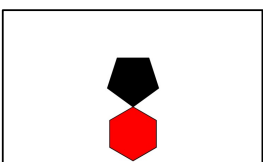
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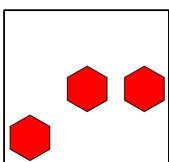
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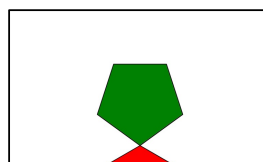
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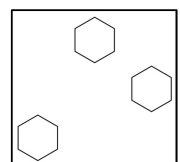
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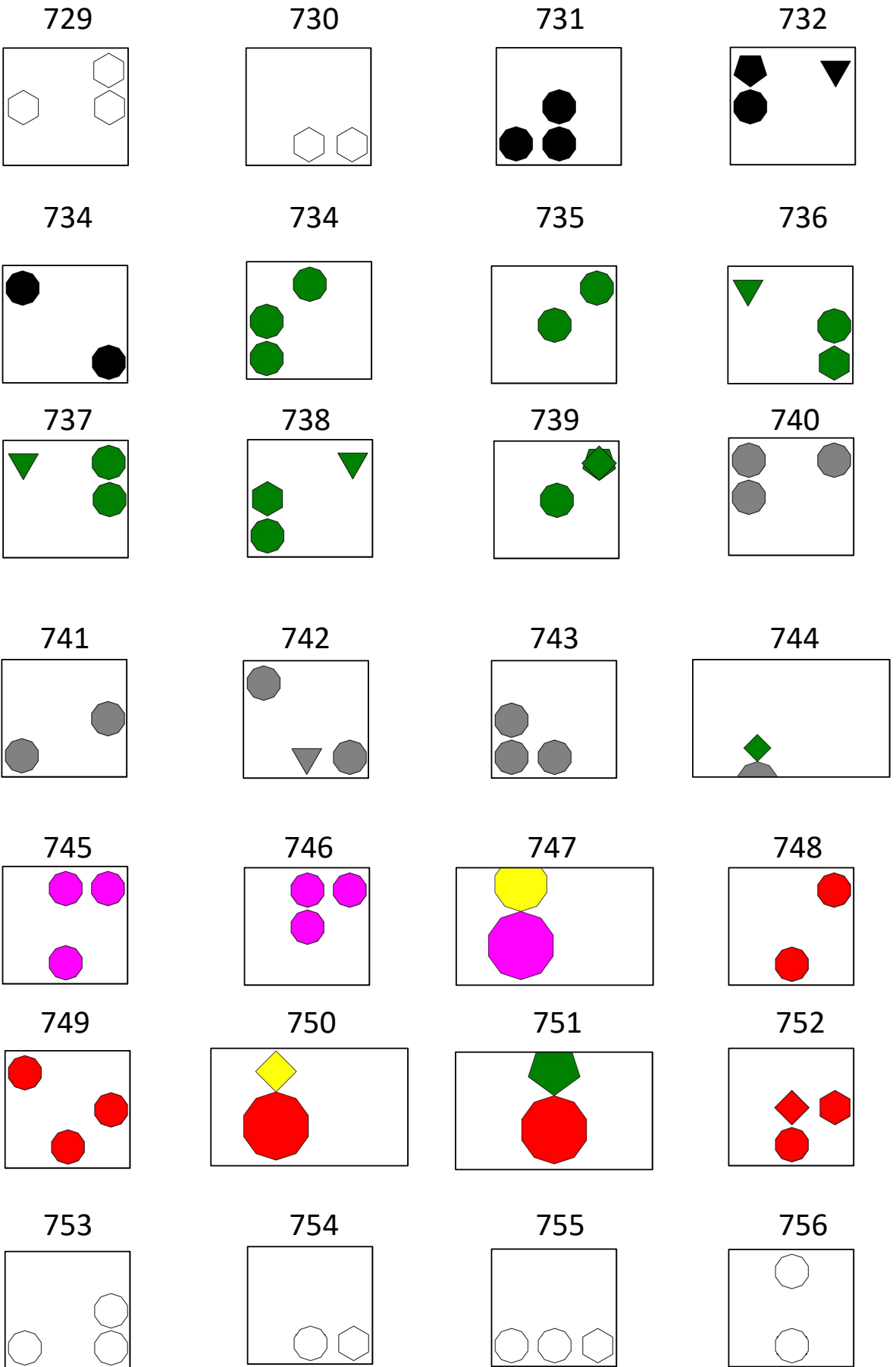


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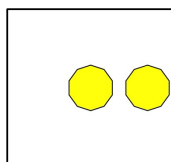


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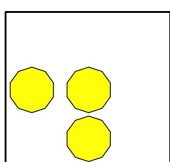




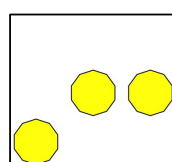
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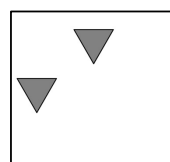
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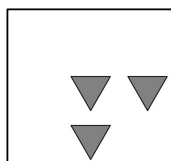
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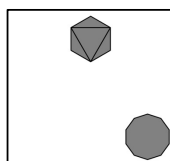
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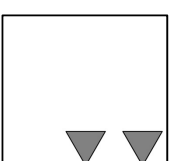
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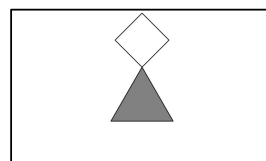
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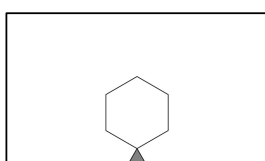
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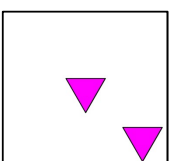
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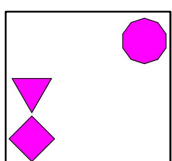
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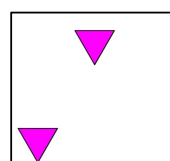
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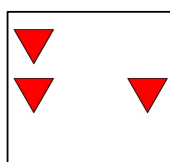
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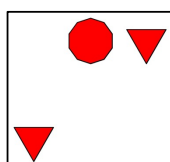
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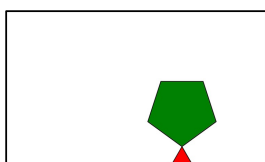
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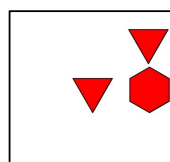
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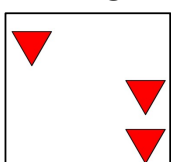
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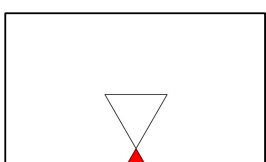
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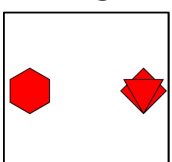
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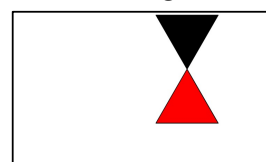
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Annexe 2.

List of objects for training different grip/requirement of the tenodesis grasp.

objet	id	grip(s)	size (mm)	weight (g)	Note
Foam form 1: grasp on the width	1	PG / LG	(L x w x h) 100*135*25	9	
Foam form 1: grasp on the thickness	2	PG / LG	(L x w x h) 100*135*25	9	
Foam form 2: grasp on the thickness	3	PG / LG	(L x w x h) 60*100*25	4	
Foam form 2: grasp on the width	4	PG / LG	(L x w x h) 60*100*25	4	
Foam form 3: grasp on the thickness	5	PG / LG	(L x w x h) 40*105*25	2	
Foam form 3: grasp on the width	6	PG / LG	(L x w x h) 40*105*25	2	
Foam form 4: grasp on the thickness	7	PG / LG	(L x w x h) 25*100*25	2	
Foam form 4: grasp on the width	8	PG / LG	(L x w x h) 25*100*25	2	
Foam form 5: grasp on the thickness	9	PG / LG	(L x w x h) 25*65*25	1	
Foam form 5: grasp on the width	10	PG / LG	(L x w x h) 25*65*25	1	
Foam form 6: grasp on the thickness	11	PG / LG	(L x w x h) 40*40*25	1	
Foam form 6: grasp on the width	12	PG / LG	(L x w x h) 40*40*25	1	
Foam form 7: grasp on the thickness	13	PG / LG	(L x w x h) 35*40*30	1	
Foam form 7: grasp on the width	14	PG / LG	(L x w x h) 35*40*30	1	
Foam form 8: grasp on the thickness	15	PG / LG	(L x w x h) 35*35*30	1	
Foam form 8: grasp on the width	16	PG / LG	(L x w x h) 35*35*30	1	
Foam form 9: grasp on the thickness	17	PG / LG	(L x w x h) 35*30*30	1	
Foam form 9: grasp on the width	18	PG / LG	(L x w x h) 35*30*30	1	
Foam form 10: grasp on the thickness	19	PG / LG	(L x w x h) 30*30*25	< 1	
Foam form 10: grasp on the width	20	PG / LG	(L x w x h) 30*30*25	< 1	
Foam form 11: grasp on the thickness	21	PG / LG	(L x w x h) 25*35*25	< 1	
Foam form 11: grasp on the width	22	PG / LG	(L x w x h) 25*35*25	< 1	

Cube25	23	PG	(L x w x h) 25*25*25	11	
Cube30	24	PG	(L x w x h) 35*35*25	12	bottle neck diameter = 30mm
Cotton	25	PG / LG	(diam * h) 40*20	1	
Tongue depressor	26	PG	(L x w x h) 150*19*03	2	
Swab standing	27	PG / LG	L=145; w(head)=20; w(stem)=5	< 1	
Swab lying	28	PG / LG	L=145; w(head)=20; w(stem)=5	< 1	
Plastic glass	29	LG (PG)	(diam * h) 70*80	4	
Glass standing	30	LG (PG)	(diam * h) 70*90	180	
Glass lying	31	LG (PG)	(diam * h) 70*90	180	
Glass 2 standing	32	LG (PG)	(diam * h) 65*95	156	
Glass 2 lying	33	LG (PG)	(diam * h) 65*95	156	
Mug on the top	34	LG (PG)	(diam * h) 90*95	267	
Mug by the cove	35	LG (PG)	(diam * h) 90*95	267	
Plastic box: grasp on the thickness	36	LG (PG)	(L x w x h) 100*60*50	24	
Plastic box: grasp on the width	37	LG (PG)	(L x w x h) 100*60*50	24	
0.5L plastic bottle (spherical) empty standing	38	LG	(L x w x h) 160*60*60	20	ADL and strength requirement
0.5L plastic bottle (spherical) full standing	39	LG	(L x w x h) 160*60*60	520	ADL and strength requirement
0.5L plastic bottle (spherical) empty lying	40	LG	(L x w x h) 160*60*60	20	ADL and strength requirement
0.5L plastic bottle (spherical) full lying	41	LG	(L x w x h) 160*60*60	520	ADL and strength requirement
1.5L plastic bottle (square) empty standing	42	LG	(L x w x h) 300*80*80	37	ADL and strength requirement
1.5L plastic bottle (square) empty lying	43	LG	(L x w x h) 300*80*80	37	ADL and strength requirement
1.5L plastic bottle (square) 30% full (0.5L) standing	44	LG	(L x w x h) 300*80*80	537	ADL and strength requirement
1.5L plastic bottle (square) 30% full (0.5L) lying	45	LG	(L x w x h) 300*80*80	537	ADL and strength requirement
1.5L plastic bottle (square) 66% full (1.0L) standing	46	LG	(L x w x h) 300*80*80	1037	ADL and strength requirement
1.5L plastic bottle (square) 66% full (1.0L) lying	47	LG	(L x w x h) 300*80*80	1037	ADL and strength requirement

1.5L plastic bottle (square) full standing	48	LG	(L x w x h) 300*80*80	1537	ADL and strength requirement
1.5L plastic bottle (square) full lying	49	LG	(L x w x h) 300*80*80	1537	ADL and strength requirement
1.5L plastic bottle (square) empty standing	50	LG	(L x w x h) 300*80*80	37	ADL and strength requirement
1.5L plastic bottle (square) empty lying	51	LG	(L x w x h) 300*80*80	37	ADL and strength requirement
0.75L champagne glass bottle (spherical) empty standing	52	LG	(L x w x h) 300*90*90	875	ADL and strength requirement
0.75L champagne glass bottle (spherical) empty lying	53	LG	(L x w x h) 300*90*90	875	ADL and strength requirement
0.75L champagne glass bottle (spherical) half full standing	54	LG	(L x w x h) 300*90*90	1250	ADL and strength requirement
0.75L champagne glass bottle (spherical) full standing	55	LG	(L x w x h) 300*90*90	1625	ADL and strength requirement
Champagne cork standing	56	PG / LG	(L x w x h) 50*30*30	9	
Champagne cork lying	57	PG / LG	(L x w x h) 50*30*30	9	
Rehabilitation cone standing larger part on the table	58	PG / LG	(diameters x h) 45*75*165	70	
Rehabilitation cone standing smaller part on the table	59	PG / LG	(diameters x h) 45*75*165	70	
Rehabilitation cone lying	60	PG / LG	(diameters x h) 45*75*165	70	
Fork	61	PG / LG	L=205; w=30	20	ADL
Spoon	62	PG / LG	L=205; w=30	13	ADL
Magnifier standing	63	LG (PG)	(diam * h) 80 *30	7	ADL
Magnifier lying	64	PG (LG)	(diam * h) 80 *30	7	ADL
Spoon magnifier	65	PG / LG	(L* diam * h) 130 * 80 *30	23	ADL
Toothbrush	66	PG / LG	(diam * L) 12 *180	10	ADL
Urinary catheter	67	PG	(diam * L) 6 *360	9	ADL
1 centime	68	PG	(diam) 18	2	ADL

2 centimes	69	PG	(diam) 19	2	ADL
5 centimes	70	PG	(diam) 22	4	ADL
10 centimes	71	PG	(diam) 20	4	ADL
20 centimes	72	PG	(diam) 22	5	ADL
50 centimes	73	PG	(diam) 23	8	ADL
1 euro	74	PG	(diam) 22	8	ADL
2 euros	75	PG	(diam) 26	8	ADL
Pen	76	PG	(diam * L) 8 *145	7	ADL
Highlighter	77	PG	(diam * L) 25 *105	18	ADL
Phone / tablet charger head standing	78	PG / LG	(L x w x h) 60*35*20	43	ADL
Phone / tablet charger head lying	79	PG / LG	(L x w x h) 60*35*20	43	ADL
Phone / tablet charger cable	80	PG / LG	(diam * L) 6 *720	43	ADL
Scissors: grasping by blades	81	PG	(L x w x h) 120*10*5	14	ADL
Scissors: grasping by wrist	82	PG	(L x w x h) 120*55*5	14	ADL
Cap standing	83	PG	(L x w x h) 53*14*6	2	ADL
Cap lying	84	PG	(L x w x h) 53*14*6	2	ADL
Bottle cap 50 (plastic)	85	PG / LG	(diam * h) 50 *18	2	ADL
Bottle cap 80 (metal)	86	PG / LG	(diam * h) 80 * 8	11	ADL
Bottle cap 60 (metal)	87	PG / LG	(diam * h) 60 * 8	7	ADL
Bottle cap 50 (metal)	88	PG / LG	(diam * h) 50 * 8	5	ADL
Bottle cap 41 (plastic)	89	PG / LG	(diam * h) 41 * 12	2	ADL
Bottle cap 33 (plastic)	90	PG / LG	(diam * h) 33 * 12	1	ADL
Bottle cap 20 (plastic)	91	PG / LG	(diam * h) 20 * 12	1	ADL
Glass jar 80 empty	92	PG / LG	(diam * h) 80 * 62	141	capacity 180g
Glass jar 66 empty	93	PG / LG	L:90 diam base: 90; top: 66	188	capacity 250g
Glass jar 50a empty	94	PG / LG	(L x w x h) 72*50*50	75	capacity 80g

Glass jar 50b empty	95	PG / LG	(L x w x h) 72*60*60	93	capacity 130g
Glass jar 80 half full	96	PG / LG	(diam * h) 80 * 62	231	capacity 180g
Glass jar 66 half full	97	PG / LG	L:90 diam base: 90; top: 66	313	capacity 250g
Glass jar 50a half full	98	PG / LG	(L x w x h) 72*50*50	115	capacity 80g
Glass jar 50b half full	99	PG / LG	(L x w x h) 72*60*60	158	capacity 130g
Glass jar 80 full	100	PG / LG	(diam * h) 80 * 62	321	capacity 180g
Glass jar 66 full	101	PG / LG	L:90 diam base: 90; top: 66	438	capacity 250g
Glass jar 50a full	102	PG / LG	(L x w x h) 72*50*50	155	capacity 80g
Glass jar 50b full	103	PG / LG	(L x w x h) 72*60*60	223	capacity 130g
Tennis ball	104	PG	diam 60	58	
Ping pong ball	105	PG	diam 40	2	
Scotch	106	PG	(diam * h) 40 * 26	10	
Coiled tourniquet	107	PG	(diam * h) 36 * 19	22	may be used as a support for marbles
Marbles	108	PG	diam 15	4	generally supported by the coiled tourniquet as a support
Aluminum marble8	109	PG	diam 08	<1	generally supported by the coiled tourniquet as a support
Aluminum marble9	110	PG	diam 09	<1	generally supported by the coiled tourniquet as a support
Aluminum marble10	111	PG	diam 10	<1	generally supported by the coiled tourniquet as a support
Aluminum marble12	112	PG	diam 12	<1	generally supported by the coiled tourniquet as a support
Sewing needle a: grasping on the table	113	PG	L:32 (head:4)	<1	harder
Sewing needle b: grasping on the table	114	PG	L:32 (head:3)	<1	harder
Sewing needle c: grasping on the table	115	PG	L:28 (head:2)	<1	harder

Sewing needle d: grasping on the table	116	PG	L:30 (head:5)	<1	harder
Sewing needle a: stick in a foam object	117	PG	L:32 (head:4)	<1	easier
Sewing needle b: stick in a foam object	118	PG	L:32 (head:3)	<1	easier
Sewing needle c: stick in a foam object	119	PG	L:28 (head:2)	<1	easier
Sewing needle d: stick in a foam object	120	PG	L:30 (head:5)	<1	easier
Screw35: lying	121	PG	(diam * h) 3 * 35	2	
Screw15: lying	122	PG	(diam * h) 3 * 15	1	
Screw35: standing on the head	123	PG	(diam * h) 3 * 35	2	
Screw15: standing on the head	124	PG	(diam * h) 3 * 15	1	
Trombone50: lying	125	PG	(L x w x h) 50*10*3	2	
Trombone35: lying	126	PG	(L x w x h) 35*10*1	< 1	
Trombone25: lying	127	PG	(L x w x h) 35*10*1	< 1	
Trombone50: standing supported by the coiled tourniquet	128	PG	(L x w x h) 50*10*3	2	
Trombone35: standing supported by the coiled tourniquet	129	PG	(L x w x h) 35*10*1	< 1	
Trombone25: standing supported by the coiled tourniquet	130	PG	(L x w x h) 35*10*1	< 1	
Drawing pin10	131	PG	diam 10	1	
Jar cup perforated 15	132	PG	cup diam=50mm; hole=15mm	7	accuracy grasping small objects (e.g., screw, needle, trombone), manipulate and release it within the hole of the cup on the top of the glass jar 50a.

Abbreviations: L: Length; w: width; h. : height; mm: millimetre; ADL: Activity of daily life; diam : diameter.